

# WHAT IT TAKES TO BE AN IRB COMMUNITY MEMBER

A RESOURCE MANUAL IN TWO PARTS



University of Southern California  
Office for the Protection of Research Subjects

2013





## CODE OF ETHICS OF THE UNIVERSITY OF SOUTHERN CALIFORNIA

At the University of Southern California, ethical behavior is predicated on two main pillars: a commitment to discharging our obligations to others in a fair and honest manner, and a commitment to respecting the rights and dignity of all persons. As faculty, staff, students, and trustees, we each bear responsibility not only for the ethics of our own behavior, but also for building USC's stature as an ethical institution.

We recognize that the fundamental relationships upon which our university is based are those between individual students and individual professors; thus, such relationships are especially sacred and deserve special care that they not be prostituted or exploited for base motives or personal gain.

When we make promises as an institution, or as individuals who are authorized to speak on behalf of USC, we keep those promises, including especially the promises expressed and implied in our Role and Mission Statement. We try to do what is right even if no one is watching us or compelling us to do the right thing.

We promptly and openly identify and disclose conflicts of interest on the part of faculty, staff, students, trustees, and the institution as a whole, and we take appropriate steps to either eliminate such conflicts or insure that they do not compromise the integrity of the individuals involved or that of the university.

We nurture an environment of mutual respect and tolerance. As members of the USC community, we treat everyone with respect and dignity, even when the values, beliefs, behavior, or background of a person or group is repugnant to us. This last is one of the bedrocks of ethical behavior at USC and the basis of civil discourse within our academic community. Because we are responsible not only for ourselves but also

for others, we speak out against hatred and bigotry whenever and wherever we find them.

We do not harass, mistreat, belittle, harm, or take unfair advantage of anyone. We do not tolerate plagiarism, lying, deliberate misrepresentation, theft, scientific fraud, cheating, invidious discrimination, or ill use of our fellow human beings – whether such persons be volunteer subjects of scientific research, peers, patients, superiors, subordinates, students, professors, trustees, parents, alumni, donors, or members of the public.

We do not misappropriate the university's resources, or resources belonging to others which are entrusted to our care, nor do we permit any such misappropriation to go unchallenged.

We are careful to distinguish between legal behavior on the one hand and ethical behavior on the other, knowing that, while the two overlap in many areas, they are at bottom quite distinct from each other. While we follow legal requirements, we must never lose sight of ethical considerations.

Because of the special bonds that bind us together as members of the Trojan Family, we have a familial duty as well as a fiduciary duty to one another. Our faculty and staff are attentive to the well-being of students and others who are entrusted to our care or who are especially vulnerable, including patients, volunteer subjects of research, and the children in our daycare and community outreach programs.

By respecting the rights and dignity of others, and by striving for fairness and honesty in our dealings with others, we create an ethical university of which we can all be proud, and which will serve as a bright beacon for all peoples in our day and in the centuries to come.

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# Dedication & Acknowledgments

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## DEDICATION

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This work is dedicated to Melinda Hurst, a decades-long USC community member and catalyst for community member recognition. Melinda's public service record as a teacher, counselor, and member of various USC and state Institutional Review Boards, Ethics Committee of Cedars-Sinai Medical Center, and USC Institutional Animal Care and Use Committee, is unrivaled. Melinda is the author of many bioethics opinion articles. At many committee meetings, her forceful presence highlighted important ethics issues. Melinda served on the USC Health Sciences Campus IRB from 1973 until her retirement in 2006. In December 2012, Melinda was recognized by Public Responsibility in Medicine and Research (PRIM&R) at their annual conference for Advancing Ethical Research. This dedication is given in recognition of the inspiration Melinda Hurst is to many of us in the Human Subjects Protection Program at USC. Thank you, Melinda.

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## ACKNOWLEDGMENTS

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The Office for the Protection of Research Subjects wishes to express its appreciation to all those who helped in the preparation of this booklet, and in particular to:

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This booklet would not exist without her insistence that IRBs be held responsible for training and supporting ALL of their members.

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and Susan Rose, Executive Director OPRS*

For providing insightful comments and edits to improve the content of this booklet.

*USC IRB Community Members*

For dedication and inspiration.

To access and online version of this manual with  
live links, visit

<https://oprs.usc.edu/education/booklets/>

# Foreword

Why was this book written?

It has been a common lore that community members on the IRB are the same as institutional members. Some believe that any attempt to treat or educate them differently is not justified. That is a myth! This booklet was written in the interest of providing community members with the tools, reality, and attitude they need to become confident, contributing IRB members.

A true community member should provide the voice of the participant when studies are being reviewed. This role requires the person to be independent of the research, the institution and initially unfamiliar with the culture of the IRB.

This book is written to provide basics that will “level the playing field” earlier for new community members. Observing IRB meetings and listening to community members for many years gives us confidence that this endeavor is needed and it will be a well-used resource.

Susan L. Rose, Ph.D., Executive Director  
Office for the Protection of Research Subjects  
University of Southern California

# Thoughts from a Community Member

June 6<sup>th</sup>, 2007

Dear fellow IRB community member:

I have the honor of introducing this guidebook to you. I am a community member on an IRB, and even after serving for 5 years, I continue to learn about medicine and science. I like knowing that I am part of the advancement of medicine. When I am not attending meetings, I am busy with three children. Parental duties keep my calendar full with homework help, after school activities, friends, and lots of driving. Juggling the trek to twice monthly board meetings at 7:30am, making enough time to understand the complex protocols we review, early morning traffic and securing babysitters is a balance I work on constantly. Serving on the Institutional Review Board (IRB) gives me an opportunity to think beyond my own family and daily routine. Many times during a meeting I wonder how the protocol being reviewed will affect my children in the future.

I have a degree in Political Science and Urban Planning and Studies. I am a Latina and bilingual and that qualified me to become the Latina liaison for a US Senator from California. I consider myself fortunate at present to not need to work outside my home but I plan on returning to the workforce.

Given my background, I just assumed I would be fine on the IRB and that I would “get it” – and I did but it took work on my part. I have always kept IRB notes. Since my first meeting my notes have lessened and my participation increased. Referring to my notes has addressed many of the questions I had when I first began as a community member, and I recommend you do the same.

My first impression after joining was feeling intimidated, as I had no clinical background and I felt surrounded by doctors. I didn't know much about my role other than I was to give my opinion. I would have liked to understand some of the terms that were used. This changed with time. First, I was very fortunate to have been nurtured by a very outspoken advocate subject's rights, Melinda Hurst, a community member on our IRB. On her own, she handed me an article to read and her telephone number to call with any questions I had. Second, I soon realized that I was not expected to give a critical analysis of the medical portion of the protocol. Instead I focused on the informed consent process, recruitment process, and of course the moral issues.

The great thing about this handbook is that you can read as much of it as you like or as little of it as you like but it is in your hands when you need it.

My last thought: even if you do not feel comfortable asking questions during the meeting, it is the best time and place. At the end of each protocol discussion you will vote on it. And if you blink, the rest of the board might vote and you will miss the opportunity to voice your opinion.

Best wishes,

Malena Avila Hough  
IRB Community Member, USC Health Sciences Campus

# A Few Simple Truths about Community Members form a Former UCLA Community Member

Community members are the unsung heroes of the IRB. I know because I am one. Week after week we read mountains of paper, often struggling to make sense of poorly worded submissions that would curl an English teacher's toes. We trudge through the dual thickets of scientific jargon and ethical uncertainty. We educate ourselves on medical procedures that make strong men gag. We do this not for power, recognition, financial reward, or the alma mater. We're not burnishing our resumes. We do it because we want to make sure medical research helps humankind without harming individual humans. While celebrating the power of science to work miracles, we also feel it our duty to protect people who might suddenly wake up one morning and find they are on the verge of becoming subjects in research. (These people, we know, could be ourselves--or you.)

Community members are uniquely positioned on the IRB to put people first, unhampered by personal ambition, scientific bias, interdepartmental rivalry, or the profit motive. This is the implied covenant of the community member: to try our best to make the research fair and straight.

For some, like myself, the motivation to serve is more personal. We or our loved ones have been research subjects, so we bear an especially poignant responsibility. The memory of the peculiarly uneven power relationship between investigator and subject is one that still burns bright.

Despite the purity of our calling, though, many of us have noticed that serving as community IRB members doesn't necessarily win us friends and influence people. Oftentimes, we feel like the skunk at the picnic. Institutions and researchers alike view us with skepticism, or with resignation at best. It probably doesn't help that the very federal regulations mandating our presence define us principally by what we are *not* (noninstitutional and nonscientific), while our committee colleagues are widely recognized for what they *are* (doctors, scientists, and employees of the institution, for example).

Although we are charged with representing the broad interests of the public, community members often find ourselves marginalized, with numbers on IRBs that barely meet mandated minimums.

Federal regulations require each IRB to have at least five members, of which at least one is nonscientific and at least one is nonaffiliated. Most often the nonaffiliated and nonscientific members are the same person, accounting for about 10% of IRB members. It's not unusual for IRBs in large institutions to have three to four times the minimum required membership, with one nonscientist, nonaffiliated member flying solo. In the alphabet-soup world of the highly credentialed, the input of these singleton community members is easily overlooked--or, worse, discounted. Does this power imbalance make for credible research review? Not really.

It's been said that the history of science is a series of peaceful interludes punctuated by intellectually violent revolutions. Pretty clearly, today's era falls into the latter category. Day after day, we hear the news stories: Jesse Gelsinger's death and institutional research shutdowns;

Rezulin and perchlorate; allegations of misdeeds by pharmaceutical companies; and worries about genome mapping, genetically modified foods, and mad cow disease.

Whatever one may think of these stories, and I know many would like to chalk them up to journalistic excess, they are a daily reminder that the cloistered world of medical research has earned the public's suspicion. This is a significant problem. "With the public trust, everything is possible," Abraham Lincoln wrote. "Without it, nothing is possible."

There's no question that the research review process is broken and needs fixing, as the HHS Inspector General has aptly documented. With the promise of bio-breakthroughs (with possible fame and riches) around every corner, the pressure on researchers is immense. One place to start, though only one, is to enhance IRBs' public accountability by boosting the number of public IRB members who are directly involved in scrutinizing research.

Let's face it: one community member per committee isn't enough to be heard, much less respected. Neither is two. At UCLA we've got four out of twenty; we could do better.

The fact is, a solid contingent of community-oriented members can increase the effectiveness of an IRB by asking tough questions and evaluating proposals from the viewpoint of committed, independent, and fair observers.

Once a capable group of public members is present at the table, the committee may start seeing things it hadn't noticed before. Here are just a few: coercive and opportunistic recruitment plans; proposals that misstate risks and benefits or fail to disclose financial relationships between investigators and sponsors; proposals that could stigmatize people or undermine their privacy; proposals that confuse research with treatment; studies that seek to take advantage of vulnerable subjects abroad; and, of course, unintelligible consent documents.

This evolution may be painful for institutions, but there's a silver lining. Fixing problems early means they'll never show up on the evening news.

Patricia E. Bauer. *IRB: Ethics and Human Research*, 23, no. 1. (2001): pp. 7-8.



# Introduction

It is not unusual for new IRB community members to experience some sort of discomfort or difficulty when first serving on the IRB. Some new members may not be clear on what to expect or what is expected of them, and others may feel a sense of intimidation or being inadequately prepared. New community members will encounter a new vocabulary and be required to develop a sufficient understanding of human subjects research.

Basic training for new IRB members is not universally offered. While some community members receive education on human subjects regulations and ethics, most feel the training is inadequate and mentoring is absent.

This two part manual is a useful training tool and a reference designed to improve the IRB community member experience.

- **Part I** contains the **basics** of the community member experience to help newcomers acclimate to this role.
- **Part II** is a resource that provides a readable **overview of federal, state, and local laws and regulations**, as well as institutional policies and procedures.

Once comfortable with this information, it is recommended that the readers of this guide explore the following websites:

- USC Human Subjects Protection Program (<https://oprs.usc.edu/>)
- Federal Office for Human Research Protections (<http://www.hhs.gov/ohrp/>)
- Food and Drug Administration (<http://www.fda.gov/>).

These websites provide extensive resources and information on human subjects protections.

For comments or questions about this guide, contact the University of Southern California (USC) **Office for the Protection of Research Subjects (OPRS)** at [oprs@usc.edu](mailto:oprs@usc.edu) , **IRB Student Mentor** at [irbgara@usc.edu](mailto:irbgara@usc.edu), or the **IRB offices** at [upirb@usc.edu](mailto:upirb@usc.edu) (University Park Campus) and [irb@usc.edu](mailto:irb@usc.edu) (Health Sciences Campus).

**PART I – BASICS**



# CHAPTER 1 Community Members: Roles, Responsibilities, and Purpose

This chapter provides basic information for those interested in serving as a community member on an IRB and is designed to answer common questions. It also provides a short history on community member involvement in human subjects protections and outlines the community member's role within the IRB.

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## WHAT IS RESEARCH AND WHO ARE HUMAN SUBJECTS?

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Community members need to understand human subjects research, which differs in many ways from other kinds of research. When humans voluntarily enroll in research studies, a high level of respect is required to honor that choice. Federal regulations define “human subject” and “research” in a way that differs from common use of those terms.

The following are the federal definitions (45 CFR 46, also known as the “Common Rule”):

**Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject** is a living individual **about** whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.

These definitions may seem straightforward to new members, but with experience, the meanings and subtle nuances become more important.



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## THE HUMAN SUBJECTS PROTECTION PROGRAM

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The University of Southern California (USC) operates a University-wide **Human Subjects Protection Program (HSPP)** to review and approve all research involving human subjects. The HSPP encompasses many levels of administration and academic programs. Protection of human subjects in research is a shared responsibility among various components of a research institution. The IRB, the most visible part of the HSPP, is but one component. Legal

offices, oversight offices, institutional administration, researchers, and even research volunteers also share this responsibility and all play an important role in the program's success.

At USC, the Office for the Protection of Research Subjects, which reports to the Vice Provost of Research, oversees human subjects' protections through program oversight, education, policy setting, and outreach. The IRBs at USC are empowered to review all human subjects research proposals which are conducted by USC faculty, staff, graduate or undergraduate students. The researchers and participants are expected to honor the terms under which they have agreed to participate in the research process.

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## WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

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The IRB is an oversight committee charged with reviewing all research involving human subjects to ensure research complies with institutional policies and state, local and federal laws. The IRB has the authority to approve, require changes to the study procedures, or disapprove proposed research projects.

The IRB functions as a surrogate "human subject advocate." Its role is to safeguard the rights and welfare of research subjects by evaluating the research to assure an acceptable balance of risks to benefits.

Under the terms of the Common Rule, the IRB must:

- Have at least five members
- Include individuals from academic disciplines relevant to the research being reviewed
- Include at least one non-affiliated member
- Be diverse in terms of race, gender and cultural background.
- Have the necessary experience and expertise to fairly evaluate the proposed research.

IRB members can be faculty, staff or students from the institution, and members from the local community.

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## WHAT IS A COMMUNITY MEMBER?

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An IRB community member is someone from outside the organization or institution. They come from a variety of backgrounds and are chosen for their particular experience, knowledge, or relationship to the types

of studies reviewed by the IRB. These members often are drawn from the community in which an institution resides. They may be members of local clergy, interested volunteers, teachers, retirees, nurses or ethicists. Some are former research subjects. Others are interested in promoting research or are motivated by their concern about a particular disease or condition.

The community member's perspective is usually non-scientific. Because community members may not be affiliated with the institution, employees and retirees of the institution cannot serve as community members nor can their spouses.

Although federal and state regulations do not use the term 'community member' – and instead refer to people in this position as non-affiliated members (meaning they are not directly associated with the institution) – there is a historic interest in assuring that IRBs are mindful of community values.

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## HISTORY OF COMMUNITY MEMBERS ON IRBS

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In the wake of the most notable violations of human rights in the history of research, ethical codes for physician researchers were developed and oversight by ethics committees was established and became mandatory for human subjects research. Persons with interests external to academic and medical research domains were included on these newly mandated committees.

Human subjects research in the early days after WWII was primarily funded by governmental agencies and only later did pharmaceutical and other sponsors fund large numbers of studies. The ethical and legal expectations for human subjects research cover all funded / not funded sources.

The most cited ethical lapses in human subjects research were the **Nazi Doctors' Medical Experiments** in World War II and the **Tuskegee Syphilis Study** begun in 1930 on syphilitic black men in Alabama.

- **The Nazi Doctors' medical experiments:** After World War II, the world learned of the moral depravity of the 20 Nazi physicians who were convicted in Nuremberg, Germany for the part they played in the brutal human experiments at Nazi Death Camps. The moral lessons learned from the Nuremberg Trials were the need to limit human experimentation within strict moral, legal, and ethical boundaries and require voluntary consent of the human subject. The advancement of science alone is not an adequate goal when research compromises the safety and integrity of the human subject.
- **The Tuskegee Syphilis Study:** For 40 years between 1932 and 1972, the U.S. Public Health Service (PHS) conducted "research" in Tuskegee, Alabama on 399 black men in the late stages of syphilis. These men – mostly poor illiterate sharecroppers – were never told that they had syphilis, told of its seriousness, nor offered available cures. Informed that they were being treated for "bad blood", their doctors never intended to

cure them of syphilis. The data for the experiment was to be collected from autopsies of the men, and they were thus deliberately left to suffer from the severe symptoms of this debilitating disease. Public outrage eventually ended this study and provided the impetus for the esteemed Belmont Report and subsequent federal human subjects protections and regulations. The PHS, which conducted the study, acknowledged in retrospect that the scientific peer review system did not address fundamental ethical issues.

The U.S. Surgeon General's policy\* as amended in 1966 was the basis for the creation of Institutional Review Boards (IRBs). This amendment was the first to suggest the inclusion of **local communities** in the practice and ethical review of research. In 1971, the Department of Health, Education and Welfare (DHEW) *recommended* that an ethics review committee include **individuals** whose primary concerns lie outside the domain of research under the DHEW purview.

Current regulations further protect against institutional biases or conflicts of interest by *requiring* that IRBs include at least one member who is "unaffiliated with the institution." This community member is responsible for giving voice to community concerns. The impact of scientific inquiry and notions of autonomy, justice, and beneficence now have a social and historical context.

Community IRB members have become an indispensable asset to IRBs across the nation. Success with community involvement in IRBs has resulted in community consultation being utilized in diverse areas of research such as HIV/AIDS clinical trials, genetic research, stem cells and Centers for Disease Control (CDC) studies.

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## WHAT DOES THE COMMUNITY MEMBER OFFER THAT OTHER MEMBERS DO NOT?

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Community members represent the "community of research subjects"—not the interests of the institution. These members often are drawn from a particular community group, such as those who are served by the institution or who live within the surrounding area. They also may represent ethnic, socio-economic or patient groups that add a needed voice to institutional decisions.

The more community members on an IRB, the more diverse, balanced, mutually supportive, and the louder they can be in voicing concerns regarding the protection of subjects. In addition, the IRB is more enlightened by the inclusion of outside voices and thus better able to protect human subjects. Communities, institutions, research, the public, and the subjects are better served when community members are involved in the IRB process.

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\* *Clinical Research and Investigation Involving Human Beings,* Surgeon General, Public Health Service to the Heads of the Institutions Conducting Research with Public Health Service Grants

An IRB *community member* often fills both roles required by federal regulations: an IRB must have at least one member whose expertise is not in a scientific area (*non-scientific member*), and the other is to have at least one member who is not affiliated with the institution (*unaffiliated member*). The regulations added these specific functions for the following reasons:

- *Unaffiliated* members were intended to have no formal ties to the institution other than IRB membership. Thus, enabling them to provide the IRB with an unbiased view, not one driven to make the institution look good or bad, to increase funding, or approve particular projects.
- *Non-scientific* members were to provide the IRB with expertise in such nonscientific areas such as law, religion, education, or ethics and thus act as a surrogate for participants and non-research values.

Roles unique to Community Members:

- Provide non-biased opinion in relation to the institution
- Provide the voice of the participant in the research process
- Provide balance to pro-research viewpoint
- Provide unique viewpoint not biased by employment
- Provide values of the community, neighborhood, patients, public, and society to the research process

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## WHAT IS EXPECTED OF ME AS A COMMUNITY MEMBER?

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A considerable **time commitment** is required when serving as an IRB member. IRB members need to set aside blocks of time to review IRB applications and protocols, attend meetings, and avail themselves to educational opportunities. The amount of time needed will gradually lessen as the process becomes familiar. Keep in mind - some studies are so technical, complex, and dense, that other IRB members or consultants will need to review the most technical sections in addition to your review.

IRB Members are expected to:

- Submit Resume or CV to the IRB office
- Review and Critique Research Applications
  - Review all materials (IRB application, informed consent, questionnaires, recruitment documents, etc.) on the meeting agenda.
  - Review expedited actions/minutes linked to the agenda, and if issues or errors are found resolve them with the IRB staff.
  - Assure that applications include adequate protections for human subjects in the research plan.

- When assigned as a reviewer, post the review in the electronic IRB system (iStar) at least two days prior to the meeting.
- Voice issues—either publicly or privately—that are noted while reviewing the protocol. Including “gut feelings” that can’t be adequately defined.
- Attend Meetings and Education Sessions
  - **Attend a majority** of the IRB committee meetings
  - Attend **outside educational events** (such as web-based training, guest speakers, and conferences), which are in addition to educational sessions presented at the IRB meeting.
  - Allot time to read about human subjects protections, and avail yourself of education, IRB documents, and the experience of your colleagues, and the IRB staff or other members.
- Possess basic **computer, internet, and word processing skills** to review protocols and communicate with the IRB staff/members and investigators.
- Review monthly meeting minutes for accuracy and promptly notify the IRB Chair and/or staff of any corrections or additions.
- Absent yourself from discussion and voting on any project where there is a potential or real **conflict of interest**.
- **Maintain confidentiality** for all discussions, reviews, meeting minutes, and proprietary information you will encounter as an IRB member.

Note: On some IRBs, community members are paid an honorarium for each meeting they attend. Meals and snacks are often provided during the meetings. If you need something to enable your continued service – just ask!

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## WHAT CHALLENGES MIGHT I FACE?

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Adjusting to the community member role will take time as challenges faced will vary from IRB to IRB, and person to person. As community members grow more experienced, their comfort level will increase, anxiety level will decrease, and overall participation in the review process will increase.

Below are challenges and observations provided by a Biomedical IRB community member and a Social and Behavioral IRB community member:

- You will have to adjust to an environment unlike that of any other committee you’ve served on.
- You will be expected to provide and defend your opinions. Discussions may get heated, but realize you are not under attack.
- You might question whether your opinions are valid or your suggestions are feasible, and they may not always be. Be open-minded to learning, but stick to your guns if you remain unconvinced.



- You may find that you are alone in your vote.
- Other committee members may appear busy, distant, or uninterested.
- You may struggle with trying to find how the research actually benefits or is related to the community or the people who are participating in the research. IRBs have a tendency to discuss risks in depth and yet gloss over possible benefits. But benefits should also be noted and real. Ask if there are any benefits!
- You might not understand everything you read or hear. IRB members tend to use medical, scientific and regulatory jargon, making it difficult to follow discussions. Your understanding will increase as you become more comfortable with the terminology. To get you started, we've provided a glossary ([Appendix A](#)).
- If the IRB doesn't meet often, it may be difficult to develop a team atmosphere. As with any group, there may be disagreements and personality conflicts, creating an uncomfortable environment especially noted by new members.
- You might be disappointed in the quality of some of the research applications. Submissions coming from certain schools/departments may be more problematic than others. The Chair or Director should let the IRB know when efforts are being made to improve those particular applications.
- You should feel free to ask questions at the meetings.
- If you feel uncomfortable asking questions, find someone on the committee who can mentor you.

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## **WHO ARE THE OTHER IRB MEMBERS?**

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Besides IRB community members, IRBs are comprised of persons from a variety of disciplines and positions within the institution. The type of institution and its research portfolio influence those members found on the IRB (e.g. research institute, hospital, academic institution). Members commonly include faculty researchers, lawyers/judges, physicians, nurses, pediatricians, research administrators, psychologists, and other faculty, staff, and students. Members are usually recruited from departments and schools that submit research to the IRB or whose particular expertise is needed (epidemiology, urology, hematology, surgery, statistics, law, anthropology, etc.) or who have strong commitments to institutional service.

Although most members are voting members, non-voting *ex officio* attendees may also be part of the committee, and guests or consultants may also be in attendance.

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## **WHO ARE THE IRB STAFF?**

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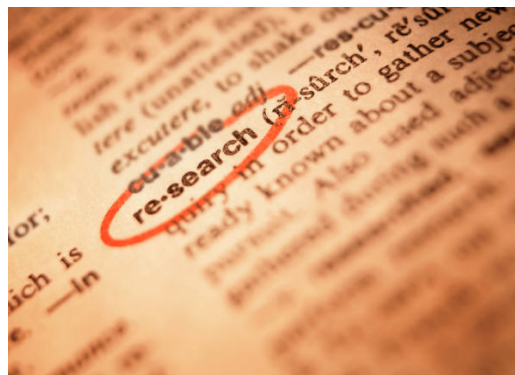
IRB staff are employed by the institution and comprise the IRB office. Their duties include preparing agendas, conducting initial screening of protocols, compiling correspondence, taking minutes, providing support for investigators and researchers, and arranging IRB meetings. Each study or protocol that is submitted for IRB review is assigned to a staff reviewer to begin the process. This person is responsible for screening the protocol and solving as many issues as possible before the study is reviewed by an IRB member. These

may include obtaining missing documents, getting answers to questions, or addressing problems that will delay IRB approval.

Staff members know a great deal about the regulations governing research. IRB staff often have backgrounds in research, including research administration, clinical research, the medical and legal fields, and the social sciences. They come to the process with a strong knowledge of the regulations, and the institutional culture. As a result, they are a great help to community members, IRB reviewers, and the research team—and a wonderful resource to call on if you have questions or want help.

# CHAPTER 2 IRB 101

This chapter provides a short introduction to IRB regulations, policies, procedures, research terminology, and the roles of research personnel. It also provides an overview of statistics, clinical trials, and tips on how to review a protocol.



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## WHAT POLICIES AND PROCEDURES SHOULD I BE FAMILIAR WITH?

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IRBs are expected to follow federal, state, and local laws, as well as regulatory and institutional policies. In addition to these requirements, IRBs examine ethical issues when reviewing research projects. For USC's Human Subjects Protection Program, a comprehensive set of policies and procedures was created: <https://oprs.usc.edu/rules/>. IRB Community members should familiarize themselves with these policies and procedures and refer to them when completing reviews.

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## WHAT IS INFORMED CONSENT?

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Informed consent is the process of informing potential subjects about the key facts of a research study and what their participation will involve. The human subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a vulnerable population (see [Code of Federal Regulations](#)), such as pregnant women, prisoners or children, additional protections are required.

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## WHAT ARE THE REGULATORY LEVELS OF IRB REVIEW?

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The "Common Rule" ([45 CFR 46](#)) provides for three levels of review for human subjects research. They are exempt, expedited and full board:

**Exempt Review:** protocols commonly involve less than minimal risk (e.g. anonymous survey) to subjects and fall within at least one of the six federally defined categories. These projects are reviewed by one designated reviewer or IRB member. This level of review has no continuing IRB oversight requirements. The federally defined exempt categories\* are:

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\* Refer to Part II of this book for the complete descriptions of the review categories

- **Exemption 1:** Research conducted in commonly accepted educational settings involving normal educational practices
- **Exemption 2:** Educational tests, surveys, interviews, or observation of public behavior unless subjects can be identified and disclosure of data could place subject at risk
- **Exemption 3:** Educational tests, surveys, interviews, or observation of public behavior that involve elected/appointed public officials/candidates for public office or research conducted under federal statute
- **Exemption 4:** Collection/study of existing data, documents, records, specimens, if publicly available or if the information is not identifiable
- **Exemption 5:** Research and demonstration projects conducted/approved by Department/Agency heads designed to study/evaluate public benefit or service programs
- **Exemption 6:** Taste and food quality evaluation and consumer acceptance studies

**Expedited Review:** protocols involve minimal risk (e.g. blood draw, longitudinal study on attendance and graduation outcomes) and fall within one of nine federally defined categories. These projects are reviewed by one designated, well trained IRB member. This level of review has ongoing IRB oversight requirements. The federally defined expedited categories\* are:

- **Category 1:** Clinical Studies that do not involve an investigational drug or device exemption (e.g.: FDA - IND/IDE NOT required)
- **Category 2:** Blood sample collection (routine methods-small amounts)
- **Category 3:** Prospective collection of biological samples through noninvasive means
- **Category 4:** Data collected through noninvasive means (routinely practiced in clinical settings)
- **Category 5:** Materials, data, documents, specimens etc. that have been collected or will be collected for non-research purposes
- **Category 6:** Collection of voice, video or digital data for research purposes
- **Category 7:** Individual or group behavior, surveys, interviews
- **Category 8:** Continuing Review of research previously approved by the convened IRB with no further direct subject participation
- **Category 9:** Continuing review of research (not under an IND or IDE) where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

**Full Board Review:** protocols involving greater than minimal risk (e.g. drug, device, biologics, and collecting/recording private information). These projects are reviewed by a fully convened IRB committee. This level of review is extensive and has continuing IRB oversight requirements.

**Not Human Subjects Research** – a non-reviewed category:

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\* Refer to Part II of this book for the complete descriptions of the review categories

- Not all research using human subjects require IRB review. However, the IRB must be involved in determining applicability. Studies that do not meet the regulatory definitions of “human subject” or “research” are relegated to a category USC calls [Not Human Subjects Research \(NHSR\)](#). An additional regulatory exclusion refers to research projects that use coded (not identified) specimens or information. See federal guidance “[Coded Private Information or Biological Specimens](#).”

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## WHAT ARE THE TYPES OF IRB RESEARCH SUBMISSIONS/INTERACTIONS?

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There are a variety of types of IRB submissions and various reasons that may warrant IRB – researcher interaction. The IRB staff, chair, vice-chair, or designated reviewers perform some actions the community member will not be involved with. Some submissions are filed without action. Although community members may not see all of the different types of IRB submissions, a list of these are provided below as a reference.

Common types of submissions include:

- *Full Board*: more than minimal risk, requires IRB review
- *Expedited*: minimal risk, requires review by one designated IRB reviewer
- *Exempt*: less than minimal risk, can be reviewed by IRB staff
- *Continuing Review*: yearly review required for full board and expedited projects
- *Amendment*: any change in risk, personnel, scope, procedures, etc.
- *Reportable Event*: adverse events and unanticipated problems involving risks to subjects or others, protocol deviations, noncompliance
- *Not Human Subjects Research*: research with “coded data or specimens” or studies that do not meet the federal definition of “human subject” and/or “research”
- *Suspension*: temporary hiatus of study procedures resulting from decision of IRB, PI, or sponsor
- *Termination*: IRB decision to halt a study, and usually requires a new submission to reactivate

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## HOW TO REVIEW A PROTOCOL

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Using a reviewer checklist is a good way to review protocols, support materials, and consent documents. Reviewer checklists help organize thoughts, provide reminders of issues to be addressed, and give useful formats to present the review at the full committee meeting. The complete set of USC IRB reviewer checklists can be found in Part 2, or can be downloaded here: <https://oprs.usc.edu/review/tipsheets/>.

Once Community Members establish system for review research that work well for them, the process will become easier over time. IRB community members may always call the IRB staff or another IRB member if something is unclear, missing or prompts questions about the proper course of action.

#### Tips for Reviewing

1. Establish a review routine by using a **systematic approach** to review each new protocol in the same way.
2. Read the **consent document** to understand the important aspects of the study. The consent document should serve as a good introduction to the study protocol. It should also orient you to the overall design of the study.
3. Read the **abstract** in the IRB application which provides key aspects of the study.
4. Read the **full protocol** and **supporting materials** carefully. The investigator provides the IRB with detailed information such as the study background and rationale, methodology, inclusion/exclusion criteria for subject enrollment, and other documents. Funding documents provide additional information. Take notes as needed.
5. Reread the consent document. **Record suggested corrections or questions** for the investigator, and ensure that the consent form adequately describes the actual study design and procedures in a language that can be understood by the subject.
6. Contact the staff reviewer if there is information missing that is needed for full board review.

The reviewer checklist is included in [Appendix B](#).

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## WHO ARE VULNERABLE SUBJECTS?

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The term “vulnerable subjects” refer to research subjects that have been designated as vulnerable by federal regulations. Federal regulations outline special protections investigators must incorporate into their research when enrolling and conducting research with vulnerable subjects. Vulnerable subjects are:

- pregnant women, human fetuses, and neonates ([45 CFR 46 Subpart B](#))
- prisoners ([45 CFR 46 Subpart C](#))
- children ([45 CFR 46 Subpart D](#))

IRBs and researchers must bear in mind that vulnerability extends beyond the regulatory definitions. Vulnerability is an important consideration in all IRB deliberations. Individuals, as well as entire cohorts of subjects, may be susceptible to coercion depending on the particular study. Adequate justifications must be provided for studies that enroll vulnerable subjects.

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## WHAT IS THE CALIFORNIA BILL OF RIGHTS?

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In addition to federally required protections, another layer of protection is found in the California Health and Safety Code\* for subjects participating in medical experiments†. While not all research with human subjects involves medical experiments (e.g. drug study), these ethical principles do apply to human subjects research in general.

***California law (as interpreted from the California Experimental Subject's Bill of Rights) requires that the following be addressed in the first page of the informed consent when the research involves a medical experiment:***

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- (i) Be given a copy of the signed and dated written consent form.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.



\* Section 24172 of the California Health and Safety Codes

† A "medical experiment" is defined as follows: (a) penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; (b) The investigational use of a drug or device; (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

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## THE COMMON RULE

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The U.S. Department of Health and Human Services (DHHS) Policy for the Protection of Human Subjects ([45 CFR 46](#), Subpart A) is also known as “**The Common Rule**”. This policy was designed to standardize regulation of human subjects research by all federal agencies and departments. This policy has been adopted by 17 Federal agencies and departments.

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### WHAT CRITERIA MUST BE MET TO APPROVE A PROTOCOL?

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The “Common Rule” sets forth certain criteria ([45CFR 46.111](#)) that must be met in order for the IRB to approve a protocol. Proposed research must satisfy each requirement below:

**(1) *Minimized Risks***

Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

**(2) *Reasonable risk/benefit ratio***

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

**(3) *Equitable subject selection***

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

**(4) *Obtain Informed Consent***

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section [46.116](#).

**(5) *Document Informed Consent***

Informed consent will be appropriately documented, in accordance with, and to the extent required by Section [46.117](#).



**(6) Data monitored for safety**

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

**(7) Confidentiality/privacy maintained**

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.



Additional safeguards must be included when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. These safeguards for federally designated vulnerable subjects may be found at 45 CFR 46, Subparts B, C, and D.

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## WHAT IS CONFLICT OF INTEREST

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The term “conflict of interest” (COI) refers to situations in which financial or other personal considerations compromise, or have the potential to compromise, an individual’s professional judgment or objectivity. Conflict of interest may occur with the researcher, IRB member, or the institution. All three types of COI must be reviewed and managed by the institution or its designated committee.

**Researcher COI** may occur in proposing, conducting or reporting research. The bias caused by such conflicts may affect collection, analysis, and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects, and the use of statistical methods. Federal funding requires researchers to annually disclose financial interests such as consultation fees or sponsored travel that could influence their research. See [NIH COI](#).

**Institutional COI** is a growing issue that is increasingly being noted by institutions and regulatory bodies. Finding those projects where the institution has interests that may conflict with the research outcome is of special concern in human subjects research. Institutional COI is a difficult issue to identify and resolve because of the variety of ways an institution can be an “interested stakeholder” or have other interest in the conduct or outcome of a project.

**IRB Members** who have an “outside” interest or relationship to a research project or investigator are prohibited from participating in the vote and discussion of the project. IRB members are both required to recuse themselves (leave the meeting room) before the discussion and prohibited from voting on a study in which they have a COI. In some

cases, the IRB may request a member to be present in order to provide information to the committee. Unless an IRB member declares a conflict of interest, their unbiased ability to review a project is assumed.

The IRB is not in a position to adequately evaluate disclosures of researcher conflicts of interest and must seek determination from the Financial Disclosure Review Committee (FDRC). At USC, a policy has been established to provide for IRB review by an outside entity when there is an institutional COI.

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## THE DIFFERENCE BETWEEN BIOMEDICAL AND SOCIAL/BEHAVIORAL RESEARCH

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Community members may be on IRBs that review biomedical or social and behavioral research, or both. Human Subjects Protection Program policies and the federal regulations focus on biomedical rather than social/behavioral research. The IRB will make every effort to review social/behavioral research in an appropriate context. In order to feel comfortable understanding the differences between social/behavioral and biomedical research, the following matrix illustrates some typical differences:

	Social Behavioral	Biomedical
<b>Terms commonly used to describe the research</b>	interpretative, qualitative, action, observational, community based, emergent	quantitative, positivist, objective,
<b>Intended Research Outcome</b>	produce rich description or theory	use of controlled/limited variables to test a biomedical outcome
<b>Validity of Outcome Provided by</b>	a research strategy utilizing verification/validation measures and reliable observation techniques	fixed procedures
<b>Interaction with Subjects</b>	social scientist is often an involved participant	researcher is a non-participant
<b>Methods Used</b>	observations, surveys, interviews, focus groups, comparisons, internet	drugs, medical procedures, interventions, test devices, biologics
<b>Hypothesis Driven?</b>	can be yes or no	yes
<b>Interpretation by Experimenter vs. Experiment</b>	experimenter and experiment	experiment
<b>Social Distance between Researcher and Subjects</b>	can be close relationship	should be more distant relationship
<b>Dynamic/flexible/iterative Study Design?</b>	yes	no
<b>Power Differential</b>	can be minor or major	usually major

<b>Perception of PI over Subject</b>		
<b>Risk of Physical Harms (e.g. illness, death, etc.)?</b>	no (though yes rarely)	yes
<b>Risk of Social Harms (e.g., embarrassment, employability, etc.)?</b>	yes	yes
<b>Generalizable to other settings/populations?</b>	can be yes or no	yes
<b>Requires IRB review?</b>	can be yes or no	yes

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## WORDS TO LEARN

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As a new IRB community member, you will come across terminology you may not be familiar with. Don't worry; this is common for anybody who is new to the IRB. The list below includes definitions/descriptions of some of the common terms used in human subjects research. A more comprehensive list can be found in the glossary ([Appendix A](#)). This section on terminology provides:

1. Project review terms
2. Study related personnel terms
3. IRB related personnel terms
4. Research related statistics terms

a. PROJECT REVIEW TERMS

**Amendments** – These are changes to an IRB approved research protocol and must be submitted and approved by the IRB before implementation (e.g. revised consent document, change in personnel, additional risks). Amendments involving more than minor changes or changes that pose more than minimal risk will be reviewed by the full committee.

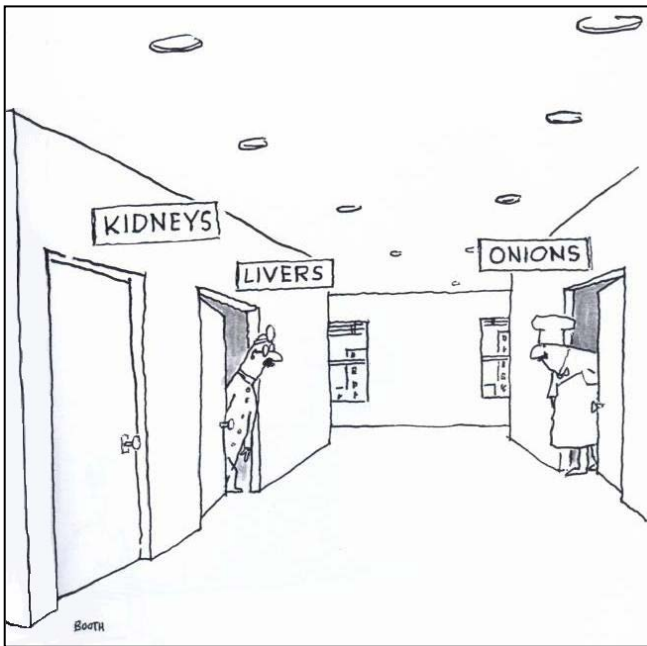
**Coded Data** – Replacing identifiable data/private information (e.g., name or social security number) with a 'code' (e.g., letters, symbols or numbers). The goal is to protect the identity of the subject. The key is that the code is not kept with the data.

**Common Rule** – The federal rules and regulations that IRBs must adhere to were codified in 1991 Policy for the Protection of Human Subjects ([45 CFR 46](#)). This policy is frequently called the “The Common Rule” because it has been adopted by all federal agencies and departments conducting or supporting human subjects research.

**Confidentiality** – Describes the protections taken to safeguard data/information obtained from a subject.

**Continuing Review** – Periodic re-review of a research study by the IRB to evaluate if risks to participants remain reasonable in relation to potential benefits, and to evaluate if the study continues to meet regulatory and institutional requirements. Continuing review shall be conducted at intervals appropriate to the degree of risk but not less than once per year. ([45 CFR 46.109\(e\)](#); [21 CFR 56.109\(f\)](#))

**Deception** – Deception is the intentional misleading of subjects or intentional withholding of information about the nature of a study. Deception limits the ability of subjects to provide truly ‘informed consent’; however, it is sometimes necessary for certain types of behavioral research. Deception is often justified because humans act differently depending on study circumstances, and full disclosure of study information/goals may bias the results.



**De-identified Data** – Data is considered de-identified when unique identifiable information (e.g., name, address, social security number, telephone number, etc.) is removed from the data so that the subjects/source cannot be identified.

**Exempt Research** – Certain kinds of research involving minimal or less than minimal risk may be “exempt” from IRB oversight when the activities fall into one or more of the exempt categories at [45 CFR 46.101](#). Investigators are not permitted to determine if their research is exempt. Investigators must submit proposed exempt research to the IRB for review and exempt determination.

**Expedited Review** – Federal regulations allow for an expedited review (one reviewer only) for certain kinds of research involving no more than minimal risk. For a list of the expedited research categories, [click here](#). IRB Chairs and other experienced/trained IRB members designated by the IRB chair may conduct expedited reviews.

**Federal Regulations** – Concerning human subjects research: The *Department of Health and Human Services (DHHS)* human subject regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. The *Food and Drug Administration (FDA)* regulations on the protection of human subjects are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations.

**Full Board Review** – Research involving greater than minimal risk must be reviewed at a fully convened meeting, where a majority of the committee members are present.

**HIPAA** – Health Insurance Portability and Accountability Act (“Privacy Rule”) was updated on January 25, 2013. The law generally prohibits health care providers such as

health care practitioners, hospitals, nursing facilities and clinics from using or disclosing protected health information without written authorization from the individual (HIPAA Authorization). The updated HIPAA rules allow research to be conducted with different expectations than medical care.

**Human Subject** – Under the federal regulations, human subjects are defined as: living individual(s) **about whom** an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**Human Subjects Training Certification** – Human subjects training certification is required for research approval at many institutions, including USC. USC uses an online educational program called CITI Human Subjects Research. Many funding agencies require key research personnel to complete educational modules relevant to their research as a condition of funding.

**Informed Consent** – A person's voluntary agreement to participate in research, once they've understood the possible risks and benefits of participation. Consent may be written or oral in defined circumstances, or translated from a language other than English.

**Institutional Review Board** – The IRB is an independent committee comprised of at least five members from academic disciplines (preferably) relevant to the research being reviewed. At least one member must be unaffiliated with the institution, and one must be a non-scientist. The membership should consist of both men and women. Members can include faculty, staff, and students from the institution, and persons from the local community.

**Key Personnel** – These are individuals in a research project who include but are not limited to: Principal Investigators (PIs), Co-PIs, faculty advisors, study coordinators, recruitment staff, and anyone else conducting study procedures or interventions.

**Minimal Risk** – A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests.

**Multi-site research** – A research study conducted at more than one institution (nationally and/or internationally) using the same protocol, each with its own Principal Investigator. Many clinical trials involving drugs/devices/biologics are conducted at more than one site.

**Privacy** – Privacy refers to the subject and his/her control over the extent, timing and circumstances of sharing oneself (physically, emotionally, behaviorally, or intellectually) with others.

**Protocol** – The formal design of an experiment or research activity. The protocol includes a description of the research methodology, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. Research involving drugs, devices, or biologics

will have a formal clinical protocol, which is submitted with an IRB application. For non-clinical social and/or behavioral research, a properly completed IRB application can serve as the protocol.

**Reportable Events** – At USC, the term “reportable events” refers to: adverse events, unanticipated problems involving risk to subjects or others, protocol violations, and data safety monitoring reports. Reportable events are submitted to the IRB in a reportable events application through the iStar system.

**Research** – Federal regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” ([45 CFR 46.102\(d\)](#)). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

**Sponsored/funded research** – Sponsored or funded research is research that is financially supported by an outside entity. The funding may come from a pharmaceutical company, from a foundation, a donor, or the government. The following are among the government funding agencies sponsoring research at USC:

- [Centers for Disease Control \(CDC\)](#)
- [National Institutes of Health \(NIH\)](#) – includes multiple institutes such as [National Cancer Institute \(NCI\)](#) and [National Institute for Mental Health \(NIMH\)](#)
- [National Science Foundation \(NSF\)](#)
- [Department of Defense \(DOD\)](#)
- [Department of Energy \(DOE\)](#)
- [Department of Education \(DOEd\)](#)

**Target Accrual** – The number of subjects the investigator wishes to enroll in a particular study. This number can change, depending on the stage and goal of the study. For example, a pilot study may have 5 subjects, and a Phase III clinical trial may have 500 subjects. A social and behavioral study could have a whole tribe or selected individuals. Target accrual must be justified in IRB applications.

#### b. STUDY RELATED PERSONNEL TERMS

**Co-Principal Investigator (Co-PI)** – In addition to the principal investigator, the co-principal investigator is the scientist or scholar who shares responsibility for the design and conduct of a research project. The Co-PI may be involved with a large portion of the research, or a small portion. The type and amount of study involvement depends on the responsibilities agreed upon by the PI and the Co-PI.

**Data Manager** – An individual who handles the data gathered during a study. Responsibilities may also involve managing data entry, database generation and/or maintenance, compliance with regulations, and protection and integrity of private information and study data.

**Data Monitor** – An individual assigned by the study sponsor/IRB to monitor data collection and study results. This individual is often independent of the research team.

**Data and Safety Monitoring (DSM) Board or Committee** – A committee of scientists, physicians, statisticians, and others that collect and analyze data during the course of a clinical trial. The DSMB monitors adverse events and data to identify trends (such as an indication that one treatment is significantly better than another) that warrant study modification, termination, or notification to subjects when information is obtained that might affect their willingness to continue. The National Institute of Health (NIH) requires that DSMBs oversee all Phase 3 clinical trials. USC policy requires data safety monitoring when the degree of risk is significant.

**Faculty Advisor** – Faculty advisors are faculty members who supervise and oversee research being conducted by students. Advisors are responsible for guiding students through the IRB process, helping with research design, methodology, and ethical considerations.

**Fellow** – A graduate doctor continuing to study in a medical specialty, and conducting independent research with minimal teaching duties. This individual holds a temporary academic post and as such, may obtain a fellowship and associated research funding.

**Graduate Assistant** – A graduate student employed temporarily by the institution while they work towards an advanced degree.

**Key Study Personnel** – Individuals responsible for the protocol development or design, conduct, or reporting of research. These include but are not limited to: Principal Investigators (PIs), Co-PIs, faculty advisors, study coordinators, recruitment staff, and anyone else performing study procedures or interventions.

**Monitor** – A monitor is a type of research auditor, usually employed by a drug sponsor/pharmaceutical company, who ensures that research protocols are being followed and documented appropriately. Monitors visit research sites regularly to inspect study documents and medical records, and to validate research data.

**Principal Investigator (PI)** – The lead scientist or scholar who holds the ultimate responsibility for the conduct of a research project. The PI is the signatory authority of the study.

**Research/Subject Advocate** – Individuals who work with research subjects and promote subject rights. Their range of activities can vary. Some advocates may help subjects make an informed decision about research participation by explaining possible risks and benefits.

**Research Assistant (RA)** – An undergraduate or graduate student who works for an investigator/faculty member for a specified term. RAs usually work on a research project and are supervised by a full-time staff or faculty member. RA duties may include assisting

investigators with recruiting and enrolling research participants, completing IRB correspondence and assisting with grant applications.

**Study/Research/Clinical Trials Manager/Coordinator** – This person is responsible for the day-to-day research activities being conducted at the research site. The study coordinator usually serves as the main contact person for IRB and subject related issues.

**Research/protocol nurse** – A member of the research staff for a clinical study, who follows the interventions/interactions described in the protocol.

c. IRB RELATED PERSONNEL TERMS

**Institutional Official** – A senior institutional official authorized to act for the institution in assuming overall responsibility for compliance with the federal regulations for the protection of human subjects.

**IRB Chair** – The role of IRB chairs vary by institution, but commonly IRB chairs direct the proceedings of IRB meetings. IRB chairs also review and approve research qualifying for expedited and exempt review. Some IRB chairs play a leadership role in creating IRB policies and procedures, and others solely run the meetings and review projects.

**IRB Director** – The IRB Director manages the day-to-day operations of the IRB administrative office. IRB directors manage IRB staff and most aspects of the IRB process. Many IRB directors set policy and guide the IRB chair. The IRB Director must be expert on interpreting regulations.

**IRB Staff/IRB Administrator** – An administrative staff person, who is responsible for screening and reviewing IRB applications prior to committee review. This job category may also include agenda preparation, taking minutes and drafting correspondence between the PI and IRB.

**IRB Vice-Chair** – The role of the Vice-Chair is to fulfill the IRB Chairs responsibilities when the Chair is unavailable. Vice-Chairs also may review and approve research qualifying for expedited and exempt review.

**Office for the Protection of Research Subjects (OPRS)** – An office responsible for overseeing the entire Human Subjects Protection Program (HSPP). At USC, the OPRS office is charged with maintaining AAHRPP accreditation, researcher and IRB education, establishing best IRB policies and practices, quality assurance, and keeping the research community updated on significant news, ethics, and regulations.

**Office of Compliance** – An office overseeing all University compliance related issues including conflict of interest, HIPAA, misconduct, and other federal mandates. The Office of Compliance investigates subject, staff or researcher complaints. Compliance officers are usually J.D.s.



d. RESEARCH RELATED STATISTICS TERMS

**Central Tendency** – This term refers to the single most representative value or typical value of a set of data and it is computed using a variety of measures that are each calculated differently.

**Descriptive Statistics** – Ways of summarizing and describing sets of data by using tables, graphs, measures of central tendency and measures of variability.

**Distribution** – A set of numbers and their frequency of occurrence collected from measurements of a population/data. A distribution is a summary of the data by the number of observations in each category, value or interval.

**Inferential Statistics** – These statistical methods are used to generalize from a sample of data to make inferences about a larger population.

**Mean** – The mean is defined by adding up all the values for a given variable and then dividing the sum by the number of values included. The mean is one type of measure of ‘central tendency’.

**Median** – The median literally is the value in the middle of a set of values. The median is defined by lining up the values, from largest to smallest. The one in the dead-center is the median. The median is one type of measure of ‘central tendency’.

**Mode** – This statistic tells you the value that appears the most often for a given variable. It is possible to have more than one mode, and it is possible to have no mode. The mode is one type of measure of ‘central tendency’.

**Normalizing/Standardizing/Transforming Data** – Accurate interpretation of many statistical tests is difficult if a dataset fails to satisfy important assumptions about the data. Adjustment for such violations may be achieved by normalizing/standardizing/transforming a dataset by mathematical means.

**Normative/Normed Data** – Data points of a second data set are placed relative to the original data obtained from a large sample for the purpose of comparison. The originally collected sample is typically referred to as the norm group because it is the group upon which the new group’s data is compared.

**Range** – The range is the mathematical difference between the highest and lowest values for a given variable. It is the simplest measure of variability to calculate but it depends only on the extreme values in the data set and does not use all of the data. The range is one type of measure of ‘variability’.

**Sample Size** – The number of subjects participating in the research, typically denoted  $N$  or  $n$  in research literature. Generally, different sample sizes lead to different accuracies of reported effects.

**Standard deviation** – Indicates how tightly all the various data points are clustered around the mean in a set of data. When the data points are tightly bunched together around the mean, the standard deviation is typically small. When the data points are spread apart around the mean, this tells you that you have a relatively large standard deviation. The standard deviation is defined as the square root of the variance. Standard deviation is one type of measure of ‘variability’.

**Statistical Significance** – Used to assess the probability or error in a study’s findings. Tests of statistical significance allow researchers to determine the probability of the results occurring by chance alone. Typically, as probability level decreases, confidence increases that the results are not due to chance but due to the intervention.

**Variability** – This term refers to how 'spread out' the values in a distribution are and it is computed using a variety of measures that are each calculated differently. The greater the spread a dataset displays, the greater variability that dataset shows.

**Variance** – A statistic used to define how close values in a distribution are to the middle of the distribution. The mean, median or mode of a distribution may be used as an indication of the middle of the distribution. The variance is defined as the average squared difference of the scores from the measure of central tendency. The variance is one type of measure of ‘variability’.

## CHAPTER 3 What Are Clinical Trials?

The number of clinical trials conducted nationally and internationally is dramatically increasing so community members serving on biomedical IRBs will need to understand the goals and process of clinical trials. All marketed drugs/devices/biologics in the USA have gone through the same FDA approval/trial process.



**Clinical trials** refers to research that involves the comparison of a drug/device/biologic with a placebo (inactive ingredient or “sugar pill”), and/or standard treatment. Clinical trials utilizing investigational drugs, devices, or biologics provide data on new or different ways to prevent, diagnose, and/or treat diseases or conditions.

[ClinicalTrials.gov](http://ClinicalTrials.gov) offers information on clinical trials for a wide range of diseases and conditions. This website lists both federally funded and privately funded studies. Studies listed are conducted in all 50 States and in 153 countries. The website is useful for tracking study progress, study completion, study findings and also identifying studies that are open to enrollment.

At USC, **clinical trials** are conducted at the Health Sciences Campus and are reviewed by the **Health Sciences IRB (HSIRB)**. The HSIRB is composed of physicians, nurses, faculty members, and specialists in various medical fields qualified by training and experience to review this kind of research.

In comparison, **non-clinical research** generally refers to research in the social and behavioral sciences and may involve surveys, questionnaires, focus groups, interviews, and/or observations. At USC, most non-clinical research is conducted at the University Park Campus and is reviewed by the **University Park IRB (UPIRB)**. The UPIRB is composed of psychologists, educators, sociologists, and other faculty members qualified by training and experience to review this kind of research.

At some institutions, a single IRB is charged with reviewing both clinical and non-clinical research.

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### DRUG/DEVICE DEVELOPMENT PROCESS: IN BRIEF

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- a. A researcher formulates an idea for a new drug or device, or a better version of a drug/device that already exists, or a researcher applies for and obtains sponsor funding for a study of interest to the sponsor. Significant funding must be sought/obtained to move this potential drug or device from an idea to a testable entity.

- b. Laboratory studies on the drug or device begin with animal studies or biochemical testing to validate/verify the concept. This type of research takes place in government, pharmaceutical and/or academic settings.
- c. Positive indications from early non-human studies lead to submission of an investigational new drug (IND) or device (IDE) application to the Food and Drug Administration (FDA). FDA applications and approvals are needed for all drugs and devices marketed in the U.S.A.
- d. The Food and Drug Administration will evaluate all non-human findings, other literature and comparable drugs or devices, and then make a decision about allowing the drug or device to be tested in humans.
- e. Clinical trials with human subjects begin (Phase 0 – III).
- f. If results with humans are promising, a new drug/device application is filed with FDA.
- g. FDA verifies scientific claims and approves the drug/device for market.
- h. Once the drug/device is marketed, large numbers of people will use it. Collecting data from the user population provides an expanded data set in which additional risks may be observed. This so called phase IV study may result in the drug/device/biologic being pulled off the market, necessitate a label change, require a warning, and recommend a different route of administration...

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## TYPES AND PHASES OF CLINICAL TRIALS

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**Types of Clinical Trials** – Clinical trials vary depending on the goal of the test object or the population to be studied. These are:

- Treatment trials – studies designed to cure or arrest a disease, or lessen symptoms or pain.
- Prevention trials – studies designed to prevent an illness or a condition
- Exploratory trials – studies designed to generate a hypothesis from research on a few subjects
- Early-detection /screening trials – studies designed to detect a disease at a very early stage
- Diagnostic trials – studies designed to identify a disease or condition
- Quality-of-life trials /supportive care trials – studies designed to increase the quality of living for disease sufferers
- Post-marketing trials – studies designed to collect safety and/or efficacy data on a large population currently using an FDA approved drug/biologic/device.

**Clinical Trial Phases and Descriptions** – The four common phases of clinical trials are provided below along with some basic differences between them:

**Phase 0** – Very low doses of the study drug (doses where no effect is anticipated) are administered to gather preliminary data in healthy volunteers and to establish whether the drug behaves in human subjects as was anticipated.

*Typical number of people studied:* 10 – 15

*Answers the question:*

How does the human body process the drug?

**Phase 1** - Researchers test a new drug or treatment in a small group of healthy volunteers to evaluate safety, determine a safe dosage range, and identify any side effects.

*Typical number of people studied:* 15 – 30

*Answers the questions:*

What dosage is safe?

How does the agent affect the human body?

How should treatment be administered?

**Phase 2** - The drug or treatment is given to a large group of affected volunteers to see observe efficacy and to further evaluate its safety in greater numbers of subjects.

*Typical number of people studied:* Less than 100

*Answers the questions:*

Does the agent or intervention have an effect on the disease or the condition?

How does treatment affect the body?

**Phase 3** - The drug or treatment is given to large groups of affected volunteers to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely in the population for which it will be marketed.

*Typical number of people studied:* From 100 to 1000s

*Answers the question:*

Is the new agent or intervention (or new use of an existing treatment) better than the standard treatment, if there is one?

**Phase 4** - After the drug or treatment has been marketed, information is gathered on the drug's effect in populations using the medication to note side effects associated with long-term use and larger numbers of users.

*Typical number of people studied:* From 100s to 1000s

*Answers the questions:*

Has the expanded use of the drug or treatment revealed any adverse events that were not previously known?

Are these findings serious enough to require removal from the market?

**Note:** Some drug manufacturers (e.g. sponsors) combine drug phases, such as a phase II/III clinical trial or other.



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## **IMPORTANT SUBJECT PROTECTION CONCEPTS IN CLINICAL TRIALS**

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Benefits of Participating - At minimum, subjects will receive the standard treatment. If the new treatment/intervention is shown to work, subjects may be among the first to benefit. By participating in such trials, subjects may advance medical knowledge.

Risks of Participating - New treatments/interventions are not always better than, or even as good as, standard care. If a new treatment has benefits, it may not work for every patient. In addition, participation in clinical trials is not always covered by health insurance or managed care providers and can cause unforeseen harms or injuries.

Subject Protections – Human subject protections are regulated / overseen by many different entities: IRBs, other institutional committees, federal regulations, statutes, government agencies, pharmaceutical monitors/auditors, and others. Subject protections vary by state and between institutions.

### Informed Consent

A research subject's voluntary agreement, obtained after receiving adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights. Subjects may not be asked to release or appear to release the investigator, the sponsor, the entity or agents thereof from liability for negligence. Obtaining consent involves informing the subject about their individual rights, the purpose of the study, procedures they will undergo, and risks and potential benefits of participation.

### Conflict of Interest (COI) Disclosure

COI occurs in situations where financial or other personal considerations compromise, or have the potential to compromise, an individual's professional judgment or objectivity. Conflict of interest may occur with the researcher, IRB member, or the institution. All three types of COI must be reviewed and managed by the institution or its designated committee.

### Significant New Information/Findings (SNIF)

Regulations require that subjects be provided with SNIF developed during the course of the research, which may affect a subject's willingness to continue participation. The IRB may require all previously enrolled subjects to be provided with new information concerning these findings. The IRB must review and approve the new information to be provided to the research participant.

### Reporting of Adverse Events

Adverse Events are defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. After an Adverse Event occurs, the principal investigator is required to submit a reportable event application to the IRB. The principal investigator's report should contain enough information for the IRB to determine whether the event increases the level of risk to participants, requires a research design change or necessitates modification to the informed consent form.

### Scientific Review

Proposed clinical research must undergo scientific review. Scientific review can be accomplished by a funding agency such as the NIH or a sponsor, the local institution, outside peer reviewers, or an expert IRB member. The IRB has the right to disapprove proposed research due to poor scientific merit and/or methodological flaws. It is unethical to subject persons to research when a research plan is flawed.

### Data Safety Monitoring Board

A data safety monitoring board (DSMB) consists of a committee of scientists, physicians, statisticians, and/or others that analyze data collected as a trial is going on. The board examines the data on an ongoing basis to detect adverse events and note trends that warrant modification or termination of the trial. If safety concerns arise, the DSMB will make a recommendation to the sponsor that the trial be suspended or terminated. Trials that show unexpected positive results may also be terminated so that all subjects benefit from the drug/device and none continue on a placebo.

### Drug Sponsor

A drug sponsor is a pharmaceutical company, corporation, government, agency, or individual, whose goal is to develop and research new and/or existing drugs. Sponsors generally do not conduct research studies themselves. They seek out physicians/PhDs in varied settings to conduct clinical trials to test the drugs/devices. In some cases, an investigator may also be the sponsor, and is subject to all rules that apply to sponsor initiated research.

### FDA

The Food and Drug Administration (FDA) is an agency of the U.S. federal government established by Congress in 1912 and part of the Department of Health and Human Services (DHHS). This agency is responsible for ensuring safe and effective biological products, drugs and medical devices. FDA approval is required before marketing.

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## **NEGATIVE RESEARCH RESULTS CAN BE POSITIVE**

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Often, when results of a clinical research trial are negative, inconclusive, or the study ends early, the results are not published nor are they shared with the research community, the medical community, or even the subjects who had been enrolled in the study. This is a serious problem because knowing when procedures/interventions/drugs/devices do not work is as important as knowing when they do work. Sharing negative results can avoid duplicating the same study or exposing people to agents already known not to work. Researchers and journals too often think negative results do not further their interests, so no publications results.

To combat this absence of important information, the federal government now requires federally funded or regulated clinical trials research to be posted on [clinicaltrials.gov](http://clinicaltrials.gov). Study outcomes are expected to be published whether positive or negative. In practice, this mandate has not been fully enforced but federal actions to address this are underway.

## CHAPTER 4 The Full Board Meeting

Full board meetings can be intellectually demanding. The credibility and integrity of the IRB review process depends upon the committee's ability to identify and address ethical issues in human subjects research. All IRB members must pay attention to written material and meeting discussions, voice their opinions when appropriate, and ask questions when they need clarification. This chapter guides a community member's initial experience of a full board meeting by describing the review process, defining voting options, and providing tips for reviewing a study.



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### SEQUENCE OF EVENTS AT MEETINGS

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The format for discussion of protocols at the full board committee meeting is not set by federal regulations or guidance documents. Thus, IRBs are able to develop a routine that works for their institution and membership.

What follows is a basic order of IRB meetings. It is one that has worked well for several IRBs:

- The meeting starts with review and approval of the minutes from the previous meeting (see [Appendix E](#) for minutes template). The Chair reminds members about the IRB member Conflict of Interest Policy and asks if any conflicts exist among those present.
- The Chair/Vice-Chair/IRB member presents amendments to prior studies if any, and votes are taken.
- **Primary reviewers** present new study applications to the board.
- The primary reviewer summarizes important issues they noted related to research ethics, safety, and/or science. The reviewer may decide not to discuss all the study details because other IRB members/reviewers are expected to have read the materials and time is limited for many IRBs. The presentation ends with a summary of unresolved issues and/or issues requiring revision. The reviewer makes a recommendation for how the committee should vote on the protocol.
- The **secondary reviewer** comments on the protocol. The secondary reviewer does not repeat the information presented by the first reviewer, but indicates where he or she agrees or disagrees with the issues as outlined by the first reviewer. The secondary reviewer adds or clarifies information and ends with a recommendation that may or may not agree with the primary reviewer's recommendation.
- If there are three (or more) assigned reviewers, the **tertiary/other reviewers**, provide additional information or raise other questions. Discussion begins after the reviewers have had a chance to complete their presentation.
- It is the responsibility of the chair to open the discussion, make sure every issue and question is addressed, and to ensure the meeting is carried out in a courteous and



productive manner. The chair ends the discussion and calls for a vote to approve, accept with contingencies, table, or disapprove.

An ideal environment is one that promotes an open discussion and encourages all members to express their views in a warm atmosphere, and all IRB members participate in identifying and discussing the issues. There is no formula for this process so it is essential that the IRB chair manage this aspect of the meeting. Some IRBs let a discussion continue until an IRB member seconds a motion for a vote. In other committees, the chair determines when all of the important issues have been raised, declares the discussion over, and calls for the vote. Questions of regulatory or policy matters are often addressed by the Chair or IRB Director as IRB members are not expected to be as expert in these areas.

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## VOTING OPTIONS AT MEETINGS

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Voting options differ by institution and are chosen to meet individual IRB needs. Common voting options include:

- approved
- conditionally approved
- approved pending modifications
- table
- disapprove
- substantive revisions required
- not approved
- abstain
- recuse

Voting options used by the University of Southern California IRBs are:

### **Approve**

The study meets the regulatory criteria for IRB approval as defined by 45 CFR 46.111 and/or 21 CFR 56.111 (see [Chapter 2: “What criteria must be met to approve a protocol”](#)).



The application has secured approval, thus the investigator is not required to make changes to the protocol or IRB application. IRB approval is valid for one year, unless the committee designates a shorter period due to higher levels of risk. An approval letter is sent to the investigator. The consent documents (if any) are stamped with the IRB approval dates. The investigator may start enrolling subjects.

### **Approve with contingencies**

“Contingencies” are IRB’s request for clarification, modification or additional information. This term is often used during a full board continuing review, but may be used for all levels of review and types of submissions. At USC, this is used when a continuing review has been approved for another year, but the committee requires some changes/revisions to be made.

In a continuing review, if the contingencies are minor, the investigator may continue to enroll subjects using the previously IRB approved consent document (unless the committee has stated otherwise). If contingencies are minor and do not affect the consent form, they will need to be satisfactorily addressed by the next continuing review. If contingencies are major, the IRB requires a response and verification that these contingencies were addressed before approval is granted and new subjects can be enrolled.

### **Disapprove**

This term is used when the magnitude and/or number of concerns, questions, and problems are such that “Accepted/Approved with contingencies” is not appropriate. A letter describing reasons the study was not approved is sent to the investigator.

The investigator must make significant changes and may resubmit the study. On occasion, the investigator may be invited to answer committee questions in person. If a study is resubmitted for full review and approved at a subsequent meeting, the date of approval is the date of the subsequent meeting.

### **Defer**

This is used when the IRB application lacks sufficient information to make an appropriate determination. When a study is deferred, the investigator’s response must be reviewed by the full committee.

### **Recuse**

If an IRB member is listed in a study under IRB review or has any other conflict of interest, they may not participate in the initial or continuing review of the study except to provide information requested by the IRB. The IRB member must leave the room (e.g. “recuse” themselves for the discussion and vote). The meeting minutes will reflect this. The chair requests IRB members with a conflict of interest to leave the room and not participate in the vote or discussion. Conflicts of interest include financial interest, active participation in the trial as principal investigator or co-investigator, or any other issue for which the member feels his or her vote could be potentially conflicted.

### **Abstain**

If an IRB member does not have a “conflict” but is unable to vote (e.g., left the room during discussion, does not comprehend the study or the issues) the member may “abstain” from voting. A vote to “abstain” will be included as part of the voting quorum. The meeting minutes will reflect this.

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## **WHEN MIGHT I BE ASKED TO BE A PRIMARY REVIEWER?**

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When the IRB Chair or Director determines that a new member is ready to take on assigned reviewer responsibilities, they are assigned to be secondary or tertiary reviewers, or review informed consent documents. The following requirements and scenarios may indicate readiness to serve as a primary reviewer:

- Attended a sufficient number of IRB meetings to feel comfortable

- Attended IRB education sessions
- A sufficient knowledge of IRB policies and procedures to give a meaningful review
- Completed satisfactory reviews as a secondary reviewer
- Expertise in the area of the study
- Adequate time to prepare for the meeting and give a thorough review
- Achieved sufficient confidence to proceed with a review
- Availability when other members are unavailable, on vacation, or have a large number of items pending review
- Spoken up at a meeting with concern about the study or consent form

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## STUDY REVIEW

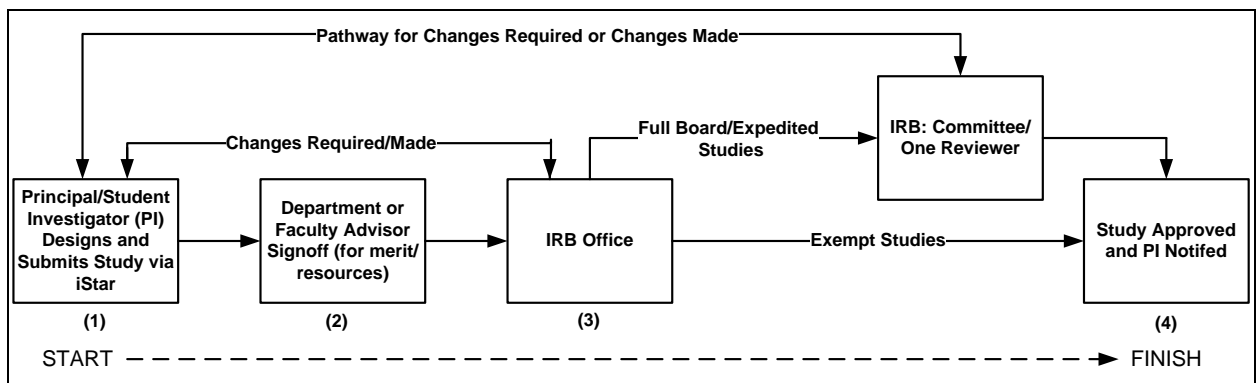
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What follows is an overview of the IRB review and approval process, an introduction to the IRB application system, and a list of points to consider when reviewing research protocols. This information is provided to help the new community member understand the IRB review process.

### IRB Review and Approval Process Overview

The chart below provides an outline of the IRB review process, starting with the online IRB submission by the researcher and ending with the IRB granting approval of the research.

#### IRB Review Process



### iStar (IRB Submission Tracking and Review)

At USC, all IRB applications are submitted online through iStar (IRB Submission Tracking And Review system). Familiarity with the iStar system is required to review IRB applications. IRB members are required to post their reviews (comments, issues raised, changes required) via iStar. For detailed information on how to use iStar and how to post a review, refer to [Chapter 6](#).

All new community members are expected to meet individually with the IRB staff for an orientation session on how to review a protocol through iStar. The IRB staff and/or iStar

helpdesk will be available to work with community members until they achieve a sufficient level of comfort with the IRB review process and the iStar system.

### Reviewer Checklists

Reviewer checklists have been created to help identify regulatory requirements and to note the ethical expectations that must be met. It is highly recommended that these checklists be used while reviewing IRB applications. The complete set of reviewer checklists is included in [Appendix B](#). To download the IRB reviewer checklists from the IRB website, click [here](#).

### Points to Consider When Reviewing a Project

Being mindful of certain requirements will help you identify ethical and regulatory issues while reviewing the IRB application. Here are some points to consider:

- What are the subjects required to do? Will they take a drug, fill out a survey, or be interviewed about criminal activity? Are the research activities potentially harmful or embarrassing?
- Would you participate in this study, or would you want your parents, children, spouse or other family members to participate?
- Does the study make sense as written? Is it overwhelming with too much jargon or too many details?
- Is the informed consent document easy to understand and an accurate reflection of the study procedures?
- Who are the subjects and are they vulnerable to coercion (e.g. children, prisoners)?
- Is it necessary to keep the identifying information? Is more information being requested than is needed?
- If identifying information is collected, is there a mechanism in place to protect the subjects' identities or other private information? If so, is it adequate?
- Is the information provided in the protocol, consent, and recruitment materials consistent?
- Are there adequate safeguards to protect the subjects if an untoward event occurs? What action will the PI/researchers take if something goes wrong?
- If the intervention/treatment proves beneficial, will those subjects not in the intervention/treatment group (i.e. control group) be able to partake in the intervention or receive the treatment once the study has been concluded?
- What "gut" feelings do you get after reading the protocol? Sometimes, something about the study seems questionable and may make you feel uneasy. Express this unease and attempt to get the issue resolved, or vote "no" when the vote is taken.

### Regulatory Criteria for IRB Approval

In order to approve research, reviewers must evaluate whether the rights and welfare of the human subjects are being protected. While reviewing a project, reviewers will be asked to determine that the criteria below are met. If the regulatory criteria are not met, the study will not receive IRB approval until the study is amended to meet the requirements or the IRB receives the missing information. The details of these requirements are provided in [Chapter 2: "What criteria must be met to approve a protocol."](#)

Approval Criteria (45 CFR 46.111)

1. Minimized Risks
2. Reasonable risk/benefit ratio
3. Equitable Subject Selection
4. Obtain Informed Consent
5. Document Informed Consent
6. Data Monitored for Safety
7. Confidentiality/privacy maintained

# CHAPTER 5 Developing into an Experienced Member

Community members may face additional challenges as their IRB membership progresses. This chapter provides tips and strategies for overcoming challenges and transitioning from an inexperienced member into a confident and well-trained one. It is important to note that a community member's success is influenced by the culture of the institution and the personalities of members already serving on the IRB.



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## MENTORING THE COMMUNITY MEMBER

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New community members need guidance from the IRB staff and other IRB members. Because new community members are not yet familiar with the institution's culture, assistance and advice from a mentor can be very beneficial. IRB chairpersons, other community members (past and present), IRB members, and/or IRB staff should provide mentoring to new community members. Ideal mentor qualities include knowledge, patience, and a willingness to share their personal experience with serving on the IRB.

A mentor should be available to help the new community member review their first protocol. Having another person go over the review before it is presented during the IRB meeting will help boost the new member's self-confidence and assure that the important points have been captured in the review.

Submitting IRB reviews online can be challenging. If computer programs and the internet are intimidating, the community member should meet with a mentor when submitting the review. At USC, additional online iStar assistance may be obtained through the iStar helpdesk, the step-by-step guidance documents on the iStar website, and/or attendance at an iStar training session. Contact the IRB office to schedule computer training.

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## BUILDING COMMUNITY MEMBER SKILLS

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Achieving confidence, familiarity, and understanding of the IRB review process can come from a variety of sources. Below are recommendations for building community member skills:

**a. Observe research activities**

A useful way to become familiar with human subjects research is to observe the conduct of research as it is occurring. Getting a sense of what subjects undergo while participating in research will not only make reviewing a protocol easier, but it will help the new member empathize with the subject portion of the review. In addition, witnessing the informed consent process may influence reviewer recommendations. Contact the IRB Director to request an opportunity to observe research activities.

**b. Attend full board committee meetings**

Attending IRB meetings before becoming a member allows for a thorough understanding of IRB member expectations, an opportunity to be introduced to other members, the possibility of connecting with a future mentor, and help in deciding whether the culture of the IRB is the right fit.

**c. Don't be afraid to ask questions**

If it is discomfoting to raise questions during a meeting, submit questions and/or concerns to the IRB staff or Chair either before or after the meeting. Providing insight into protocol review depends partly on the community member's willingness to seek out explanations about unfamiliar procedures/concepts/methodology. Note: agreement is assumed if no questions are asked, or concerns are raised.

**d. Learn about regulations and controversial research and ethics issues**

Read journal articles given out at meetings and/or related articles online or in newspapers. Educational sessions focusing on regulatory concepts or hot issues are offered during full board meetings. USC's [OPRS](#) publishes a variety of educational literature available on its website, as well as many other resources and links.

**e. Join an internet community/listserv**

Join a group that shares common interests in the IRB process such as the Department of Energy community listserv ([U.S. Dept of Energy](#)) or the IRB Forum (<http://www.irbforum.org/>). With these groups, members can ask questions and get opinions and thoughts from other IRB members outside of the institution. Joining will provide supplementary education on important debates and new programs/initiatives from IRBs across the nation. Some online community listservs include monthly newsletters which cover essential and controversial topics. To sign-up for USC's human subjects listserv, click [here](#).

**f. Attend IRB related conferences**

IRB members should seek educational opportunities in addition to those provided at IRB meetings. Attending conferences is an excellent way to learn about issues on a national level and to share knowledge and experiences of peers. Meetings offer great networking opportunities to meet like- minded members, some of whom may be leading experts in

human subjects research ethics. Ask the IRB Director/Chair about funding for conference attendance.

**g. Keep a notebook**

Taking notes on important, sometimes controversial issues gives a permanent resource for reference. It will allow you to refer back to a previous meeting's discussion where a particular issue was discussed. The notebook can also provide important information for reviewing protocols because issues often recur.

**h. Read other member reviews or the IRB staff comments**

Reviews completed by other IRB members or staff will help validate and support concerns or answer questions. IRB Staff reviewers' comments are especially thorough. Reviews completed by the other IRB members provide a coherent summary of the protocol and/or highlight ethical issues and serve as a good model and background for what you should be reviewing and commenting on.

**i. Foster relationships with other board members**

The IRB Chair should create an environment where ALL members feel empowered to contribute opinions. Attending more full board meetings will result in becoming comfortable with the other committee members. Interacting with other members outside of the meeting fosters the exchange of IRB related information and many will be willing to offer assistance outside meeting sessions.

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## **POST MEETING DIALOGUE**

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Once a vote is taken, an IRB community member may feel as if they were pressured, made a mistake, or even voted incorrectly at an IRB meeting. It is recommended that institutions have a mechanism to allow for community members to voice/vent any concerns and to seek feedback after a decision, should they so choose. The mechanism for making community members comfortable with a vote already taken may be an email sent to the IRB Chair after the meeting, a one-on-one conversation with another IRB member who is knowledgeable about the topic, or a discussion with the IRB Director/Staff. Bringing the project back for a re-vote is unlikely but the community member and staff will be sensitive to these issues going forward. More often than not, speaking to other IRB members after an IRB meeting is a good way to facilitate learning and build knowledge. To further explore issues or to discuss ethical considerations, the community member should talk to the other member(s) who reviewed the same protocol.

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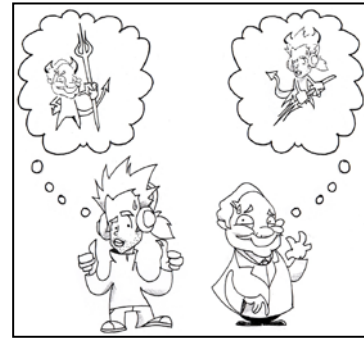
## **DEALING WITH DISCOURTESY**

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IRBs are generally burdened with a heavy workload and voluminous agendas. This can result in inadequate time to explain research terminology or technical procedures to laypersons during the



IRB meeting. Some IRB Chairs/Directors may exhibit impatience when community members ask for clarification or details about a particular procedure. In some cases, particular IRBs or members may be discourteous and dismiss community member concerns. If the community member believes their concerns were improperly dismissed, they should bring this to the attention of the IRB Chair or Staff. If the Chair is dismissive, bring this to the attention to the IRB Director or the Administrative Office that oversees the IRB. If possible, the discourtesy should be dealt with when encountered.



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## INSTITUTIONAL STRATEGIES TO FOSTER COMMUNITY MEMBER STRENGTHS

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This section provides insights into how IRBs should foster all members – especially community members. Can some of these ideas benefit you or your IRB? Suggest them.

### **IRB phone support and online chat forum**

Some institutions offer regular hours for phone support or office hours provided by the IRB staff. The IRB staff can provide guidance on the use of IRB forms, document preparation, adverse event reports, protocol violations, frequently asked questions, and many other issues. Posting questions on online chat forums ([IRB Forum](#)) is another way of getting assistance.

### **Human subjects website**

Websites should have downloadable templates, forms, brochures, and guidance documents. The website should include the recent institutional human subjects research policies, regulations, and news. At USC, a comprehensive website ([USC OPRS](#)) provides information on human subjects research issues.

### **Finding willing IRB community members**

IRB community members can be recruited from communities or organizations that care about science, research, ethics, and/or protecting research subjects. Potential candidates are often recommended by other community members, local community organizations, schools, or religious institutions. Candidates who are reluctant to commit to time requirements and do not show interest or enthusiasm should not receive further consideration. Available time, commitment to the IRB effort, and basic computer skills are vital requirements.

### **Provide training and education**

Community members are recruited for a certain level of naiveté and objectivity regarding human subjects research. Thus to learn the IRB review process, community members must receive training and education. An initial orientation to the IRB process, followed up with ongoing

training and supplementary materials, acclimatizes new members and keeps them current as science and ethics evolve.

### **Eliminate jargon**

IRBs use highly specialized jargon and many abbreviations. The IRB Chair should regularly remind the committee of the need to provide clarity and that non-experts/clinicians are present. Difficult language and terms should be minimized or explained.

### **Create a level playing field**

To avoid hierarchical distinctions, the IRB Chair should encourage committee members to address each other in a uniform manner, regardless of degree or title. Community members may sometimes feel overwhelmed when surrounded by faculty members and scientists. A respectful form of address, applied uniformly, can eliminate perceived inequality.

### **Civil discourse**

All attendees (i.e. students, staff, and faculty) must be courteous and should expect courtesy in return. If a discussion becomes heated, the IRB Chair, responsible for overseeing the conduct of the meeting, must diffuse any tensions. The Chair should take control of the debate, settle the issues, and terminate any unpleasant line of discourse.

### **Improving the quality of IRB applications**

The IRB Chair/Staff should create an ongoing program to educate and provide outreach to all schools/departments that consistently submit poorly written applications to the IRB. At IRB meetings, the outreach improvement efforts should be decided. Committee members may contribute to the outreach process by discussing IRB issues with PIs and researchers.

### **Mentoring**

New community members should be assigned to an experienced IRB member for mentoring. New members can call on this mentor to answer simple and/or complex questions. Institutions should formalize the mentoring process.

### **Schedule regular meetings and education sessions**

If members do not interact with one another on a regular basis, it is difficult to create a sense of collegiality. The frequency with which IRBs meet may influence the team or group dynamics. Infrequent meetings may create a lack of consistency and continuity in the IRB review process.

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## CONTACTS AND RESOURCES

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The offices below can assist USC community members with questions or concerns with protocols, regulatory interpretations, or ethical issues.

### UNIVERSITY OF SOUTHERN CALIFORNIA

<p><b>OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS</b>          3720 South Flower, Third Floor          Los Angeles, CA 90089-0706          Phone: 213.821.1154          Fax: 213.740.9299          E-mail: <a href="mailto:oprs@usc.edu">oprs@usc.edu</a>  <a href="https://oprs.usc.edu/">https://oprs.usc.edu/</a></p> <p>For questions about any of the Human Subjects Protections Program (HSPP) policies and procedures, OPRS.</p>	<p><b>OFFICE OF COMPLIANCE</b>          3500 Figueroa St.          University Gardens Building, Room 105          Los Angeles, CA 90089-5013          Tel: (213)740.8258          Fax: (213)740.9657          E-mail: <a href="mailto:compliant@usc.edu">compliant@usc.edu</a>  <a href="http://www.ooc.usc.edu">http://www.ooc.usc.edu</a></p> <p>For legal questions or to report an action believed to be illegal, unethical or coercive, contact the USC Office of Compliance. This office has a 24-hour hotline where anonymous messages can be left.</p>
<p><b>IRB UNIVERSITY PARK CAMPUS</b>          3720 South Flower Street, Third Floor, 301          Los Angeles, CA 90089-0706          Tel: (213)821.5272          Fax: (213)821.5276          E-mail: <a href="mailto:5upirb@usc.edu">5upirb@usc.edu</a>  <a href="https://oprs.usc.edu/upirb/">https://oprs.usc.edu/upirb/</a></p> <p>For questions about a particular study, a good place to start is with the IRB staff reviewer assigned to the study or the IRB Director of the respective IRB.</p>	<p><b>IRB HEALTH SCIENCES CAMPUS</b>          General Hospital, Suite 4700          1200 North State Street          Los Angeles, CA 90033          Tel: (323)223.2340          Fax: (323)224.8389          E-mail: <a href="mailto:irb@usc.edu">irb@usc.edu</a>  <a href="https://oprs.usc.edu/hsirb/">https://oprs.usc.edu/hsirb/</a></p>
<p><b>iSTAR HELP DESK</b>          323-276-2238 <a href="mailto:istar@usc.edu">istar@usc.edu</a></p> <p>For questions about iStar, or any other computer related issues, contact the iStar Help Desk (located at Health Sciences Campus IRB).</p>	<p><b>CITI HELP DESK</b>          213-821-5272 or <a href="mailto:citi@usc.edu">citi@usc.edu</a></p> <p>For questions about CITI trainings, contact the CITI helpdesk.</p>

## FEDERAL AGENCY CONTACTS

### Office of Human Research Protections (OHRP)

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

Tel: (866) 447-4777

(OHRP): [www.hhs.gov/ohrp/about/](http://www.hhs.gov/ohrp/about/)

OHRP guidance documents:

[www.hhs.gov/ohrp/policy/index.html](http://www.hhs.gov/ohrp/policy/index.html)

OHRP compliance references:

[www.hhs.gov/ohrp/compliance/](http://www.hhs.gov/ohrp/compliance/)

OHRP Frequency Asked Questions:

<http://www.hhs.gov/ohrp/policy/index.html#faq>

OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

### Food and Drug Administration (FDA)

5600 Fishers Lane

Rockville, Maryland 20857

Tel: (888) 463-6332

(FDA): [www.fda.gov/](http://www.fda.gov/)

FDA guidance documents: [www.fda.gov/opacom/morechoices/industry/guidedc.htm](http://www.fda.gov/opacom/morechoices/industry/guidedc.htm)

FDA compliance references: [www.fda.gov/ora/compliance\\_ref/](http://www.fda.gov/ora/compliance_ref/)

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

### Office of Research Integrity (ORI)

1101 Wootton Parkway, Suite 750

Rockville, Maryland 20852

Tel: (240) 453-8200

(ORI): <http://ori.dhhs.gov/>

ORI policies: <http://ori.dhhs.gov/policies>

ORI oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration.



# CHAPTER 6 Online Education and e-Review System IRB Reviewers Need

This section describes the electronic systems used for IRB applications (iSTAR) and required training (CITI).

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## ISTAR ONLINE IRB APPLICATION AND CITI EDUCATION PROGRAM

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iStar is the online IRB application system used at USC to submit, review, and process research applications. Researchers and IRB members can access the iStar system 24 hours a day at [istar.usc.edu](http://istar.usc.edu). Through iStar, IRB members review new study submissions, amendments to previously approved research, and conduct continuing reviews (yearly renewals). IRB members also review reportable events (i.e. adverse events, protocol deviations, unanticipated problems). The iStar system allows IRB members to send correspondence to investigators and IRB staff, view meeting schedules, agendas, confirm or decline meeting attendance, and more. Although iStar may be intimidating at first, it becomes easier and technical assistance is available from the IRB staff, Director or iStar help line (323) 276-2238.

The iStar training website (“Sandbox”) may also be used for practice: [istartraining.usc.edu](http://istartraining.usc.edu).

CITI is the online educational system for human subjects researchers and IRB members. USC community members are required to complete online human subjects training as a condition of IRB membership.

Access information to both CITI and iSTAR is provided below.



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## CITI: ONLINE HUMAN SUBJECTS TRAINING

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To access the CITI course:

1. Go to the “CITI Login and Registration Page”: [www.citiprogram.org](http://www.citiprogram.org)
2. If you already registered for CITI, enter your username and password. If you have not registered for CITI, proceed below.
3. Click “Register Here”
4. Under the “Participating Institutions” drop down menu, select University of Southern California. Click the “submit” button.
5. Choose a unique username and password (username DOES NOT have to be your iStar username). Click the “submit” button.
6. Enter your name and email address in the appropriate fields.

7. Fill in the required fields in the “Member Information” page. (This is the section where you will input your iStar username). Only asterisked fields are required. Click the “submit information” button.
8. Select a group appropriate to your research activities. [Unsure of what user group applies to you?](#)
9. You can begin the course from the “Learner’s Menu” page. Click “Enter”, located under the “Status” header.
10. You can elect which modules to complete. Some users choose to complete modules related to their research, or modules that their department or advisor may require, or modules that are of interest. Yet it is mandatory that users obtain a cumulative score of at least 80% on the quizzes before a certificate is issued. You can retake any quiz as many times as you would like to improve your score.
11. Log in as many times as necessary to complete the course. Once you have completed the course, a certificate will be issued and stored in your CITI account. Your certificate validity dates will be automatically uploaded into iStar.
12. For questions regarding CITI access, certification, FAQs, or for technical support, call the USC CITI help desk at (213)-821-5272. Information on CITI can also be found here: <https://oprs.usc.edu/education/citi/>.

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## **USING ISTAR AS AN IRB COMMUNITY MEMBER**

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### **Creating an iStar Account**

1. To request an iStar account, email [istar@usc.edu](mailto:istar@usc.edu).
  - a. explain which role is needed: “IRB member user role”,
  - b. specify a campus: Health Sciences or University Park, for the Health Sciences Campus, include the IRB committee number: 1, 2, or 3
2. Once the account is created, an email from will be sent with the username and a temporary password. During the first login, change the temporary password to a permanent password. Follow the iStar prompts to change the password.

### **Institutional Email / USC Accounts**

Community members at USC are provided with institutional email accounts in order access electronic resources such as: online libraries, digital archives, and computer software free of charge. Community members can receive training on how to use these resources if requested. For more information about accessing USC email accounts and university resources, contact an IRB Director or visit [www.usc.edu/its](http://www.usc.edu/its).

### **Accessing USC Online Libraries**

USC online libraries have a wealth of journals, periodicals, magazines, and other electronic resources available online. The online library resources are accessible to USC email account holders. Below are links to some of these resources:

- **USC Libraries:** [www.usc.edu/libraries](http://www.usc.edu/libraries)
- **Electronic resources:** [www.usc.edu/libraries/eresources](http://www.usc.edu/libraries/eresources)
- **Help with USC Libraries:** [www.usc.edu/libraries/services/contactus.php](http://www.usc.edu/libraries/services/contactus.php)

a. **My Home Page**

Once logged in to iStar, the homepage will appear. This page lists all of the studies assigned to the committee member for review.

Each numbered item is explained below the screenshot.

The screenshot shows the iStar system interface for a user named Ann Hamilton. At the top, there is a yellow header with the USC logo and 'Childrens Hospital Los Angeles' branding. Below the header is a navigation bar with 'Home', 'Committees', 'Studies', and 'System Information'. The main content area is titled 'Folder for Ann Hamilton' and includes a sidebar on the left with 'My User Roles' (Committee Member) and 'My Committees' (HSIRB 3). The main content area has tabs for 'My Inbox', 'Previously Reviewed', 'Studies', 'Meetings', and 'Reports'. Below these are four empty tables for 'Studies', 'Continuing Reviews', 'Amendments', and 'Reportable Events'. A footer contains copyright information and contact details for three USC IRB boards.

1. There are 3 different links here. Clicking on **your name** goes to the user profile, where contact information can be edited (e.g. work address, phone number, etc.). Click **My Home** to go back to the homepage (above). Click **logout** to sign-out of iStar. Closing the browser window will also cause the account to sign-off.
2. **My User Roles** displays different levels of access available in the iStar system. For example, if the user is an IRB Member and a PI, those levels of access will be displayed as the **Committee Member** user role and the **PI/Staff** user role. Community members will have access to only one homepage because they have only one user role.



**My Committees** lists the IRB committee(s) on which the user serves. Clicking on the committee name (e.g. HSIRB 3) will open the IRB meeting schedule. From this section, minutes from past meetings can be printed or viewed, and attendance for an upcoming meeting can be confirmed or declined.

- To view and access applications as an IRB committee member, the user has to be assigned to the application and has to click the **Committee Member** user role. To view and access applications as part of the research team (PI, CO PI, collaborator, coordinator, etc.) click the **PI/Staff** user role.
- My Inbox** tab shows all items requiring an action. If the user has been assigned a study to review, the study title will appear under the **Studies** section. If the user has been assigned an amendment to review, the amendment title will appear under the **Amendments** section. The same is true for **Continuing Reviews** and **Reportable Events**.
- Clicking the **Previously Reviewed** tab will display all the applications the user has reviewed previously. Click on any of these items to view them. Clicking the **Studies** tab will display a list of all studies approved by the IRB. This tab allows the user to view those activities approved by the full committee, and those activities approved by expedited review. Clicking the **Meetings** tab lists the upcoming IRB meetings. The **Reports** tab lists the reports/queries available.

**b. Confirm / Decline Attendance to a Committee Meeting**

IRB Committee Members are expected to attend a minimum of 75% of meetings. Members must use this screen to confirm/decline attendance to a meeting, well in advance.

To report attendance:

**Current State**

**Reviewers Assigned**

Printer Friendly Agenda

CM Confirm Attendance

CM Decline Attendance

Attendees History

**Agenda Items**

Type	ID Number	Title	PI	Primary Reviewer	Secondary Reviewer	Tertiary Reviewer
[View]	Continuing Reviews HS-022044-CR001	Continuing Review for Legacy Study HS-022044	Douer			
[View]	Continuing Reviews HS-035034-CR002	Continuing Review	Mateo			
[View]	Continuing Reviews HS-041025-CR001	Continuing Review for Legacy Study HS-041025	Mishell Jr			
[View]	Continuing Reviews HS-043016-CR001	Continuing Review for Legacy Study HS-043016	Larsen			
[View]	Continuing Reviews HS-045031-CR002	0C-04-04 Continuing review 2007	Lenz	Chingos		
[View]	Continuing Reviews HS-04B055-CR001	Continuing Review for Legacy Study HS-04B055	Smogorzewski			
[View]	Continuing Reviews HS-05-00032-CR002	Continuing Rev. #2	Towfigh			
[View]	Continuing Reviews HS-05-00331-CR002	Carolina Bradshaw	Simpson			
[View]	Continuing Reviews HS-051008-CR001	Continuing Review for Legacy Study HS-051008	Udin			
[View]	Continuing Reviews HS-051044-CR001	Continuing Review for Legacy Study HS-051044	Tulpule	Larsen		
[View]	Continuing Reviews HS-051045-CR001	Continuing Review for Legacy Study HS-051045	Chung			
[View]	Continuing Reviews HS-052007-CR002	2007 Continuing Review	Barbers			
[View]	Continuing Reviews HS-054005-CR002	Continuing Review Study Expires 4/17/07	Lew			
[View]	Continuing Reviews HS-055004-CR003	Continuing Review	Mateo			
[View]	Continuing Reviews HS-06-00084-CR001	Continuing Review 2007	Mohrbacher			
[View]	Continuing Reviews HS-06-00123-CR001	Continuing Review Year 1	Akmal			
[View]	Continuing Reviews HS-06-00133-CR001	Continuing Review #1 (1/25/07)	Towfigh			
[View]	Continuing Reviews HS-06-00158-CR001	2N-05-5 Phase 2 Study of HG-272 (HS-06-00158)	Oitlitz			
[View]	Continuing Reviews HS-06-00167-CR001	Continuing Review	Elkayam			
[View]	Continuing Reviews HS-06-00179-CR002	0C-05-8 Continuing review 2007	Pinski			

**Prior to each full board meeting, you must inform the IRB of your attendance.**



1. Login with the username and password.
2. From **My Home Page**, select the **Meetings** tab (see #5 in **My Home Page** graphic above).
3. Click a meeting (date and location) under **NAME** to accept/decline attendance for that meeting.
4. Click either the 'Confirm Attendance' or 'Decline Attendance' button.

### c. Study Workspace

This page has many parts and functions. From here, users can access/view/print the IRB application and associated documents (consents, etc.), navigate to all activities and all official correspondences related to a study, and post a review.

The screenshot shows the IRB Study Workspace for study BAY 43-9006: Gallbladder/Cholangiocarcinoma. The interface is divided into several sections:

- Header:** USC University of Southern California and Children's Hospital Los Angeles logos. User: Ann Hamilton | My Home | Logout.
- Navigation:** Home, Committees, Studies, System Information.
- Current State:** Expired. Buttons: View Study, Printer Friendly Version, View Changes.
- My Activities:** Log Comment.
- Study Details:**
  - Study:** BAY 43-9006: Gallbladder/Cholangiocarcinoma (HS-05-00345)
  - Full Title of Study:** Phase II Study of BAY 43-9006 (NSC #724772) as Single Agent in Unresectable or Metastatic Gallbladder Carcinoma and Cholangiocarcinoma.
  - Principal Investigator:** Anthony El-Khoueiry
  - Faculty Advisor:** Marie Reyes
  - IRB Administrator:** Yu Chung
  - Review Type:** Full Committee Review
  - Date Approved:** 10/3/2006
  - IRB Received Date:** 10/31/2005
  - Expiration Date:** 10/2/2007
  - Letter of Approval:** [View]
- History Table:**

Activity	Author	Activity Date
Amendment Opened	Marie Reyes	2/13/2006 1:07 PM PST
Message Sent to Investigators	Nayade de Cumbe	12/9/2005 8:24 AM PST
Spanish version of IC ready at iStar		
Consent Forms and Documents Finalized	Nayade de Cumbe	12/9/2005 8:23 AM PST
Study Approved	Yu Chung	12/1/2005 3:29 PM PST
See Approval Letter		
Consent Forms and Documents Finalized	Yu Chung	12/1/2005 3:27 PM PST
Consent Forms and Documents Finalized	Yu Chung	12/1/2005 3:19 PM PST
Consent Forms and Documents Finalized	Yu Chung	12/1/2005 3:12 PM PST
Contingency Review Results Recorded	Yu Chung	12/1/2005 2:58 PM PST
Your correspondence dated and received on 11/30/05 and attachments were reviewed by Dr. Larsen on 12/1/05. The proposed changes qualify for expedited review according to 45CFR46.110 (b) 2) minor changes in previously approved research during the pe...		
Contingency Review Findings Submitted-Approve	Robert Larsen	12/1/2005 1:23 PM PST
Yellow Form		
Brown Form		
Study Claimed by Contingency Reviewer	Robert Larsen	12/1/2005 1:16 PM PST

1. The **Current State** indicates what stage the study is in, in the IRB review/approval process. Examples include: changes required by IRB, contingencies pending, and approved.
2. Clicking the **View Study** navigates to page 1 of the study application. Click the continue button to move to the next page in the application, or the back button to return to the previous page.

Click the **Printer-Friendly Version** button to display the complete application in one scrolling screen (use the mouse to scroll from page to page). To print out the entire application, click the “Print” button in the top right corner. Any documents attached/uploaded to the application (consents, flyers, clinical protocols, etc.) are listed as hyperlinks. Click on the hyperlinks one at a time to view and/or print those documents. When the linked document is closed, the screen returns to the printer-friendly version.

The **View Changes** button allows the user to see changes made by the investigator/researcher. It shows a before and after of the individual screens that were changed. Use this button to verify that required changes were completed.

3. The **My Activities** section displays the available actions/buttons. These buttons change as the study moves through the review process. Use the **Log Comment** button to post a comment or note about the study. Only IRB members and staff will see this comment.
4. The tabs are: **History, Amendments, Continuing Reviews, Reportable Events, Documents, and Change Log**. Click each tab to view that application.

The **History** tab allows the user to see all of the various actions related to the application. Activities are date and time stamped. Activity examples include Co-Investigator sign-off, application submission, IRB staff review, reviewer contingencies, amendment opened, etc. If you are conducting an initial review, the study history will not be present. To view the latest IRB approval letter (if any), find the “Study Approved” activity and click the “see approval letter” link.

Click the **Amendments, Continuing Reviews, or Reportable Events** tab to see a list of all the applications submitted for this study. Remember that amendments, continuing reviews, and reportable events are additional applications linked to the study application. To get the details of any of these applications, click the respective tab and then the application title under “NAME”. Click the **printer-friendly version** button to view the entire application in one scrolling document.

Click the **Documents** tab to see all of the documents attached to the iStar applications. Researchers upload and attach clinical protocols, consent forms, flyers, grant proposals, budgets, and other supporting documents to the iStar application. Click on any of the listed documents, and then open, save, or cancel.

Click the **Change Log** to see a list of all changes made to the application. Note: it is much easier to use the **View Changes** button for verifying that contingencies were met. It can also be helpful to open multiple tabs using the “right click” on the mouse.

## e. POST A REVIEW IN ISTAR

IRB members receive email notices when they are assigned applications to review. IRB members review new applications, amendments, continuing reviews, and/or reportable events.

The screenshot shows the iStar web application interface for Ann Hamilton. The header includes the USC logo, University of Southern California, and Children's Hospital Los Angeles. The navigation menu includes Home, Committees, Studies, and System Information. The main content area is titled "Folder for Ann Hamilton" and contains a welcome message, a list of guidelines, and several data tables. The tables are for Studies, Continuing Reviews, Amendments, and Reportable Events, each with columns for ID, Name, Owner, State, Last State Change, Committee, Meeting, and PI. All tables currently display "There are no items to display".

Folder for Ann Hamilton

Committee Member

My User Roles  
Committee Member

My Committees  
Name  
HSIRB 3

Welcome to your **Personal Folder**, the central resource for managing your reviews of IRB/CCI submissions. Your Personal Folder provides all the tools you need in order to complete your role in the IRB/CCI submission process. Use the following guidelines to review your assigned studies:

- All study submissions you are assigned to review will appear under the **My Inbox** tab. The submissions are categorized by type of submission.
- You can see all the submissions you have previously reviewed under the **Designated Primary Reviews** and **Secondary Reviews** tabs.
- View the committees you serve on by using the links under **My Committees** on the left.

My Inbox | Previously Reviewed | Studies | Meetings | Reports

**Studies**

ID	Name	Owner	State	Last State Change	Committee	Meeting	PI
There are no items to display							

**Continuing Reviews**

ID	Name	Owner	State	Last State Change	Committee	Meeting	PI
There are no items to display							

**Amendments**

ID	Name	Owner	State	Last State Change	Committee	Meeting	PI
There are no items to display							

**Reportable Events**

ID	Name	Owner	State	Last State Change	Committee	Meeting	PI
There are no items to display							

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Committee on Clinical Investigation, CHLA, Los Angeles, CA 90027. (323) 669-2265  
Health Sciences Institutional Review Board, USC, Los Angeles, CA 90033. (323) 223-2340  
University Park Institutional Review Board, USC, Los Angeles, CA 90089. (213) 821-5272

1. To get started, login to iStar with the username and password.
2. The application(s) requiring review are listed under **My Studies**. Applications are separated by the type of submission: Studies, Continuing Reviews, Amendments, or Reportable Events.
3. Click the application title/name.
4. Review the application and attached documents.
5. From the computer, open a blank Microsoft Word document or other word processing program directly (i.e. outside of iStar). Type the review comments into this document. Save this document on the computer (i.e. desktop or my documents).
6. In iStar, click the **Enter Primary Reviewers Notes** or **Enter Secondary Reviewers Notes** button.

7. Copy and paste the comments from the open MS Word document or other program. (You may also type the review directly into the window, but it is best to save a copy in a Word document.)

OR

Upload the saved Word file using the **Add** button in the attachments section of the window.

8. Click the OK button to post the review. (Note: make sure to answer all questions, as missing ones can prevent the review from being posted).
9. To make changes to the already posted review, repeat steps 6 – 8. The newest posting will be placed above the original, previously posted review. The original review is not removed, and can be accessed through the History tab.

## PART II - REGULATIONS



# CHAPTER 7 Ethical and Regulatory Basis for Human Subjects Research

The modern history of ethical standards for human subjects research began in the 1940s with the Nuremberg Code. Since then, the U.S. federal government has increased awareness for protecting the rights and welfare of human subjects by establishing regulatory codes and regulations. This section provides a brief background on the history of the regulations and ethics that are required when human subjects are involved in research.



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## NUREMBERG CODE

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The Nuremberg Code was developed following the Nuremberg Military Tribunal which judged Nazi doctors conducting human experimentation. The Code encompasses many of the basic principles governing the ethical conduct of human subjects research today. The Nuremberg Code states that “the voluntary consent of the human subject is absolutely essential” and it further explains the details implied by this requirement: capacity of participants to consent, participants’ rights to participate or not, freedom from coercion, no penalty for withdrawal, and comprehension of the risks and benefits involved. More information can be found at: <http://www.nihtraining.com/ohsr/site/guidelines/nuremberg.html>.

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## DECLARATION OF HELSINKI

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In 1964, the World Medical Association established recommendations to guide medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki was revised in 1975, 1983, 1989, 1996, 2000, and 2008 and is the basis for Good Clinical Practices used today. More information can be found at: <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

Issues addressed in the Declaration of Helsinki include:

- Research involving medical interventions with humans should be based on the results from laboratory and animal experimentation.
- Research protocols should be reviewed by an independent committee prior to initiation.
- Informed consent from research participants is necessary.

- Research should be conducted by medically/scientifically qualified individuals.
- Risks should not exceed benefits.

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## **BELMONT REPORT**

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In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” The Belmont Report sets forth the basic three ethical principles expected to be followed when doing research involving human subjects: respect for persons (autonomy), beneficence, and justice. More information can be found at: <http://www.hhs.gov/ohrp/policy/belmont.html>.

### ***Respect for Persons***

“Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.” This states that the person must be capable of making the decision on whether or not to participate in a human subjects research project.

### ***Beneficence***

“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term “beneficence” is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense:

(1) do not harm and (2) maximize possible benefits and minimize possible harms.”

### ***Justice***

“Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.”

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## **FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (COMMON RULE)**

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In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subjects (Title 45, Part 46). These regulations, called the “Common Rule,” provide for the basic foundation of Institutional Review Boards. This Federal Policy has been codified by the 18 federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title “Common Rule.” The Policy also provides additional protections to populations deemed vulnerable by the federal government, such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research. More information can be found at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

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## **UNITED STATES FOOD AND DRUG ADMINISTRATION REGULATIONS**

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The U.S. Food and Drug Administration, within the Department of Health and Human Services, regulates drugs, medical devices, and biologics. FDA regulations 21 CFR Part 50 (Protection of Human Subjects), and 21 CFR Part 56 (Institutional Review Boards) must be adhered to when studies are conducted using drugs, medical devices, or biologics. Although FDA regulations are similar to the regulations found in the Common Rule there are some differences. The differences between OHRP and FDA can be found at:

[http://www.hopkinsmedicine.org/institutional\\_review\\_board/guidelines\\_policies/guidelines/fda\\_ohrp.html](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/fda_ohrp.html). More information can be found at <http://www.fda.gov/oc/ohrt/irbs/>.

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## **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) / PRIVACY RULE**

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The Health Insurance Portability and Accountability Act “Privacy Rule (HIPAA) is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing "protected health information" (PHI) without written authorization from the patient.

If an investigator intends to create, use or release to others (e.g., sponsors, other investigators, collaborators) any identifiable health information in connection with their research, he/she must indicate that in the IRB application.

Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and

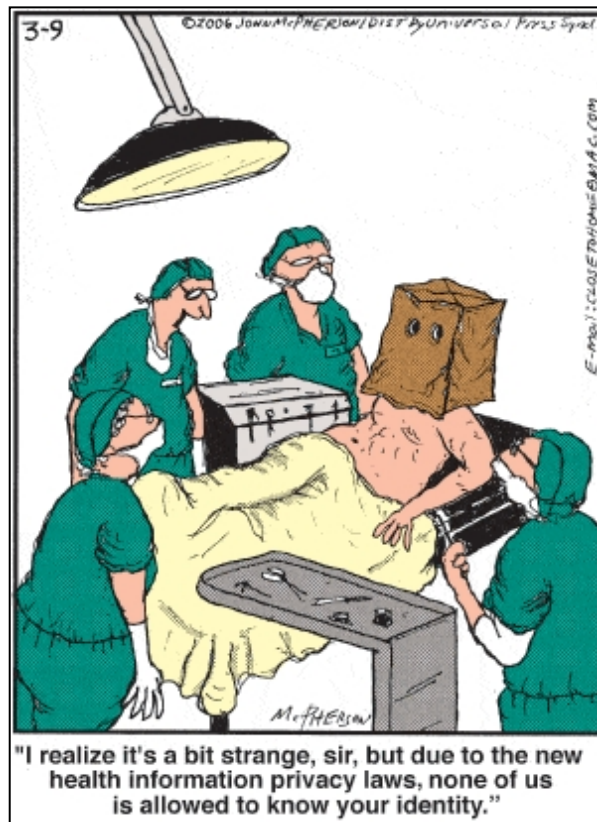


- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The full text of the updated HIPAA Privacy Rule can be found at the Office for Civil Rights (OCR) website: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>.

The recent Hi-Tech HIPAA amendment can be accessed here:

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/index.html>.



# CHAPTER 8 Types of IRB Review: Exempt, Expedited, and Full Board

Research involving human subjects requires IRB review under one of the following three levels: **exempt**, **expedited**, or **full-board**. Studies involving minimal risk\* (or less than minimal risk) generally qualify for review at the exempt or expedited level. For studies that are deemed greater than minimal risk, review by the full-board is required. An explanation of each review level is described below.

\* “Minimal risk” is defined by OHRP as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.

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## EXEMPT REVIEW

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Exempt research involves research with human subjects, but because of its nature and “minimal risk” it is “exempt” from the provisions of the Code of Federal Regulations (i.e. a consent form is not required). Exempt research projects must still be submitted to the IRB for initial review; however they do not require annual re-review by the IRB (continuing review). Changes to exempt research must be submitted to the IRB for review and approval only if the project is amended in such a way that it no longer meets the exemption criteria. IRB member or designated staff determine if a research project falls under one or more of the following six exempt categories listed in the federal regulations ([45 CFR 46.101\(b\)](#)):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.\*\*
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.\*\*
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National Center

for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.

4. Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

\*\*Studies involving children can only be exempt if the PI plans to only observe and not interact with the children.

Exempt 2 may not be used for minors.

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## **EXPEDITED REVIEW**

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If the level of risk in a research project is considered to be no greater than minimal, and the research meets at least one of the expedited categories below, the IRB may review the project as expedited. Expedited review covers the same considerations as a full committee review; however the project can be reviewed and approved by the IRB Chair or one Designated Reviewer, rather than the whole convened IRB committee. In reviewing research, expedited reviewers may exercise all of the authorities of the IRB, except the reviewer may not disapprove the research. In this case, the expedited reviewer must defer review to the full IRB committee. There are nine expedited categories listed in the federal regulations ([45 CFR 46.110](#)):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required. (b) Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.

For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

Note: The following 2 expedited categories apply to continuing review of research:

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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## **FULL BOARD (CONVENED) REVIEW**

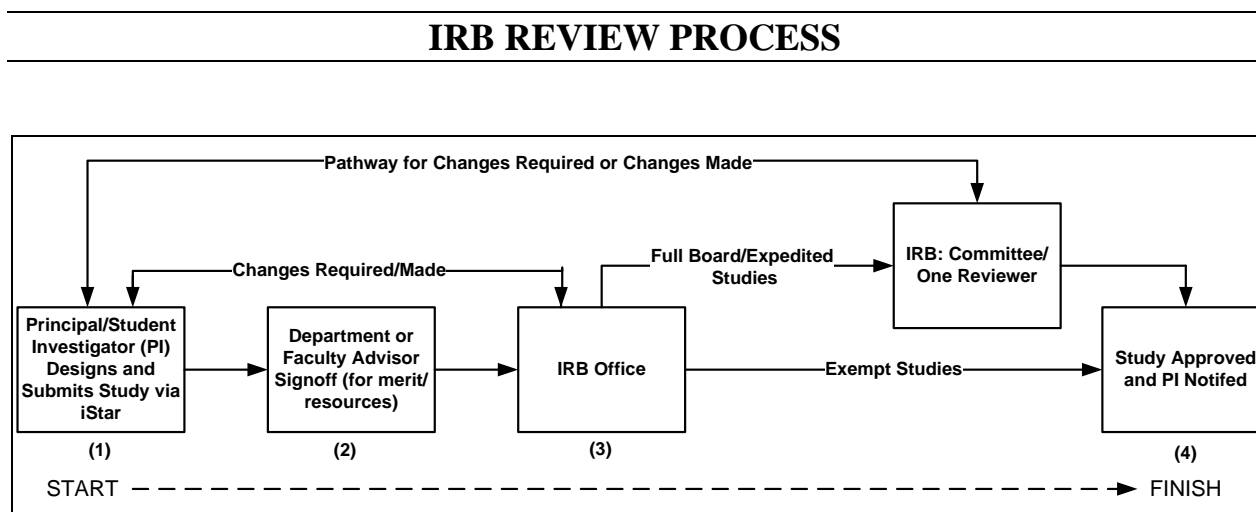
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Studies that involve more than minimal risk require full board review at a convened meeting, at which a quorum of IRB members is present, including a community member. For the research to be approved, it must receive the approval of a majority of those members present. While federal regulations do not specifically list categories that would fall under full board review, below are certain criteria that may require full board review.

1. clinical procedures involving drugs, devices, or biologics;
2. studies using vulnerable populations;
3. drug, device, or biologics studies taking place internationally (particularly those countries with little or no provisions for protection of human subjects);
4. studies where information may be disclosed to researchers that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.);
5. studies involving deception which raise the risk level;
6. studies where the IRB staff, chair, member, or designee, determines to be greater than minimal risk.

# CHAPTER 9 IRB Review Process

What follows is a basic overview of each stage in the IRB review process from online submission to IRB approval. A description of each stage is provided below the flowchart.



## (1) Principal Investigator (Faculty/Staff/Student) Designs and Submits Study via iStar:

Investigators design their protocol and submit it via the iStar application system. Investigators must indicate if the application requires exempt, expedited, or full board review. The final determination of the review category is made by the IRB.

## (2) Department or Faculty Advisor Signoff to Ensure Adequate Proposal:

Once the application is submitted (via the online iStar application system) the department and/or faculty advisor must review and sign off on the application. This signoff represents consideration of scientific merit, availability of resources, or other issues at the department level.

## (3) IRB Office:

After department or faculty advisor approval is obtained, an initial review of the application is conducted by the IRB staff or designated IRB member. At USC, the IRB staff conducts a thorough pre-review of the application to verify the correct level of review, and to evaluate the protocol and supporting documents (e.g., consent form, recruitment materials, etc.). If a study is approved as exempt or determined to be “not human subjects research,” no further IRB action is required. Any significant changes to the approved study must be submitted and reviewed by the IRB prior to initiation.

For studies designated as expedited or full board, IRB review is required from a designated reviewer or the full board, respectively. The possible determinations that can be made on a study are as follows:

- *Approved* – the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.

- *Approved with Contingencies* – the application is complete but there are issues/changes that must be addressed before the project can begin. Once a satisfactory response to these contingencies is received the IRB will grant final approval and the research may then be initiated.
- *Deferred* – applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher’s response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.
- *Disapproved* – Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed. This determination can only be made by the full board at a convened meeting. Institutional administrative officials may not override this decision.

#### **(4) Study Approved and PI Notified:**

The researcher will be notified through an iStar generated email when the study has been approved.

NOTE: Investigators and key personnel must fulfill the University’s CITI Human Subjects Education requirement before the IRB will give final approval.

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### **IRB APPROVAL CRITERIA: KEY POINTS**

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When reviewing proposed research, the IRB must consider the 7 regulatory requirements, provided below. Among the concepts that must be well understood to review human subjects research are informed consent (elements and process), privacy and confidentiality, and risk and benefit. The information below is not all inclusive and is provided to establish familiarity with these critical topics.



#### **Regulatory Criteria for IRB Approval**

USC investigators proposing a research project that involves human subjects must submit an [iStar](#) application to the IRB. The IRB shall determine that all of the following federal requirements are satisfied before approving the research ([45 CFR 46.111](#) and [21 CFR 56.111](#)):

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result

from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

### **Informed Consent**

Informed consent is the process of informing potential subjects about the key facts of a research study and what their participation will involve. The human subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a vulnerable population\*, such as pregnant women, prisoners or children, additional protections are required.

Consent documents must be clearly written and at a level understandable by the subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. It is often recommended that the informed consent be written at the sixth to eighth grade reading level. Assent forms for minors and any related recruitment materials must reflect the reading level of the minors. The informed consent must be translated into the primary language of the subject if he/she is not fluent in English.

What elements should be included in an informed consent?

For human subjects to participate in a research study, they need to have enough information to give a truly voluntary informed consent. Information subjects must be given include:

- *Purpose* of the research
- *Procedures* involved in the research



- *Alternatives* available should a subject decide not to participate in the research
- All reasonably *foreseeable risks and discomforts* to the subject
- Note: these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Benefits* of the research to the individual human subject and society
- *Length of time* the subject is expected to participate
- *Payment* for participation (if applicable)
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' *right to confidentiality* and *right to withdraw* from the study at any time without any consequences

### **There are three types of consent:**

- Consent – An adult subject, capable to give permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate.
- Parental Permission – When children/minors are included in research, the parent/guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents. In some cases, waiving the requirement to obtain parental permission may be necessary. Refer to [45CFR46 subpart D](#) for more information.
- Assent – Assent is a child's affirmative agreement to participate in research. If the subject is 7-17 years of age, assent must be obtained. The assent form must include simple language written at the appropriate reading level of the youngest subject in the age range.

Informed consent templates and guides can be found in the following links:

UPIRB: <https://oprs.usc.edu/upirb/upirb-forms/>

HSIRB: <https://oprs.usc.edu/hsirb/hsirb-forms/>

\*See Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

### **Privacy/Confidentiality**

The protection of privacy and confidentiality are important issues in the protection of human research subjects. The investigator must describe plans to protect the subject's identity as well as the confidentiality of the research records. Privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report.

### **Privacy**

Can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects. The concept of privacy relates to the means for obtaining the data from subjects. For example, when a researcher is interviewing a participant, they must make provisions to protect what is being discussed. Holding the interview in a private office is one method to protect the participant's privacy. Another consideration for privacy is limiting the data being obtained to essential data only. For example, collecting information not related to the research hypothesis is inappropriate.

### **Confidentiality**

Pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure.

The investigator must provide a plan to keep research records confidential. For example, storing research records in locked file cabinets and password protecting electronic files helps to ensure confidentiality. Investigators should also describe, in their IRB application, who has access to the research records. Without appropriate safeguards, problems may arise from a long-term retention of records. In some cases, to prevent potential criminal or civil prosecution of the research subjects, the IRB may require the destruction of all data that can identify the subjects. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose and for what period of time. Video and audio taped data, as well as photographs require specific plans for confidentiality since these media can provide additional means for subject identification.

### **Risk/Benefit**

When reviewing research studies, the IRB must assess the risks and benefits (if any) to subjects who participate in the research. The IRB's assessment of risks and anticipated benefits involves a series of steps. The IRB must: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible; (3) identify the probable benefits to be derived from the research; (4) determine that the risks are reasonable in relation to the benefits to subjects, if any, and the importance of the knowledge to be gained; (5) assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits; and (6) determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected.

**Risk.** Defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Risks also include possible breaches of confidentiality. Both the probability and magnitude of possible harm may vary from minimal to significant.

**Physical Harms.** Medical research often involves exposure to pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered "risks" for purposes of IRB review. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical research usually result in no more than minor discomfort (*e.g.*, temporary dizziness, the pain associated with venipuncture). Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and can cause serious or disabling injuries.

**Psychological Harms.** Participation in research may result in undesired changes in thought processes and emotion (*e.g.*, episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but IRBs should be aware that some research has the potential for causing serious psychological harm.

- Subjects may feel stress caused by certain research questions or procedures such as surveys or face-to-face interviews. Some questions may raise painful memories or unresolved issues. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or legal liability when that behavior is generally illegal or socially unacceptable.
- Provisions for psychological support and referrals can be built into studies when emotional distress may be an outcome. Consent forms describing the kinds of questions the researcher will ask allows participants to choose whether they are comfortable with answering certain types of questions or exploring certain issues.
- A breach of confidentiality may be damaging to a subjects reputation, their employability may be negatively affected, and/or their ability to obtain insurance coverage may be jeopardized if confidentiality is not maintained.
- Information about certain behaviors may place subjects at risk of legal action. For example, if a researcher asks parents how they discipline their children, information about child abuse may be obtained and must be reported. Similarly, if subjects divulge information about illegal activities or stigmatized activities, any disclosure of that information could place the subjects at risk of significant harm.

**Benefit.** Defined as a valued or desired outcome; an advantage. The benefits of research fall into two major categories: benefits to subjects and benefits to society. Frequently, the research subjects are undergoing treatment, diagnosis, or examination for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subjects by ameliorating their conditions or providing a better understanding of their disorders. Patients and healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or **therapeutic** benefit. Such research is designed principally to increase our understanding and store of knowledge about human physiology and behavior. Research that has

no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. The IRB should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

# CHAPTER 10 Investigator Reporting Responsibilities

After a research project is approved, there are many situations requiring communication with the IRB during the conduct of the research. These communications result from events that unfold (and may or may not be expected) as the research is taking place. Investigators are required to submit reports or communication on: adverse events, unanticipated problems, changes, study continuing reviews, expiration of approval period, study completion, and terminations/suspensions. This chapter provides an introduction to each of these sections.



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## REPORTABLE EVENTS: ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

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After an Adverse Event or an Unanticipated Problem occurs, the principal investigator is required to submit a reportable event application to the IRB through the iStar system. The time frame for reportable events is set by USC policy and may be found in the [Policies and Procedures](#). The principal investigator's report should contain enough information for the IRB to determine whether the event increases the level of risk to participants, requires a research design change or necessitates modification to the informed consent form.

### *Definitions*

Adverse Events are defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Events (SAEs) are those that: are fatal or life threatening, result in significant or persistent disability, require or prolong hospitalization, result in a congenital anomaly/birth defect, or in the opinion of the investigators,



represent other significant hazards or potentially serious harm to research subjects or others.

Unanticipated or Unexpected refers to adverse events or other problems in the research, the specificity or severity of which is not consistent with the information already provided to the IRB, including the investigator's brochure, research protocol or consent form.

Unanticipated Problems Involving Risks to Subjects or Others (UPX) includes any incident, experience, or outcome that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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## CHANGES TO PREVIOUSLY APPROVED RESEARCH

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Any proposed change to a previously IRB approved research project must be submitted to and approved by the IRB before the change is implemented, except when necessary to eliminate apparent immediate hazards to the subjects. Amendment submissions can be reviewed by the expedited review procedure or require review by the fully convened IRB depending on the assessment of associated risk. Typically, minor changes are reviewed by the expedited procedure. Minor changes do not alter the risk/benefit ratio in previously approved research (e.g. correction of typos, adding PIs to the project, etc.).

All USC investigators proposing modifications to a previously approved human subject research project must submit an amendment application via iStar. The amendment application serves as a "cover letter" that lists/details the proposed changes to the study. In addition to the amendment application, investigators must make the changes to the originally submitted new study application. In reviewing amendments, the IRB analyzes whether the changes pose additional risks to subjects or represents a significant change in study procedures and may impose additional contingencies before approving the amendment.

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## CONTINUING REVIEW

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In accordance with federal regulations, all non-exempt research protocols undergo continuing review at intervals appropriate to the degree of risk, but not less than once per year. The frequency and extent of continuing review for each study is based upon the nature of the study, the degree of risk involved, the novelty of the research procedures, and the vulnerability of the study's subject population. After a careful consideration of each of these factors, each protocol is assigned an approval period, after which the study must be re-reviewed by the IRB. In some instances, such as the use of innovative procedures/techniques (i.e. surgical procedure), the IRB may choose to grant an approval period based on number of subjects accrued, rather than on a specific time period. ***This type of approval is usually assigned when there are significant concerns regarding the potential risks of participation.***

Each investigator must abide by the approval period imposed by the IRB at the time of the most recent IRB approval. Each IRB approval notice designates a period of time during which activities involving human research subjects may be *undertaken*. No research project may

continue to recruit, enroll, or treat subjects or analyze data after the IRB approval expiration date (except where doing so would cause harm to the subjects).

It is the investigator's responsibility to ensure that approval for an active protocol remains current. The IRB expiration date can be found on the protocol summary view in the iStar system.

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## **EXPIRATION OF APPROVAL PERIOD**

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If the investigator does not submit a continuing review application through iStar by the current expiration date, the investigator is notified by e-mail that IRB approval has expired. The email includes a notice that all study related activities must cease (including recruitment, enrollment, interventions, interactions, or data analysis). After 60 days, the iStar system automatically closes the study.

In the event that a protocol expires and the withdrawal of research interventions may place study subjects at risk, the investigator may request that the IRB grant permission to allow the continuation of activities required for subject safety prior to renewal of IRB approval. If subject safety would be compromised by study closure, investigators can request that the IRB allow continuation of study activities for currently enrolled subjects. If research-related interventions have been continued with subjects on an expired protocol, the IRB must be immediately informed of the circumstances that necessitated this action.

Requests justifying continuation of currently enrolled subjects will be forwarded to an IRB Chair for consideration. If the IRB Chair grants permission to allow the continuation of research interventions with previously enrolled subjects for reasons related to subject safety, the IRB will send written notification to the investigator. Other research activities (such as recruitment, enrollment, data analysis, etc.) may only be resumed after the investigator receives continuing approval for the research.

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## **STUDY COMPLETION**

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A research project is closed when subject accrual, subject follow-up and data analysis are completed at USC. Once a study is closed, no further research activity, including data analysis, may occur. It is permissible for a study to be closed at USC and still be open to accrual at other sites. In the event that a serious adverse event or an unanticipated problem occurs at a non-USC site after the closure of the study at USC, the USC investigator is required to submit the report via iStar.

Upon study completion, the investigator should submit a continuing review through iStar, indicating the study status as "closed". By doing so, the researcher confirms that the study is finished and that no further interactions with subjects or their data will take place. Once the study is closed in iStar, the researcher is no longer required to submit yearly continuing review applications. If the investigator wishes to enroll new subjects for the closed study, he/she must reactivate the protocol with the IRB. The IRB, in consultation with the principal investigator, may consider closing a study when active data analysis and publication pursuant to the approved

study has ceased, even if the investigator retains records that may identify individual subjects. Additional research projects using data acquired in the approved study may constitute new human subjects research studies subject to separate IRB review.

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## **TERMINATION/SUSPENSION OF A STUDY**

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Termination is when the IRB permanently withdraws approval of ALL research activities for a particular study. Terminated research is no longer required to undergo continuing review. The convened IRB, IRB Chair, and IRB Vice Chair (in the absence of the Chair) are authorized to suspend or terminate research. If there is an urgent situation requiring suspension or termination of a study, the IRB Chair or Vice Chair may make this determination. If the IRB Chair or Vice Chair terminates or suspends a study on his/her own, the IRB is notified by the Chair at the next IRB meeting.

Suspension is when the IRB temporarily or permanently withdraws approval of some or all research activities. Suspended research is still under the jurisdiction of the IRB



# APPENDICES



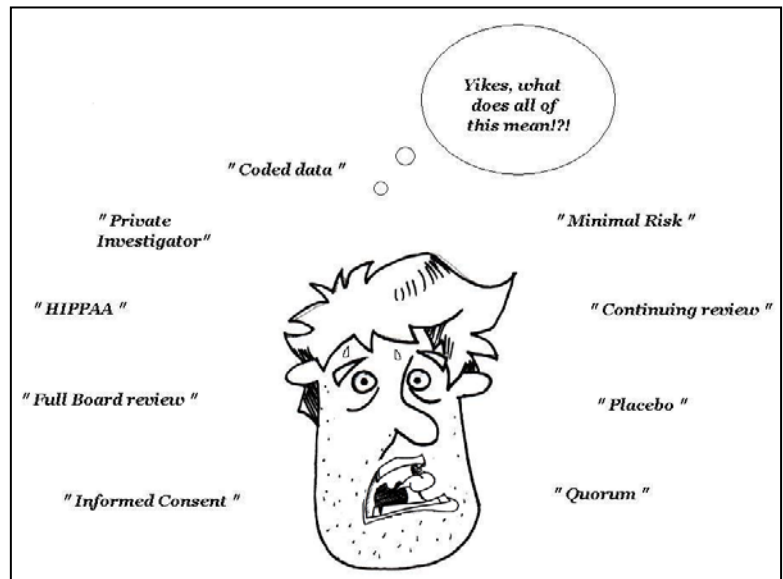
# APPENDIX A Glossary of Common Terminology

## ***Adverse Event/Effect (AE)***

Any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, or a symptom or disease associated with the research. Adverse events may or may not have a causal relationship with the research.

## ***Approved Drug / Device***

An approved drug/device means the drug/device being studied has been cleared by the U.S. Food and Drug Administration (FDA) for marketing.



## ***Assent***

Agreement to participate in research obtained from an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person). An assent form is like an informed consent form but is tailored to the status/age of the individual not competent to give consent. It is only binding in conjunction with parent/guardian consent.

## ***Audit***

A systematic and independent examination of research activities and documents, to verify that the activities were conducted according to the protocol, sponsor's expectations, institutional procedures, good clinical practice (GCP), and applicable regulatory requirement(s).

## ***Autonomy***

Personal capacity to consider alternatives, make choices, comprehend information, and act without undue influence or interference of others.

## ***Belmont Report***

The National Commission for the Protection of Human Subjects in 1978 authored the Belmont report. It establishes the basic ethical principles for conducting human subjects research: autonomy, beneficence, and justice.

## ***Beneficence***

Beneficence is an ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

***Benefit***

A benefit is a valued or desired outcome; an advantage.

***Bias***

When objectivity is impaired by personal gain or personal judgment. In clinical studies, bias is minimized by blinding and randomization.

***Biologics***

Biologics, as regulated by the U.S. Food and Drug Administration, include therapeutic serum, toxin, anti-toxin or microbials used for the prevention, treatment, or cure of diseases or injuries.

***Blinded Study Design***

Study designs comparing two or more interventions in which the investigators, subjects, or some combination thereof do not know group assignments.

***Case Report Form (CRF)***

A printed, optical, or electronic document designed to record regulatory and protocol-required data from each individual enrolled in the study. The CRF is reported to the sponsor for each subject and also provides documentation for quality assurance and monitoring.

***Clinical Trial***

A clinical trial is a research study to evaluate the safety and efficacy of vaccines, new therapies, or new ways of using known treatments. Clinical trials are often staged (e.g., phase I, II, III) to learn essential information putting fewest subjects at risk.

***Coded Information***

Coded means replacing identifiable information (such as name or social security number) with a number, letter, symbol, or combination thereof (i.e., the code).

***Cognitively Impaired***

Having a disorder (psychiatric or developmental) that affects cognitive or emotional functions that impair the capacity for sound judgment and reasoning. Other conditions that may impair judgment and reasoning are: being under the influence of drugs or alcohol, having a degenerative disease, having a terminal illness or having disabling handicaps.

***Cohort***

In epidemiology, a group of individuals selected for common characteristics.

***Community Based Clinical Trial (CBCT)***

A clinical trial conducted primarily through primary-care physicians rather than academic research facilities.

***Community Member/ Non-Affiliated Member***

Member of an Institutional Review Board who has no ties to an institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker, etc.).

***Compassionate Use***

A method of providing experimental therapeutics prior to the final FDA approval. This allows treatment for sick individuals who have no other options. Often, case-by-case approval must be obtained from the FDA for "compassionate use" of a drug, therapy or device.

***Compensation***

Payment for participation in research.

***Competence (Capacity to consent)***

A legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

***Compliance***

Adherence, in this case, to federal regulations, state laws, institutional policies and sponsor requirements.

***Confidentiality***

Pertains to the handling of information/data that an individual has disclosed in a relationship of trust. The expectation is that the information/data will not be divulged to others without permission, or in ways that are inconsistent with the original disclosure.

***Continuing Review***

Periodic review of a research study by an IRB to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify the study continues to meet regulatory and institutional requirements. Continuing review shall be conducted at intervals appropriate to the degree of risk but not less than once per year. ([45 CFR 46.109\(e\)](#); [21 CFR 56.109\(f\)](#))

***Contract***

An agreement that a specific research activity will be performed under the direction of an entity providing funds. Research performed under a contract is more closely controlled by the entity than research performed under a grant.

***Contraindication***

A specific circumstance when the use of certain treatments is not recommended.

***Control/Normal Subject(s)***

Subject(s) who do not receive the treatment being studied, who are then used for comparison to subjects who do receive the treatment. Or, subjects who do not have a given condition, background, or risk factor that is being studied.

***Controlled Study***

Research that involves at least two groups: one that receives the study intervention and the other that receives a placebo or another intervention. These studies are also referred to as "blind" / "masked" (i.e. the subjects do not know which treatment they are receiving) or "double blind" / "double-masked" (i.e. neither the subjects nor the researchers know the treatment assignments).

### ***Cross-Over Design***

A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

### ***Data Analysis***

The process of applying statistical techniques to describe, summarize, and compare data to extract useful information and facilitate conclusions.

### ***Data and Safety Monitoring Board (DSMB)***

An independent committee that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends that would warrant changes or early closure of the trial.

### ***Debriefing***

Providing subjects with previously undisclosed information about the research project or the study's real purpose.

### ***Deception***

Deception, when referring to studies, is the intentional misleading of subjects or the withholding of full information about the nature of the study. Deception increases ethical concerns because it interferes with the ability of the subject to give fully informed consent. However, deception is arguably necessary for certain types of behavioral research to prevent biased behavior or answers.

### ***Design***

A research design is a plan or analytical approach for answering research questions. Some examples of research designs are experimental, correlational, observational, and single case. The selection of a particular study design depends on the information sought.

### ***Device/Medical Device***

A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body (which would be considered medicine). Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

### ***Diagnostic Trials***

Trials that are conducted to find better diagnostic tests/procedures for identifying a particular disease or condition. Diagnostic trials enroll people who have signs or symptoms of a disease or condition being studied.

### ***Double Blind Study***

A clinical trial design in which neither the participating individuals nor the study staff knows which trial regimen participants are receiving. Double blind trials are used to increase objectivity so expectations do not influence outcome.

***Drug/Pharmaceutical***

Any chemical compound that may be administered to humans for the diagnosis, treatment, cure, mitigation, or prevention of disease or of benefit to other conditions.

***Efficacy***

The ability of a drug or treatment to produce the expected result.

***Eligibility criteria***

These are defined requirements for subject inclusion/exclusion in a given experiment. Eligibility criteria examples are age, sex, state of health, a defined range for a biologic measure (e.g. glucose level or cholesterol), blood cell counts, etc.

***Emancipated Minor***

Someone who has not reached adulthood as defined by state law but who may be treated as an adult for certain purposes (e.g., consenting to medical care). In California an emancipated minor must meet one of the following requirements set out in [California Family Code § 7002](#): (1) Have entered into a valid marriage, whether or not it has been dissolved; (2) Be on active duty with the armed forces; or (3) Have received a court declaration of emancipation.

***Empirical***

Based on experimental data; not theory.

***Endpoint***

A target outcome of a trial. Endpoints are chosen because they are measurable.

***Engagement of Institutions in Research***

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

***Equitable***

The fair or just selection of study subjects (principle of justice) to assure that the benefits and burdens of research are equally distributed.

***Ethnographic/Fieldwork/Anthropology Research***

Ethnography is the study of people and culture. Ethnographic research involves observation of a person or group studied in their own environment, often for long periods of time.

***Exempt Research***

Exempt research is Human Subjects Research that meets one of the minimal risk categories in the federal regulations.

***Expanded Access***

Increasing the inclusion criteria in an experimental drug study to allow for enrollment of participants who are failing on currently available treatments, and/or are unable to participate in any other ongoing clinical trials.

### ***Expedited Review***

A review undertaken per federal regulations by the IRB chair or a designated voting member, rather than the entire IRB.

### ***Experimental Drug***

A drug that has an Investigational New Drug (IND) application filed with the FDA, but has yet to be licensed.

### ***Federal Wide Assurance (FWA)***

An agreement between a federally funded entity and the HHS Office of Human Research Protections (OHRP) that stipulates methods by which the entity will protect research participants (66 Fed Reg 19139, 19141 April 13, 2001.). Non-HHS federal agencies also use the assurance process for their funded entities.

### ***Fetus***

A developing human from two months after conception to birth. If the delivered or expelled fetus is viable, it is designated an infant [[45 CFR 46.203\(c\)](#)]. The term "embryo" is usually used for earlier phases of development.

### ***Food and Drug Administration (FDA)***

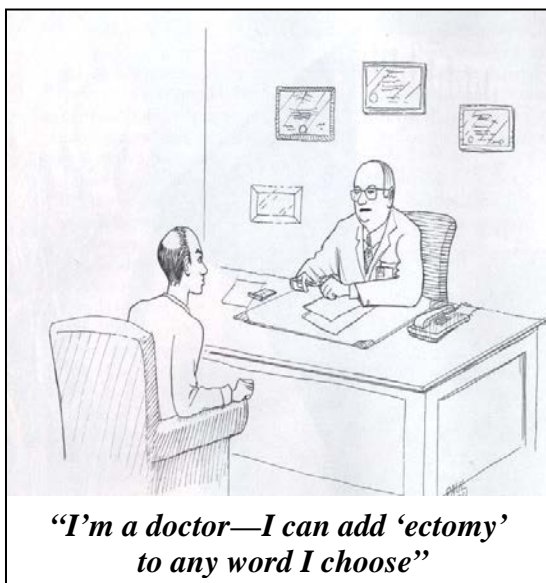
The U.S. Department of Health and Human Services agency responsible for ensuring the safety and effectiveness of drugs, biologics, vaccines, and medical devices (<http://www.fda.gov/>).

### ***Full Board Review***

Review of proposed or continuing research (primarily greater than minimal risk research) by a convened IRB meeting, at which a majority of the voting membership is present.

### ***Gene Therapy***

The treatment of certain disorders, especially those caused by genetic anomalies or deficiencies, by introducing specific engineered genes into a patient's cells.



### ***Genetic Screening***

Genetic tests or methods to identify persons who have a gene that is thought to be linked to a certain phenotype or who are at risk of inherited diseases or disorders.

### ***Guardian***

An individual who is authorized under applicable state or local law to give permission on behalf of a child or make decisions for an incompetent adult [[45 CFR 46.402\(c\)](#)].

### ***Grant***

Financial support provided for a research study. Fund givers typically do not exercise strict control over the grants they have awarded.

***Health Insurance Portability and Accountability Act (HIPAA)***

HIPAA's Privacy Rule of 2003 prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from disclosing protected health information without written authorization from the individual (HIPAA Authorization).

***Human In Vitro Fertilization***

Fertilization involving human sperm and ova that occurs outside the human body (e.g. a test tube).

***Human Subjects***

Under the federal regulations (45 CFR 46), human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

***Identifiable Personal Information***

Data containing enough information to reveal the identity of the subject.

***Inclusion/Exclusion Criteria***

The pre-determined conditions of a clinical trial that allow or exclude participation. These criteria are factors such as age, gender, type and stage of a disease, previous treatment history, and/or other medical conditions.

***Investigational Device Exemptions (IDE)***

Investigational devices that are exempt from regulations found in the [FDA Medical Device Amendments](#) because of their low risk profile. This allows such unapproved devices to be used in clinical investigations such as IDE.

***Investigational New Drug or Device (IND)***

A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

***Informed Consent***

A person's voluntary agreement – based upon adequate knowledge and understanding of relevant information – to participate in research or undergo a diagnostic, therapeutic, or preventive procedure.

***Informed Consent Document***

A document that provides prospective participants with the purpose, procedures, potential risks and benefits of involvement in a research study, as well as alternatives to participating. This document is also what participants sign to demonstrate their consent to participate in research.

***Institutional Official***

An officer of an organization who has the authority to speak for and legally commit the entity to comply with federal regulations regarding the involvement of human subjects in research.



***Institutional Review Board (IRB)***

To protect the welfare of human subjects participating in research, a specially constituted review body designated by an entity to review human subject research protocols.

***International Studies***

Procedures and policies that apply to research taking place outside the U.S. often differ from those set forth in the U.S. federal policies. U.S. federally funded research activities in a foreign country may be approved only if the ethical protections are equivalent to those in the U.S. This is also true for FDA approval of drugs/devices/biologics tested outside the United States.

***Investigator Initiated Research***

Research that is initiated and conducted by an individual rather than a sponsor/pharmaceutical company. The investigator has the same responsibilities that a sponsor would have.

***Investigator's Brochure***

A compilation, created by the sponsor of all the clinical and nonclinical data on the investigational product(s).

***In Vitro***

Refers to processes occurring outside of a living organism.

***In Vivo***

Refers to processes carried out within a living organism.

***IRB Records***

IRB records include but are not limited to: minutes from IRB meetings, proposals reviewed, amendments, investigator brochures, and supplemental information including recruitment materials, consent forms, continuing reviews, correspondence, and IRB membership.

***iStar***

IRB Submission Tracking and Review System - the online system through which all USC IRB applications are submitted, reviewed, and approved.

***Justice***

An ethical principle discussed in the Belmont Report requiring fairness in the equitable distribution of burdens and benefits within the study population.

***Legally Authorized Representative***

A person authorized by statute, court appointment, or a health care proxy to make health decisions for another person. In human subjects research, this refers to an individual, judicial body or other body authorized under applicable law, to consent to research on behalf of a prospective subject [Federal Policy § .102(c)].

***Longitudinal Study***

A study designed to follow groups of subjects for an extended period of time.

***Minimal Risk***

A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [[45 CFR 46.102\(i\)](#)].

***Minor***

Persons who have not attained the legal age to consent to treatment or procedures in research, as determined under the applicable law of the jurisdiction in which the research will be conducted [[45 CFR 46.401\(a\)](#)].

***Monitoring***

A systematic, ongoing process to evaluate or oversee the conduct of research procedures.

***New Drug Application (NDA)***

The New Drug Application (NDA) is the application drug sponsors submit to the FDA for approval of a new pharmaceutical for sale and marketing.

***Non-Significant Risk Device***

An investigational medical device that does not present significant risk to the research subject (e.g., tongue depressor, or swab).

***Non-Viable Fetus***

An expelled or delivered fetus, which although living, cannot possibly survive to the point of independently sustaining life, even with the support of available medical therapy [[45 CFR 46 203\(d\)\(e\)](#)]. Although it may be presumed that an expelled or delivered fetus is nonviable at a gestational age less than 20 weeks and weight less than 500 grams [*Federal Register* 40 (August 8, 1975):33552], a specific determination as to viability must be made by a physician in each instance.

***Off Label-Use***

A drug used for conditions other than those approved by the FDA.

***Office for Human Research Protections (OHRP)***

The U.S. Department of Health and Human Services office responsible for regulations [[45 CFR Part 46](#)] governing research involving human subjects.

***Office for the Protection of Research Subjects (OPRS) at USC***

The USC office responsible for the oversight and direction of the Human Subjects Protection Program. This includes administrative oversight of the IRBs, maintenance of institutional Human Subjects Research policies and setting educational requirements.

***Open Label Design***

An experimental drug trial in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.

***Orphan Drugs***

An FDA category of medication used to treat rare diseases and conditions.

***Peer Review***

Experts with the same scholarly background as the person submitting a project, who review research for scientific merit, participant safety, and ethical acceptability.

***Pharmacokinetics***

The study of mechanisms of absorption, distribution, metabolism, and excretion of a drug or vaccine.

***Placebo***

A chemically inert substance used in controlled clinical trials to provide data that helps distinguish and determine whether improvement and side effects reflect imagination or anticipation rather than the actual power of a drug.

***Placebo Controlled Study***

A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective than the placebo in treating the condition.

***Preclinical***

Refers to the testing of experimental drugs in the test tube or in animals - the testing that occurs before human trials.

***Prevention Trials***

Refers to trials that find improved ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle interventions.

***Primary Data Collection***

Primary data collection involves direct contact with, or observation of, one or more people for the purpose of collecting data from or about them.

***Principal Investigator (PI)***

The scientist, scholar, or student with ultimate responsibility for the design and conduct of a research project.

***Prisoner***

An individual confined or detained in a penal entity.

***Privacy***

Control over the extent, timing, and circumstances of sharing oneself (physically or behaviorally) with the PI or other research staff.

***Prospective Studies***

A study designed to follow groups of subjects for an extended period of time with defined outcomes.

***Protected Health Information (PHI)***

PHI is health information transmitted or maintained in any form or medium that includes ALL of the three following parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

***Protocol***

The formal design or plan of an experiment or research activity.

***Quorum***

A majority of voting members (50% + 1) who are present at a convened meeting. Must be maintained and documented for all votes.

***Random, Random Assignment, Randomization, Randomized***

A method of assigning subjects to different treatment groups based on chance.

***Recruitment/Recruitment Materials***

Recruitment is the process by which potential subjects are informed about a study. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must be accurate, non-coercive, and must not emphasize monetary compensation. These materials must be approved by the IRB.

***Research***

Systematic investigation, including research development, testing, and evaluation, designed to produce or contribute to generalizable knowledge [[45 CFR 102\(d\)](#)].

***Respect for Persons***

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

***Retrospective Studies***

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews, surveys or measurements.

***Risk***

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations only define “minimal risk”.

***Risk/Benefit Ratio***

Comparing the potential benefits to the risks of participating in a research study.

***Secondary Data***

Secondary data collection involves accessing information that has already been obtained either individually or in aggregate form.

***Serious Adverse Event (SAE)***

Defined by the FDA as an event that jeopardizes the research subjects and may require medical or surgical treatment (e.g., death, a life threatening experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly and/or birth defects).

***Side Effect***

Any undesired action or effect of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects.

***Significant Risk Device***

An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject.

***Single-Blind/Blind Study***

A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking.

***Sponsor***

A person, federal agency, corporation, or other entity that provides funds for a research project.

***Standard Treatment / Standard of Care***

A treatment or regimen in wide use and considered to be effective in the treatment of a specific disease or condition. (Often used as comparator for a new drug, device, biologic or treatment).

***Stratification***

A statistical method used to categorize subjects into subgroups by specific characteristics. This enables researchers to look into separate subgroups.

***Study Arm***

Any of the treatment groups in a randomized trial. Most randomized trials have two “arms” but some have three or more.

***Suspension/Termination***

IRB approval is suspended/terminated and all research activity is halted as the result of: unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with [45 CFR Part 46](#), or the requirements/determinations of the IRB not being followed or met.

***Survey***

A means to obtain information from respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

***Toxicity***

A detrimental effect produced by a drug or condition.

***Unanticipated Problem Involving Risks to Subjects or Others (UPX)***

Any event that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

***Viable Infant***

When referring to a delivered or expelled fetus, the term “viable infant” means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy [45 CFR 46.203(d)]. In research, this judgment must be made by a physician unaffiliated with the research project.

***Voluntary***

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's willingness to participate (or continue to participate) in a research activity.

***Vulnerable Populations***

Any individual who may be subject to coercion due to a situation or a malady can be considered vulnerable in that context. Federal regulations however, define only three groups of vulnerable subjects: (a) prisoners, (b) children, and (c) pregnant women, fetuses, and neonates.

# APPENDIX B IRB Reviewer Checklists

The IRB has developed comprehensive reviewer checklists to assist IRB staff and members in performing thorough protocol reviews. Those submitting applications may also find these checklists useful to learn regulatory expectations. The checklists are meant to be used as a guide regarding essential content, but not as an official set of rules. The following checklists are included in this chapter:

1. New IRB Applications
2. Informed Consent
3. Continuing Review Applications
4. Research Involving Children (Subpart D)
5. Research Involving Pregnant Women, Human Fetuses, and Neonates (Subpart B)
6. Research Involving Prisoners (Subpart C)



Note: These checklists can be downloaded here: <https://oprs.usc.edu/review/tipsheets/>.

## ***1. New IRB Applications: Reviewer Checklists***

*These guidelines contain HHS and FDA basic human subjects protections requirements, and additional requirements for DoD sponsored research.*

<b>1. PROJECT DESCRIPTION AND METHODOLOGY</b>	<b>Yes / No / N/A</b>
a. Are the aims and underlying hypotheses of the research stated clearly?	
b. Does the research use procedures consistent with sound research design?	
c. Does the research design allow the proposed research question to address the proposed study objectives and result in scientifically and statistically valid results?	
d. Does the research contribute to generalizable knowledge?	
e. Is there an adequate justification for involving human subjects?	
f. Is there an adequate explanation of the research issues?	
g. Is there an adequate description of the activities involving human subjects?	
h. Is there a detailed description of the data collection and methods of recording?	
i. Have the questionnaires and interview tools been provided?	
j. Is there an adequate justification for the sample size?	
<b>2. RISK AND BENEFIT CONSIDERATIONS</b>	<b>Yes / No / N/A</b>
a. Are the risks (physical, psychological, legal, economic, and social) to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk?	
b. Are the risks minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?	
c. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?	
d. Are the risks to subjects reasonable in relation to the importance of the knowledge that may reasonably be expected to result?	
e. Are both risks and anticipated benefits accurately identified, evaluated, and described?	



f. Have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	
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<b>3. SELECTION OF SUBJECTS</b>	<b>Yes / No / N/A</b>
a. Is the subject selection equitable?	
b. Are the criteria for inclusion/exclusion equitable?	
c. Will the recruitment process alter equitable selection?	
d. Does the nature of the research justify using the proposed subject population?	
e. Are there adequate procedures for identifying those who might be more susceptible to the risks and who therefore ought to be excluded?	
f. Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the subject group that would pose special risks?	
g. Are some or all of the subjects likely to be vulnerable to coercion or undue influence, such as children prisoners, pregnant women, mentally disabled persons or economically disadvantaged persons?	
h. If yes to question 3g, have additional safeguards been included in the study to protect the rights and welfare of these subjects?	
i. If there is a special population (children, prisoners, pregnant women and fetuses), has the appropriate justification been provided?	
j. Is the exclusion of study subjects justified and appropriate?	
<b>4. PRIVACY AND CONFIDENTIALITY</b>	<b>Yes / No / N/A</b>
a. Are there adequate provisions to protect the privacy interests of participants?	
b. Are there adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study?	
c. If the information obtained about subjects might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained?	
d. Are the investigator's disclosures to subjects about confidentiality adequate?	
<b>5. MONITORING</b>	<b>Yes / No / N/A</b>

a. Does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?	
b. Is there documentation indicating appropriate reporting to the IRB in the event that unexpected results are discovered or there are adverse events?	
c. If appropriate has a data safety monitoring committee been established?	
d. If the study is a multi-center study and USC is the coordinating center, is the plan for the management of information that is relevant to the protection of participants, such as reporting of unexpected problems, protocol modifications, and interim results adequate?	
e. If the PI is conducting research at an external site, is there an adequate management and communication plan among the IRBs involved?	
<b>6. INCENTIVES FOR PARTICIPATION</b>	<b>Yes / No / N/A</b>
a. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population?	
b. Is the compensation or reimbursement appropriately prorated?	
<b>7. CONFLICT OF INTEREST</b>	<b>Yes / No / N/A</b>
a. Is there a conflict of interest that requires management?	
<b>8. INFORMED CONSENT PROCESS AND CONTENT</b>	<b>Yes / No / N/A</b>
a. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?	
b. Is the language and presentation of the information to be conveyed appropriate to the subject population?	
c. Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making?	
d. Is it clear who is authorized to obtain informed consent for the study?	
e. Have the informed consent issues for secondary study subjects been addressed?	

f. Will the investigator obtain legally effective informed consent of the participant or the participant's legally authorized representative?	
g. Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate?	
h. Will the circumstances of the consent process minimize the possibility of coercion or undue influence?	
i. Will the individuals communicating information to the participant or the representative during the consent process provide the information in language understandable to the participant or the representative (individuals talking to the participants and answering questions will be able to communicate in a manner that is understandable to the participant)?	
j. Did the PI report that they plan to enroll non-English speaking subjects?	
k. If yes, did the PI report that they will use the short form? *Reminder to IRB staff: PI's must be notified in IRB correspondence regarding the IRB requirements when using the short form.	
l. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights?	
m. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence?	
n. Are subjects informed to take as much time necessary to read the consent form?	
o. Are subjects informed that they will receive a copy of the consent form?	

<p>p. The consent from contains contact information for a person independent of the research team for the following:</p> <ul style="list-style-type: none"> <li>• To obtain answers to questions about the research</li> <li>• In the event the research staff could not be reached</li> <li>• In the event they wished to talk to someone other than the research staff?</li> </ul>	
<p><b>9. BASIC ELEMENTS OF INFORMED CONSENT (REQUIRED)</b></p>	<p><b>Yes / No / N/A</b></p>
<p>a. A statement that the study involves research</p>	
<p>b. An explanation of the purposes of the research</p>	
<p>c. The expected duration of the subject's participation</p>	
<p>d. A description of the procedures to be followed</p>	
<p>e. Identification of any procedures which are experimental</p>	
<p>f. A description of any reasonably foreseeable risks or discomforts to the subject</p>	
<p>g. A description of any benefits to the subject or to others which may reasonably be expected from the research</p>	
<p>h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject</p>	
<p>i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained</p>	
<p>j. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained</p>	
<p>k. An explanation of whom to contact for answers to questions about the research</p>	
<p>l. An explanation of whom to contact for answers to questions about injury</p>	
<p>m. An explanation of whom to contact concerning rights as a research subject.</p>	
<p>n. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty.</p>	
<p><b>ADDITIONAL ELEMENTS OF INFORMED CONSENT</b></p>	<p><b>Yes / No / N/A</b></p>

o. A statement that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant which are currently unforeseeable.	
p. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
q. Any additional costs to the subject that may result from participation in the research.	
r. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	
s. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	
t. The approximate number of subjects involved in the study.	
u. The storage and use of research specimens disclosed.	
v. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent.	
w. Is a witness signature required?	
x. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations)	
y. Are subjects informed to take as much time necessary to read the consent form?	
z. Are subjects informed that they will receive a copy of the consent form?	
aa. The consent form contains contact information for a person independent of the research team for the following: <ul style="list-style-type: none"> <li>• To obtain answers to questions about the research</li> <li>• In the event the research staff could not be reached</li> <li>• In the event they wished to talk to someone other than the research staff?</li> </ul>	

10. WAIVER OF INFORMED CONSENT DOCUMENTATION	Yes / No / N/A
<p>a. Have the criteria for waiver of informed consent documentation been met?</p> <ol style="list-style-type: none"> <li>1. The consent form would be the only record linking the subject to the research, <u>and</u> a potential sick would be a breach of confidentiality. In such case, it is up to the subject when asked if they want documentation. <i>(This is not applicable for FDA regulated research)</i></li> <li>2. Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.</li> </ol>	
<p>b. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research?</p>	
<p>c. If children are included, have the criteria for waiver of parental/guardian consent been met?</p> <ul style="list-style-type: none"> <li>- IRB must determine parental/guardian permission is not a reasonable requirement to protect subjects</li> <li>- Appropriate mechanisms must be implemented to protect children as subjects</li> </ul> <p><i>(Provisions for waivers of parental permission are not applicable for FDA regulated research)</i></p>	
11. WAIVER OR MODIFICATION FOR REQUIRED ELEMENTS IN INFORMED CONSENT <i>(THESE PROVISIONS ARE NOT APPLICABLE FOR FDA REGULATED RESEARCH.)</i>	Yes / No / N/A
<p>a. If waiver or modification to required consent elements proposed, have all the criteria been met?</p> <ol style="list-style-type: none"> <li>1. The research involves no more than minimal risk to the subjects?</li> <li>2. The waiver/alternation will not adversely affect the rights and welfare of the subjects.</li> <li>3. The research could not practicably be carried out without the waiver or alteration, and</li> <li>4. When appropriate, the subject will be provided with pertinent information after participation.</li> </ol>	
12. ASSENT FROM CHILDREN	Yes / No / N/A
<p>a. Is assent required? (Assent is required unless the child is not capable (due to age, psychological state, sedation), or the research holds out the prospect of direct benefit that is only available within the context of the research.)</p>	

b. Will assent be documented?	
c. Is the process of obtaining/documenting assent adequate?	

<b>13. CONSENT FOR CHILDREN UNDER THE JURISDICTION OF DEPENDENCY COURT</b>	<b>Yes / No / N/A</b>
a. Has a court order been obtained to allow the child to participate in the research without parental consent?	
b. Is the research either related to the children's status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards?	
c. Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis?	
<b>14. PARENTAL PERMISSION</b>	<b>Yes / No / N/A</b>
a. Is consent of one parent appropriate?	
b. Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk, without potential for benefit.)	
<b>15. CONSENTING COGNITIVELY IMPAIRED PERSONS</b>	<b>Yes / No / N/A</b>
a. Does the research involve greater than minimal risk?	
b. If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual subjects?	
c. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonable be expected to result?	
d. Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?	
e. Are there adequate provisions for soliciting the assent of the subject and permission of their legally authorized representative?	
f. Is the proposed plan for the assessment of the capacity to consent adequate?	

<b>16. WAIVER OF INFORMED CONSENT FOR EMERGENCY USE RESEARCH</b>	<b>Yes / No / N/A</b>
<p>a. Have the criteria for waiver of informed consent for emergency research been met?</p> <ol style="list-style-type: none"> <li>1. The subject must be confronted by a life-threatening situation necessitating the use of the test article.</li> <li>2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject.</li> <li>3. Time is not sufficient to obtain consent from the subject's legal representative.</li> <li>4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.</li> </ol>	
<b>17. WAIVER OF INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH</b>	<b>Yes / No / N/A</b>
<p>a. Have the criteria for waiver of informed consent for emergency room research been met?</p> <ol style="list-style-type: none"> <li>1. The study could not practicably be carried out without the waiver.</li> <li>2. Consultation with community representatives occurs before the start of the research</li> <li>3. Public Disclosure is made before and after the study starts</li> <li>4. A therapeutic window is defined and the researcher commits to trying to locate a surrogate/legally authorized representative who can give consent within the window before proceeding to waive consent.</li> </ol>	
<b>18. RESOURCES</b>	<b>Yes / No / N/A</b>
a. Does the IRB have the appropriate expertise to review this research? If no to question , should a consultant be used to assist in the review of the research	
b. Will the Investigator have access to a population that will allow recruitment of the required number of participants?	
c. Will the Investigator have sufficient time to conduct and complete the research?	
d. Will the Investigator have adequate numbers of qualified staff?	
e. Will the Investigator have adequate facilities?	



f. Does the Investigator have an adequate process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions?	
g. Will the Investigator have adequate medical or psychological services available that participants might require as a consequence of the research, when applicable?	
<b>19. INVESTIGATOR ASSURANCE</b>	<b>Yes / No / N/A</b>
a. Is the PI the holder of the IND/IDE?	
b. If yes, has the PI assured that they are knowledgeable about additional regulatory requirements of sponsors?	
<b>20. CONTINUING REVIEW</b>	<b>Yes / No / N/A</b>
a. Does the research require more than annual continuing review? If yes, how often _____?	
b. Should continuing review be conducted under the expedited review process? (Study meets the definition of minimal risk?)	
<b>21. DOD SPONSORED RESEARCH</b>	<b>Yes / No / N/A</b>
<b>21.1 Informed Consent</b>	
A. Will prior consent be provided by the subject*?  *For research intended to be beneficial to the subject, the informed consent of a legal representative of the subject is acceptable.  * If the research involves cognitively impaired adults, there must be anticipated direct benefit to the subject  * If the research involves an interventions or interactions with subjects, a waiver of consent or parental permission is prohibited unless a waiver is obtained from the Secretary of Defense.	
<b>21.2 Protection of Subject Population</b>	
A. Does the project involve prisoners of war (e.g. civilian interness, retained persons, lawful and unlawful enemy combatants) as human subjects?  <i>“Research supported or conducted by the DoD that affects vulnerable classes of subjects shall meet the additional protections of 45 CFR Part 46, Subparts B,C, and D (reference (f)) (e.g. fetuses, pregnant women, human in vitro fertilization, prisoners, or children)”. (DoDD 3216.02 4.4.1)</i>	

<p>B. If the research will involve more than minimal risk to subjects, has a medical monitor (physician, dentist, psychologist, nurse, or other healthcare provider), independent of the study been appointed?</p> <p>Note: The monitor must be capable of overseeing the progress of research protocols and issues of individual subject/patient management and safety.</p>	
<p>C. If the project involves military personnel, unit officers, or noncommissioned officers (NCOs), are there provisions to exclude senior officers and NCOs in the chain of command during subject solicitation, consent or recruitment sessions in which members of their units are afforded the opportunity to participate in research?</p>	
<p><b>21.3 Restricted Use Materials</b></p>	
<p>A. Does the project involve fetal tissue?*</p> <p>In the event that fetal tissue will be used in a DOD funded study numerous additional contingencies apply, contact the IRB.</p>	
<p>B. Does the research involve testing of chemical or biological reagents on humans?</p> <p>In the event that chemical or biological reagents will be used in a DOD funded study numerous additional contingencies apply, contact the IRB.</p>	
<p><b>21.4 Education</b></p>	

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\* The Department of Defense defines human fetal tissue as “*tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth*” 42 USC §289g-1

<p>A. All key personnel participating in Human Subjects Research at USC are required to take CITI online Human Subjects training every three years. This is required whether or not the study is DoD funded.</p>	
<p>B. Investigators conducting DoD sponsored research must be familiar with the Nuremberg Code, the Belmont Report, 32 CFR Part 219 (reference (c)), DoDD 3216.02, and any related requirements</p>	
<p><b>21.5 Required Injury Statement</b></p>	
<p>A. Every research protocol involving greater than minimal risk shall provide an arrangement for emergency treatment and necessary follow-up of any research-related injuries to subjects.</p> <p>Has an IRB/DoD approved injury statement been included in the informed consent? Does the DoD funding document/research protocol address DoD’s injury statement requirements?</p>	
<p><b>21.6 Potential For Undue Influence</b></p>	
<p>A. Investigators should be alert to the potential for undue influence in research with those in employer-employee status, teacher-student, supervisor-subordinate relationships, or deployed active duty personnel.</p>	
<p><b>21.7 Scientific merit review</b></p>	
<p>B. At USC the IRB, IRB chair, and/or IRB consultant shall evaluate the scientific merit of DOD funded studies.</p>	
<p><b>21.8 Institutional Monitoring</b></p>	
<p>A. DoD funded research shall be subject to post-approval monitoring, periodic assessments by the IRB or OPRS using the existing continuous quality improvement procedures.</p>	
<p><b>21.9 Non-Compliance/ Misconduct and Unanticipated Problems Involving Risks to Subjects</b></p>	

<p>A. Issues related to non-compliance with DoDD 3216.02 shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious noncompliance shall be reported to the Director, Defense Research Engineering.</p>	
<p>B. The IRB must review and, if appropriate, take action on any allegations of non-compliance with human subject protections and any allegations of research misconduct, and report to DoD as required.</p>	
<p>C. According to the terms of 45 CFR Part 46, DoD and FDA regulation all unanticipated problems involving risks to subjects or others and serious events, as determined by the IRB, must be reported to the appropriate DoD/OHRP/FDA officials.</p> <p>Significant communication about DoD funded projects reported to other federal departments regarding compliance and oversight must also be reported to DoD officials.</p>	
<p><b>21.10 Multi-Site Research</b></p>	
<p>A. In multi-site research, a formal agreement between institutions is provided that specifies the roles and responsibilities of each party</p>	
<p><b>21.11 Compensation</b></p>	
<p>A. Are limitations on dual compensation for US Military personnel addressed?</p>	
<p><b>21.12 Survey Research</b></p>	
<p>A. Are the requirements for additional review for survey research or survey research within DoD addressed?</p>	
<p><b>21.13 International Research (DON Sponsored Research)</b></p>	

<p>A. If the research involves Human Subjects who are not U.S. citizens or Department of Defense personnel, and is conducted outside the United States, and its territories and possessions: (“N/A” if no category applies)</p> <ul style="list-style-type: none"> <li>• The permission of the host country has been obtained.</li> <li>• The laws, customs, and practices of the host country and the United States will be followed.</li> <li>• An ethics review by the host country, or local Naval IRB with host country representation, will take place.</li> </ul>	
<p><b>21.14 DoD Components</b></p>	
<p>A. Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)</p>	

## *2. Informed Consent: Reviewer Checklist*

<b>1. BASIC ELEMENTS OF INFORMED CONSENT (REQUIRED)</b>	<b>Yes / No / N/A</b>
a. A statement that the study involves research.	
b. An explanation of the purposes of the research.	
c. The expected duration of the subject's participation.	
d. A description of the procedures to be followed.	
e. Identification of any procedures which are experimental.	
f. A description of any reasonably foreseeable risks or discomforts to the subject.	
g. A description of any benefits to the subject or to others which may reasonably be expected from the research.	
h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	
i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.	
j. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available, as well as if injury may occur. If so, what they consist of and/or where further information may be obtained.	
k. An explanation of whom to contact for answers to questions about the research.	
l. An explanation of whom to contact for answers to questions about injury.	
m. An explanation of whom to contact concerning rights as a research subject.	
n. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty.	
<b>2. ADDITIONAL ELEMENTS OF INFORMED CONSENT</b>	<b>Yes / No / N/A</b>
a. A statement that the particular treatment or procedure may involve risks to the subject, embryo or fetus, if the subject is or may become pregnant (which is currently unforeseeable).	
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
c. Any additional costs to the subject that may result from participation in the research.	
d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	
f. The approximate number of subjects involved in the study.	
g. The storage and use of research specimens disclosed.	
h. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent.	
i. Is a witness signature required?	
j. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations)	
k. DOD – DON Sponsored research: (Greater than Minimal risk): Has an arrangement for emergency treatment and necessary follow-up of any research-related injuries to subjects been provided?	
l. Explanation on how researchers plan to enter information on <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> .	
<b>3. INFORMED CONSENT PROCESS AND CONTENT</b>	<b>Yes / No / N/A</b>
a. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?	
b. Is the language and presentation of the information to be conveyed appropriate to the subject population?	
c. Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making?	
d. Is it clear who is authorized to obtain informed consent for the study?	
e. Have the informed consent issues for secondary study subjects been addressed?	
f. Will the investigator obtain legally effective informed consent of the participant or the participant's legally authorized representative?	
g. Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate?	
h. Will the circumstances of the consent process minimize the possibility of coercion or undue influence?	
i. Will the individuals communicating information to the participant or the representative during the consent process provide the information in language understandable to the participant or the representative?	

j. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participants' legal rights?	
k. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence?	
l. Are subjects informed to take as much time necessary to read the consent form?	
m. Are subjects informed that they will receive a copy of the consent form?	
n. The consent form contains contact information for a person independent of the research team for the following: <ol style="list-style-type: none"> <li>1. To obtain answers to questions about the research</li> <li>2. In the event the research staff could not be reached</li> <li>3. In the event they wished to talk to someone other than the research staff</li> </ol>	
<b>4. WAIVER OF INFORMED CONSENT DOCUMENTATION</b>	<b>Yes / No / N/A</b>
a. Have the criteria for waiver of informed consent documentation been met? <ol style="list-style-type: none"> <li>1. The consent form would be the only record linking the subject to the research, <u>and</u> a potential risk would be a breach of confidentiality. In such cases, it is up to the subject when asked if they want documentation.</li> <li>2. Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.</li> </ol>	
b. If informed consent documentation is waived, did the investigator be required to provide subjects with a written statement regarding the research?	
c. If children are included, have the criteria for waiver of parental/guardian consent been met? <ol style="list-style-type: none"> <li>1. IRB must determine parental/guardian permission is not a reasonable requirement to protect subjects</li> <li>2. Appropriate mechanisms must be implemented to protect children as subjects</li> </ol>	
<b>5. WAIVER OR MODIFICATION FOR REQUIRED ELEMENTS IN INFORMED CONSENT</b>	<b>Yes / No / N/A</b>



<p>a. If waiver or modification to required consent elements is proposed, have all the criteria been met?</p> <ol style="list-style-type: none"> <li>1. The research involves no more than minimal risk to the subjects.</li> <li>2. The waiver/alteration will not adversely affect the rights and welfare of the subjects.</li> <li>3. The research could not practicably be carried out without the waiver or alteration.</li> <li>4. When appropriate, the subject will be provided with pertinent information after participation.</li> </ol>	
<b>6. ASSENT FROM CHILDREN</b>	<b>Yes / No / N/A</b>
Is assent required? (Assent is required unless the child is not capable – due to age, psychological state, sedation – or the research holds out the prospect of direct benefit that is only available within the context of the research.)	
<b>7. CONSENT FOR CHILDREN UNDER THE JURISDICTION OF DEPENDENCY COURT</b>	<b>Yes / No / N/A</b>
a. Has a court order been obtained to allow the child to participate in the research without parental consent?	
b. Has a court order been obtained to allow the child to participate in the research without parental consent?	
c. Is the research either related to the children’s status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards?	
d. Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis?	
<b>8. PARENTAL PERMISSION</b>	<b>Yes / No / N/A</b>
a. Is consent of one parent appropriate?	
b. Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk, without potential for benefit)	
<b>9. CONSENTING COGNITIVELY IMPAIRED PERSONS</b>	<b>Yes / No / N/A</b>
a. Does the research involve greater than minimal risk?	
b. If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual subjects?	
c. Are the risks to subjects reasonable in relation to anticipated benefits, and to the importance of the knowledge that may reasonably be expected to result?	
d. Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?	

<p>e. Are there adequate provisions for soliciting the assent of the subject and permission from their legally authorized representative?</p>	
<p><b>10. WAIVER OF INFORMED CONSENT FOR EMERGENCY RESEARCH</b></p>	<p><b>Yes / No / N/A</b></p>
<p>b. Have the criteria for waiver of informed consent for emergency research been met?</p> <ol style="list-style-type: none"> <li>1. The subject must be confronted by a life-threatening situation necessitating the use of the test article.</li> <li>2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject.</li> <li>3. Time is not sufficient to obtain consent from the subject's legal representative.</li> <li>4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.</li> </ol>	
<p><b>11. WAIVER OF INFORMED CONSENT FOR PLANNED EMERGENCY ROOM RESEARCH</b></p>	<p><b>Yes / No / N/A</b></p>
<p>a. Have the criteria for waiver of informed consent for planned emergency room research been met?</p> <ol style="list-style-type: none"> <li>1. The study could not practicably be carried out without the waiver.</li> <li>2. Consultation with community representatives occurs before the start of the research.</li> <li>3. Public disclosure is made before and after the study starts.</li> <li>4. A therapeutic window is defined and the researcher commits to trying to locate a surrogate/legally authorized representative who can give consent within the window before proceeding to waive consent.</li> </ol>	

### **3. Continuing Review Applications: Reviewer Checklist**

<b>1. CONTINUING REVIEW APPLICATION SUBMISSION</b>	<b>Yes / No / N/A</b>
a. Are all consent forms included with the application?	
b. Is an adequate protocol summary provided?	
c. Is an adequate status report on the study's progress provided?	
d. Are any significant new findings and/or interim reports provided?	
e. If yes, is there any significant info that may change a subject's willingness to participate?	
f. Is the continuing review being submitted in a timely manner?	
<b>2. PROTOCOL CHANGES &amp; AMENDMENTS</b>	<b>Yes / No / N/A</b>
a. Has the protocol changed since the last IRB Review?	
b. If yes, have all changes been documented and approved by the IRB?	
c. Is the PI requesting new changes as part of this submission?	
d. If yes, do the requested changes alter the risk/benefit ratio of the subjects?	
e. Are the requested changes updated in all appropriate study materials and included for review?	
<b>3. PROTOCOL DEVIATION &amp; EXCEPTIONS</b>	<b>Yes / No / N/A</b>
a. Has the PI submitted any new deviations or exceptions since the last IRB review?	
b. If yes, do the reported deviations/exceptions alter the risk/benefit ratio?	
c. Are any protocol changes required or recommended to prevent similar events in the future?	
d. If yes, are all the appropriate study materials updated and included for review?	

<b>4. SERIOUS ADVERSE EVENTS (SAE) &amp; UNANTICIPATED PROBLEMS</b>	<b>Yes / No / N/A</b>
a. Have there been any SAEs and/or unanticipated problems reported since the last continuing review?	
b. If yes, have all SAE/unanticipated problems been reviewed by the IRB?	
c. Do any of these events alter the risk/benefit ratio?	
d. Should other subjects be informed of the events and/or change to risk/benefit ratio?	
e. Should the consent or protocol be amended to include new information resulting from these events?	
<b>5. SUBJECT ENROLLMENT</b>	<b>Yes / No / N/A</b>
a. What is the target number of subjects to be enrolled?	
b. How many subjects are currently enrolled?	
c. Is the enrollment rate as planned reasonable to meet the goals of the study?	
d. If enrollment is notably slow, is adequate justification/explanation provided to continue with the study?	
e. Is there a notable rate of subject withdrawals?	
<b>6. INFORMED CONSENT/ASSENT</b>	<b>Yes / No / N/A</b>
a. Overall, is consent/assent written in a language easily understandable to the subject and/or guardian, and void of any exculpatory language?	
b. If consent has not been translated, should it be?	
<b>7. BASIC REQUIRED ELEMENTS OF INFORMED CONSENT</b>	<b>Yes / No / N/A</b>
a. A statement that the study involves research.	
b. An explanation of the purposes of the research.	
c. The expected duration of the subject's participation.	
d. A description of the procedures to be followed.	
e. Identification of any procedures which are experimental.	
f. A description of any reasonably foreseeable risks or discomforts to the subject.	
g. A description of any benefits to the subject or to others which may reasonably be expected from the research.	
h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	

i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.	
j. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available, as well as if injury may occur. If so, what they consist of and/or where further information may be obtained.	
k. An explanation of whom to contact for answers to questions about the research.	
l. An explanation of whom to contact for answers to questions about injury.	
m. An explanation of whom to contact concerning rights as a research subject.	
n. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty.	
<b>8. IF APPLICABLE TO STUDY, ADDITIONAL ELEMENTS OF INFORMED CONSENT</b>	<b>Yes / No / N/A</b>
a. A statement that the particular treatment or procedure may involve risks to the subject, embryo or fetus, if the subject is or may become pregnant (which is currently unforeseeable).	
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
c. Any additional costs to the subject that may result from participation in the research.	
d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	
e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	
f. The approximate number of subjects involved in the study.	
g. The storage and use of research specimens disclosed.	
h. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent.	

i. Is a witness signature required?	
j. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations).	
k. DOD – DON Sponsored research: (Greater than Minimal risk): Has an arrangement for emergency treatment and necessary follow-up of any research-related injuries to subjects been provided.	
l. Explanation on how researchers plan to enter study information on <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> .	
m. The consent form contains contact information for a person independent of the research team for the following: <ol style="list-style-type: none"> <li>1. To obtain answers to questions about the research.</li> <li>2. In the event the research staff could not be reached.</li> <li>3. In the event they wished to talk to someone other than the research staff.</li> </ol>	
<b>9. REVIEW CONSIDERATIONS</b>	<b>Yes / No / N/A</b>
a. Do risks continue to be minimized and reasonable in relation to the benefits & knowledge to be gained?	
b. Do study procedures ensuring safeguards for vulnerable subjects continue to be adequate?	
c. Do study procedures ensuring subject confidentiality continue to be adequate?	
d. Were any subject complaints documented for this study and if so, do they raise concerns?	
e. Were any outside reports submitted: monitoring reports, multi-site reports, FDA, or DSM reports?	
f. If yes, were there any notable observations or concerns that should be raised to the committee?	
g. If there is a Data Safety Monitoring Plan, is the study adequately following the approved plan?	
h. Has the source of funding changed?	
i. If yes, are there any new conflicts of interests?	
j. Should the protocol be reviewed more frequently than once per year?	
k. If this is a multi-center trial in which USC is the coordinating site, has there been evidence of communication among sites?	

<b>10. ASSENT FROM CHILDREN</b>	<b>Yes / No / N/A</b>
a. Is assent required? (Assent is required unless the child is not capable (i.e. due to age, psychological state, sedation), or the research holds out the prospect of direct benefit that is only available within the context of the research).	
b. Is assent currently being obtained?	
<b>11. PARENTAL PERMISSION</b>	<b>Yes / No / N/A</b>
a. Is consent of one parent appropriate?	
b. Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk, without potential for benefit).	
c. Is parental permission currently being obtained?	
<b>12. USE OF THE SHORT FORM</b>	<b>Yes / No / N/A</b>
a. Did the PI report the use of the short form?	
b. If yes, did the PI report if a witness was present during the oral presentation?	
c. If yes, did the PI report if the witness was conversant in both English and the native language of the subject?	

#### 4. Research Involving Children: Reviewer Checklist (Subpart D)

	Yes / No / N/A
<p>1. [Category 1, 45 CFR 46.404] The IRB finds that <b><u>no greater than minimal risk</u></b> to children is presented. The children are capable of providing assent and adequate provisions are made to do so.</p>	
<ul style="list-style-type: none"> <li>• When the capability of some or all of the children is so limited that they cannot reasonably be consulted, or the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.</li> </ul>	
<ul style="list-style-type: none"> <li>• The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been provided in the application.</li> </ul>	
<ul style="list-style-type: none"> <li>• Adequate provisions are made for soliciting the permission of each child's parents or guardian. The permission of one parent is required.</li> </ul>	
<ul style="list-style-type: none"> <li>• Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. The permission of one parent is required.</li> </ul>	
<ul style="list-style-type: none"> <li>• The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is consistent with Federal, State, or local law.</li> </ul>	
<ul style="list-style-type: none"> <li>• The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. However, an appropriate mechanism for protecting the children who will participate as subjects in the research has not been provided.</li> </ul>	
<p>2. [Category 2, 45 CFR 46.405] The IRB finds that <b><u>more than minimal risk</u></b> to children is presented by an intervention or procedure that <b><u>holds out the prospect of direct benefit</u></b> for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being. The IRB finds that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.</p>	
<ul style="list-style-type: none"> <li>• The children are capable of providing assent and adequate provisions are made for soliciting the assent of the children.</li> </ul>	



<ul style="list-style-type: none"> <li>When the capability of some or all of the children is so limited that they cannot reasonably be consulted or the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.</li> </ul>	
<ul style="list-style-type: none"> <li>The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been provided in the application.</li> </ul>	
<ul style="list-style-type: none"> <li>Adequate provisions are made for soliciting the permission of each child's parents or guardian. The permission of one parent is required.</li> </ul>	
<ul style="list-style-type: none"> <li>Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. The permission of one parent is required.</li> </ul>	
<ul style="list-style-type: none"> <li>The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is consistent with Federal, State, or local law.</li> </ul>	
<ul style="list-style-type: none"> <li>The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. However, an appropriate mechanism for protecting the children who will participate as subjects in the research has not been provided.</li> </ul>	
<p>3. [Category 3, 45 CFR 46.406] The IRB finds that <b><u>more than minimal risk</u></b> to children is presented by an intervention or procedure that <b><u>does not hold out the prospect of direct benefit</u></b> for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject. However the IRB finds that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.</p>	
<ul style="list-style-type: none"> <li>The children are capable of providing assent and adequate provisions are made for soliciting the assent of the children.</li> </ul>	
<ul style="list-style-type: none"> <li>The capability of some or all of the children is so limited that they cannot reasonably be consulted; the assent of the children is not a necessary condition for proceeding with the research.</li> </ul>	
<ul style="list-style-type: none"> <li>The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been</li> </ul>	

provided in the application.	
<ul style="list-style-type: none"> <li>• Adequate provisions are made for soliciting the permission of each child's parents or guardian. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.</li> </ul>	
<ul style="list-style-type: none"> <li>• Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.</li> </ul>	

<p>4. <b>[Category 4, 45 CFR 46.407] <u>Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.</u></b> DHHS will conduct or fund research that the IRB does not believe meets the above requirements only if: (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) that the research in fact satisfies the conditions of 45 CFR §46.404, §46.405, or §46.406, as applicable, or (2) the following: (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.</p>	
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<b>ADDITIONAL CONSIDERATIONS FOR RESEARCH IN SCHOOL SETTINGS</b>
<b>California education code 51513</b>
No test, questionnaire, survey, or examination containing any questions about the pupil's beliefs or practices in sex, family life, morality, and religion, or any questions about the pupil's parents' or guardians' beliefs and practices in sex, family life, morality, and religion, shall be administered to any pupil in kindergarten or grades 1 to 12, inclusive, unless the parent or guardian of the pupil is notified in writing that this test, questionnaire, survey or examination is to be administered and the parent or guardian gives written permission for the pupil to take this test, questionnaire, survey or examination.
<b>Family Educational Rights and Privacy Act (FERPA)</b>
The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.
FERPA gives parents certain rights with respect to their children's education records. These rights transfer to

the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.

Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information.

Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):

- School officials with legitimate educational interest;
- Other schools to which a student is transferring;
- Specified officials for audit or evaluation purposes;
- Appropriate parties in connection with financial aid to a student;
- Organizations conducting certain studies for or on behalf of the school;
- Accrediting organizations;
- To comply with a judicial order or lawfully issued subpoena;
- Appropriate officials in cases of health and safety emergencies; and
- State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

### **Protection of Pupil Rights Amendment (PPRA)**

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students in two ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and
- It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:
  - Political affiliations;
  - Mental and psychological problems potentially embarrassing to the student and his/her family;
  - Sex behavior and attitudes;
  - Illegal, anti-social, self-incriminating and demeaning behavior;
  - Critical appraisals of other individuals with whom respondents have close family relationships;
  - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
  - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Parents or students who believe their rights under PPRA may have been violated may file a complaint with ED by writing the Family Policy Compliance Office. Complaints must contain specific allegations of fact giving reasonable cause to believe that a violation of PPRA occurred.

## ***5. Research Involving Pregnant Women, Human Fetuses, and Neonates: Reviewer Checklist (Subpart B)***

**Research involving pregnant women, human fetuses, and neonates is governed by 45 CFR 46 Subpart B. Please refer to the following definitions, as defined by this subpart of the federal regulations.**

- (1) Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (UPIRB defers this research to the HSIRB)
- (2) Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means
- (3) Fetus: the product of conception from implantation until delivery
- (4) Neonate: a newborn
- (5) Nonviable Neonate: a neonate after delivery that, although living, is not viable (UPIRB defers this research to HSIRB)
- (6) Viable: as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D.
- (7) Pregnancy: encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

### **SUMMARY OF FINDINGS AND RECOMMENDATIONS**

<b>A. Research involving pregnant women or fetuses (46.204)</b>	<b>Yes / No / N/A</b>
1. When appropriate, has this type of study been done on animals and non-pregnant individuals?	
2. The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman or the fetus.	
3. There is no prospect of direct benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be maintained by any other means.	
4. If you answered 'yes' for either question 2 or 3, consent will be obtained in accordance with the federal regulations and USC's policies.	
5. Are all risks the least possible for achieving the objectives of the research?	
6. If the research holds out the prospect of direct benefit solely to the fetus, has the PI assured that consent will be obtained from the pregnant woman and the father in accordance with the federal regulations (Consent from the father is required unless	

(a) he is unable to consent because of unavailability, incompetence, or temporary incapacity, or (b) the pregnancy resulted from rape or incest)?	
7. Has the PI assured that each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus?	
8. Has the PI assured that for children as defined in Section 46.402 (a) who are pregnant, assent and permission will be obtained in accord with the provisions of 45 CFR 46 Subpart D?	
9. Has the PI assured that no inducements, monetary or otherwise, will be offered to terminate the pregnancy?	
10. Has the PI assured that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy?	
11. Has the PI assured that individuals engaged in the research will have no part in determining the viability of the neonate?	
<b>B. Research involving neonates (46.205).</b>	<b>Yes / No / N/A</b>
<p><b><u>Viable neonates:</u></b> A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirements of 45 CFR 46 Subparts A and D.</p> <p><b><u>Nonviable neonate:</u></b> means a neonate after delivery that, although living, is not viable</p>	
Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met: <i>{45 CFR 46.205 (a)}</i>	
1. Where scientifically appropriate, have preclinical and clinical studies been conducted to provide data for assessing potential risks to neonates?	
2. Has each individual who is providing consent been fully informed regarding the reasonably foreseeable impact of the research on the neonate?	
3. Will individuals engaged in the research have a part in determining the viability of a neonate?	
Neonates of uncertain viability: Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met: <i>{45 CFR 46. 205 (b)}</i>	
1. Does the research hold out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective?	
2. Is the purpose of the research the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research?	
3. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the	

legally effective informed consent of either parent's legally authorized representative is obtained except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.	
Nonviable neonates: After delivery nonviable neonate may not be involved in research unless all of the following additional conditions are met: <i>{45 CFR 46. 205 (c)}</i>	
1. The vital functions of the neonate will not be artificially maintained.	
2. The research will not terminate the heartbeat or respiration of the neonate.	
3. There will be no added risk to the neonate resulting from the research.	
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.	
5. The legally effective informed consent of both parents of the neonate is obtained. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements.	
<b>C. Research involving, after delivery, the placenta, the dead fetus or fetal material (46.206).</b>	<b>Yes / No / N/A</b>
1. Is the research involving the above mentioned materials conducted in accordance with all applicable Federal, State, or local laws regarding such activities?	
2. Is information associated with the material described above recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals (if yes, those individuals are research participants and all pertinent subparts of 45 CFR 46 are applicable)?	
<b>D. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates (46.207).</b>	<b>Yes / No / N/A</b>
The Secretary needs to review this research.	
1. Does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates?	
2. The Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, including a public meeting	

announced in the **Federal Register**, must determine that either:

- a. The research does satisfy the conditions of Section 46.204.
- b. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; the research will be conducted with sound ethical principles; and informed consent will be obtained in accordance with the informed consent provisions of subpart A and other applicable subparts.



## **6. Research Involving Prisoners: Reviewer Checklist (Subpart C)**

<b>SUMMARY OF FINDINGS AND RECOMMENDATIONS</b>	<b>Yes / No / N/A</b>
1. Do you have any association with the involved prisoners which might be viewed as a conflict of interest?	
2. Are there any possible advantages to the prisoner through his/her participation in the research, when compared with the general living conditions, medical care, quality of food, amenities and opportunity for earning in the prison, that are of such a magnitude that the potential participant's ability to weigh the risks of the research against the value of such advantages is impaired?	
3. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers?	
4. Are the procedures for selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? (Unless there is written justification, the control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project).	
5. Is the information in the consent form presented in language which is understandable to the participants?	
6. Is there assurance that court system/judicial system will not take into account a prisoner's participation in research in making decisions regarding the legal case?	
7. Is the prisoner informed in advance that participation in the research will have no effect on his/her legal case?	
8. Is there a need for follow up examination or care of participants after the end of their participation?	
9. If yes to question #8, has adequate provision been made for such examination or care, taking into account the varying lengths of prisoners' sentences and for informing participants of that fact?	

10. Types of research permitted involving prisoners (please check one below or check “none apply”):

- A. Study of the possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants (\*).
  - B. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants (\*).
  - C. Research on conditions particularly affecting prisoners as a class (for example vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.
  - D. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary of DHSS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.
- None Apply

\* Definition of Minimal Risk in prisoners: Risk of physical or psychological harm that is no greater in the probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons [45 CFR 46.303(d)].

Definition of a prisoner: An individual involuntarily confined in a penal institution, including persons (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

# APPENDIX C iStar Application Questions

Below is a listing of the questions asked in the new study/grant application.

01. Project Identification and Abstract
02. Study Personnel
02a. Collaborators from other institutions
03. Required Department Approvals
04. Type of Study Review
05. Study Location(s)
06a. HSC Location(s)
06b. UPC Location(s)
06c. Other Sites/Institutions
08. Funding Information
08b. Department of Defense Funded Research
09. Methods and Procedures - Selected Descriptors
10. Characteristics of the Study Subject Population
11. Research Objectives and Background
12. Methods and Procedures - Prospective Studies
13. Methods and Procedures - Retrospective Studies/Existing Data
14. Methods and Procedures - Biohazardous Substances
15. Methods and Procedures - Creation of a Data or Tissue Repository
15b. Methods and Procedures - Submission of Data or Tissue to an Existing Repository
16. Methods and Procedures - Deception

17. Methods and Procedures - Drug and Biologic Information
18. Methods and Procedures - Device Information
19. Methods and Procedures - Interview/Focus Groups
20. Methods and Procedures - Psychophysiological Testing
21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing
22. Special Subject Populations
22a. Special Subject Populations - Normal Volunteers
22b. Special Subject Populations - Employees/Students
22c. Special Subject Populations - Adults Not Competent To Consent
22d. Special Subject Populations - Non-English Speaking Subjects
22e. Special Subject Populations - Minors (VIEW000635)
22f. Special Subject Populations - Pregnant Women/Human Fetuses
22g. Special Subject Populations - Neonates
22h. Special Subject Populations - Wards
22i. Special Subject Populations - Prisoners/Detainees
23. Study Resources
24. Subject Recruitment and Informed Consent
24A. Assent
24P. Parental Permission
25. Financial Obligation and Compensation
26. Participant Privacy and Data Confidentiality
27. Risk/Benefit Assessment - Risks
28. Risk/Benefit Analysis - Potential Benefits and Alternatives
28a. Incidental Findings (VIEW4722D62E2E400)

35. Is the HIPAA Privacy Rule Applicable?
36. HIPAA Analysis
37. Decedent Research
38. Partial Waiver of HIPAA Authorization
38b. Full Waiver of HIPAA Authorization
39. Conflict of Interest Information
40. Additional Supporting Documents

For more information, visit <http://istar-chla.usc.edu>, click “Training Resources,” and then “Study Application” (under the Applications and Guidance section).

# APPENDIX D IRB Forms and Templates

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## PERMISSION LETTER – EXAMPLE

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When site permission is required by USC, the following form should be used:

Dear IRB Chair:

This letter is to convey that I have reviewed the proposed research study entitled “XXXXXXXXXXXX” being conducted by XXXX from the University of Southern California. I understand that research activities as described in the proposed research study will occur at XXXX Elementary School. I give permission for the above investigator(s) to conduct their study at this site. If you have any questions regarding this permission letter, please contact me at (XXX) XXX-XXXX.

Sincerely,

XXXXXX, Principal  
XXXXX Elementary  
1234 XXXX Blvd  
Los Angeles, CA 90089

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## CHILD ASSENT FOR NON-MEDICAL RESEARCH - EXAMPLE

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(version 3/8/13)

University of Southern California

(Insert Department Name & Address)

<b>ASSENT FORM TO PARTICIPATE IN RESEARCH</b>
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(Note: **PLEASE USE SECOND PERSON, SINGLE-SIDED, SINGLE-SPACED. DELETE INSTRUCTIONS IN BOLD PRIOR TO SUBMITTING THIS DOCUMENT**)

(INSERT TITLE OF THE STUDY)

(Insert PI name) wants to learn about (insert study description in language easy for the youngest child to understand). One way to learn about it is to do a research study; the people doing the study are called researchers.

Your mom/dad/Legally Authorized Representative (LAR) have told us we can talk to you about the study. You also can talk this over with your mom or dad. It's up to you if you want to take part, you can say "yes" or "no". No one will be upset with you if you don't want to take part.

If you do want to take part, you will be asked to (give a brief description of the study procedures, If audio or video-recording will take place or if photographs will be taken, let the child know; state whether the child can still participate if s/he does not want to be recorded or photographed).

Researchers don't always know what will happen to people in a research study. We don't expect anything to happen to you, but you might not like (Describe any risks, if any, to the subject. Note payment is not a benefit)

Your answers will not be graded (remove if not applicable). Only the researchers will see your answers.

If you have any questions, you can ask the researchers.

If you want to take part in the study, please write and then sign your name at the bottom. You can change your mind if you want to, just tell the researchers.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person consenting

Signature of person consenting

Date

---

## INFORMATION SHEET FOR EXEMPT RESEARCH - EXAMPLE

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Information sheets may be used in lieu of consent when the IRB waives documentation of consent, the study qualifies for exemption, when conducting online research, or other scenarios.

(version 3/8/13)

University of Southern California

(Insert Department Name and Address)

### INFORMATION/FACTS SHEET FOR EXEMPT NON-MEDICAL RESEARCH

(Note: PLEASE USE SECOND PERSON, SINGLE-SIDED, SINGLE-SPACED. DELETE INSTRUCTIONS IN BOLD PRIOR TO SUBMITTING THIS DOCUMENT FOR THE UPIRB'S REVIEW.)

- **This model is flexible based on the type of research.**
- **Use language and simple sentences understandable to the average 8<sup>th</sup> - grader. If subjects don't understand the study or procedures, they may not agree to participate.**
- **Instructions are provided below in bold, with example wording.**
- **Delete the instructions and, where applicable, the examples. Revise the document to be consistent with your study/procedures.**

(INSERT TITLE OF THE STUDY)

You are invited to participate in a research study. Research studies include only people who voluntarily choose to take part. This document explains information about this study. You should ask questions about anything that is unclear to you.

#### **PURPOSE OF THE STUDY**

**(Provide an overall summary with one paragraph describing what the study is, if there is any benefit from knowledge gained, and why it is being conducted)**

#### **EXAMPLES:**

**Example: This research study aims to understand how advertising affects your purchases.**

#### **PARTICIPANT INVOLVEMENT**

**(Describe what participants will be asked to do and provide enough detail for the participant to understand. Indicate the study procedures; how long each procedure will take along with their total length of participation. If audio/video-recording will be used, indicate whether participants can decline to be recorded and continue with their participation)**

#### **EXAMPLES:**



**Example: If you agree to take part in this study, you will be asked to complete an online survey which is anticipated to take about 5 minutes. You do not have to answer any questions you don't want to, click "next" or "N/A" in the survey to move to the next question.**

**Example: If you agree to take part in this study, you will be asked to participate in a 30 minute audio-taped interview. You do not have to answer any questions you don't want to; if you don't want to be taped, handwritten notes will be taken.**

**Example: If you agree to take part in this study, you will be asked to participate in a 5 minute survey and a 30 minute audio-taped interview. You do not have to answer any questions you don't want to; if you don't want to be taped, you cannot participate in this study.**

### **PAYMENT/COMPENSATION FOR PARTICIPATION**

**(If applicable, describe payment amount. Indicate how payment will be made cash, gift card, etc.; when payment will be given and by whom. If there is no payment, please remove this section)**

#### **EXAMPLES:**

**Example: You will receive \$10 visa gift card for your time. You do not have to answer all of the questions in order to receive the card. The card will be given to you when you return the questionnaire.**

**Example: You will be entered into a drawing for an iPod. The drawing will be held at the end of the study and the winner notified via email.**

**Example: You will receive one credit for participating in the study; the credit will be issued at the end of your participation, per the subject pool guidelines.**

**Example: You will not be compensated for your participation; however parking will be provided for you.**

### **ALTERNATIVES TO PARTICIPATION**

**(If subjects are employees, students, consumers/patients, please include their alternative. If the alternative is to not participate, remove this section)**

#### **EXAMPLES:**

**Example: If you joined the student subject pool, your alternative may be to participate in another study or to write a paper, please contact the Subject Pool Coordinator for further information.**

**Example: Your alternative is to not participate. Your relationship with your employer will not be affected whether you participate or not in this study.**

### **CONFIDENTIALITY**

(Explain how information will or will not be kept confidential. [If taping will take place, describe the participant's right to review/edit the audio/video-recordings or transcripts, who will have access (including transcribers). Describe how personal identities will be shielded/disguised and, if/when the audio/video-recordings will be erased (approximately). If the audio/video-recordings will be maintained indefinitely, state how confidentiality will be maintained. If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure.)

(Indicate how long the data will be kept. The data may be kept indefinitely; subjects should be informed of the maximum length of data storage.)

**EXAMPLES:**

**Example:** There will be no identifiable information obtained in connection with this study. Your name, address or other identifiable information will not be collected.

**Example:** Any identifiable information obtained in connection with this study will remain confidential. Your responses will be coded with a false name (pseudonym) and maintained separately. The audio-tapes will be destroyed once they have been transcribed.

**Example:** The data will be stored on a password protected computer in the researcher's office for three years after the study has been completed and then destroyed.

**Required language:**

The members of the research team, **the funding agency** and the University of Southern California's Human Subjects Protection Program (HSPP) may access the data. The HSPP reviews and monitors research studies to protect the rights and welfare of research subjects.

When the results of the research are published or discussed in conferences, no identifiable information will be used. **(Remove this statement if the data are anonymous)**

**INVESTIGATOR CONTACT INFORMATION**

**(Provide contact information for investigators)**

**EXAMPLES:**

**Example:** Principal Investigator Tommy Trojan via email at [ttrojan@usc.edu](mailto:ttrojan@usc.edu) or phone at (213) 555-1212 or Faculty Advisor Jane Traveler at [traveler@usc.edu](mailto:traveler@usc.edu) or (213) 555-1234

**IRB CONTACT INFORMATION**

University Park Institutional Review Board (UPIRB), 3720 South Flower Street #301, Los Angeles, CA 90089-0702, (213) 821-5272 or [upirb@usc.edu](mailto:upirb@usc.edu)

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## **INFORMED CONSENT FOR NON-MEDICAL RESEARCH EXAMPLE**

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Informed Consent forms provide subjects with a written source of information for future reference and document that the process of informed consent occurred prior to the subject's participation. The form generally serves as a basis for the initial presentation of the study to the potential subject.

(version 3/8/13)

University of Southern California  
(Insert Department Name and Address)

<b>INFORMED CONSENT FOR NON-MEDICAL RESEARCH</b>
--

*(Note: PLEASE USE SECOND PERSON, SINGLE-SIDED, SINGLE-SPACED. DELETE INSTRUCTIONS IN BOLD PRIOR TO SUBMITTING THIS DOCUMENT)*

- **This template is NOT for studies utilizing the Dornsife Cognitive Neuroscience Imaging Center.**
- **Be consistent throughout the document, use simple language and be concise.**
- **If the study involves using multiple consent forms for different populations, subtitle the consent with that population's name; for example: Teachers, Parents, Caregiver, etc.**
- **Use the pronoun "you" consistently throughout (except for the "Signature of Research Participant" on the last page.**
- **The consent document should be revised to be consistent with your application, please remove the instructions/examples as appropriate.**

**(INSERT TITLE OF THE STUDY)**

You are invited to participate in a research study conducted by **(insert names and degrees of principal investigator (including faculty advisor))** at the University of Southern California, because you are **(insert eligibility criteria)**. This study is funded by **(insert funding agency here/remove as applicable)**. Your participation is voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether to participate. Please take as much time as you need to read the consent form. You may also decide to discuss participation with your family or friends. If you decide to participate, you will be asked to sign this form. You will be given a copy of this form.

### **PURPOSE OF THE STUDY**

**(State what the study is designed to assess or establish. Technical or complicated language should be avoided. Participants should be able to easily understand the purpose of the study and that it is research.)**

### **STUDY PROCEDURES**

If you volunteer to participate in this study, you will be asked to **(Describe the procedures in the order they will be administered or experienced using simple language, short sentences and short paragraphs. If several procedures will be used, the use of subheadings may help to organize this section and increase readability. If scientific terms need to be used, they should be defined and explained. If experimental procedures will be used, they should be identified as**

such. If survey or questionnaire instrument(s) are used, briefly describe the types of questions asked. If applicable to the study, clearly state participants will be photographed and/or audio/video-recorded. Clarify if the participant can still participate in this research study if they do not wish to be audio/video-recorded or photographed.)

(If applicable, specify the participant's assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location where the procedures will be take place, etc. For research involving randomization, specify the randomization procedure, for example, "you will be assigned randomly, much like tossing a coin, into.....)

### **POTENTIAL RISKS AND DISCOMFORTS**

(Describe any reasonable foreseeable risks, discomforts, inconveniences, including physiological risks/discomforts; describe any psychological, social, legal or financial risks to the participant, and how these will be minimized. If there are no anticipated risks, state so.)

### **POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY**

(Describe direct benefits from participating in the study. Also, state the anticipated benefit to society. If there are no anticipated benefits to the participant, state so. Note that as this is a research study, the benefits are contingent upon the results. The investigator can state only that benefits are anticipated, not that they will occur. If there are no direct benefits to participants, there should be anticipated benefits to society.)

### **PAYMENT/COMPENSATION FOR PARTICIPATION**

(State whether the participant will receive payment/compensation or any other form of compensation, e.g. small gift, course credit, etc. If not, state clearly, "You will not be paid for participating in this research study" or remove the section. If participants receive payment, describe amount, when payment is scheduled, and pro-rated schedule should the participant decide to withdraw or is withdrawn by the investigator. If participants are reimbursed for expenses such as parking, bus/taxi, travel companion/assistant, etc., list payment.)

### **POTENTIAL CONFLICTS OF INTEREST OF THE INVESTIGATOR**

(A "Conflict of Interest (COI)" is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. If there appears to be a conflict of interest (COI) or there is a COI, include this section. Delete this section if there are no conflicts of interest.)

1. The investigator must disclose all financial or other personal considerations that compromise, or have the appearance of compromising, the investigator's professional judgment in proposing, conducting, supervising, or reporting research. Conflicts include financial as well as non-financial interests. Conflicts include financial interests (stocks, stock options, or other ownership interests, whether traded publicly or not) in a research sponsor or licensee; management roles in a research sponsor, licensee, or other company having an economic interest in the outcome of the research; and using students to perform services in which an investigator maintains an ownership interest or management role.

2. In disclosing your proprietary interest and research interest in the informed consent, you may do so in general terms, in a manner consistent with IRB requirements. At a minimum, you must disclose the nature of the interest, such as a paid consultant, a lecturer, a board member, an equity ownership, or a management or supervisory role in the sponsoring company. Such conflicts should also be disclosed to the Vice President of Research for resolution. The proposed informed consent language must be reviewed by the IRB, and if necessary, by the USC Conflict of Interest Review Committee (CIRC).
3. For more information go to: USC Office of Compliance Step by Step Guide to Conflict of Interest Disclosure: <http://ooc.usc.edu/step-step-guide-disclosure>

**Example 1:** If there may be commercial product development in the future, the following statement can be used: The University of Southern California or the biotechnology company \_\_\_\_\_ (insert company name) may use your \_\_\_\_\_ (insert type of samples) for other research studies. Those studies may develop products that can be sold. If they make money from these products, you will not receive any money.

**Example 2:** If you have a financial interest in the sponsoring company, the following statement should be used.

The investigator has a financial interest in the company sponsoring this study. (Briefly describe your financial interest.) The nature of this financial interest and the design of the study have been approved and allowed by the institutional committees.

### **CONFIDENTIALITY**

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The members of the research team, the funding agency and the University of Southern California's Human Subjects Protection Program (HSPP) may access the data. The HSPP reviews and monitors research studies to protect the rights and welfare of research subjects. **(remove references to funding agency if not applicable)**

The data will be stored (state where and how the research data will be stored). [If applicable to the study, describe the participant's right to review/edit the audio/video-recordings or transcripts, who will have access (including transcribers), if the audio/video-recordings will be used for educational purposes, describe how personal identities will be shielded/disguised and, if/when the audio/video-recordings will be erased (approximately). If the audio/video-recordings will be maintained indefinitely, state how confidentiality will be maintained. If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure. Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel (list the personnel who have access).

[Indicate how long the data will be kept. Please note that data must be kept for a minimum of three years after the completion of the study. The data may be kept indefinitely.]

### **CERTIFICATE OF CONFIDENTIALITY**

**(If a Certificate of Confidentiality is issued (or anticipated to be issued), please use the following language, otherwise remove)**

Any identifiable information obtained in connection with this study will remain confidential, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care). A Certificate of Confidentiality has been obtained from the Federal Government for this study to help protect your privacy. This certificate means that the researchers can resist the release of information about your participation to people who are not connected with the study, including courts. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others.

When the results of the research are published or discussed in conferences, no identifiable information will be used.

### **PARTICIPATION AND WITHDRAWAL**

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. **(If appropriate, describe the anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent.)**

### **ALTERNATIVES TO PARTICIPATION**

**(Please describe and explain the procedures that will be employed to provide alternate yet equal activities for those who wish not to participate.)**

**Example: If you joined the student subject pool, your alternative may be to participate in another study or to write a paper, please contact the Subject Pool Coordinator for further information.**

**EMERGENCY CARE AND COMPENSATION FOR INJURY (For greater than minimal risk studies, include the "Emergency Care and Compensation" section which provides evening/emergency phone numbers.)**

If you are injured as a direct result of research procedures you will receive medical treatment; however, you or your insurance will be responsible for the cost. The University of Southern California does not provide any monetary compensation for injury.

### **INVESTIGATOR'S CONTACT INFORMATION**

If you have any questions or concerns about the research, please feel free to contact **(identify research personnel: Principal Investigator, Faculty Sponsor (if student is the Co-P.I.), and Co-Investigator(s)). Include day phone numbers, email addresses, and school/business addresses for all listed individuals. (DO NOT INCLUDE HOME ADDRESSES FOR YOUR PERSONAL SAFETY).**

**RIGHTS OF RESEARCH PARTICIPANT – IRB CONTACT INFORMATION**

If you have questions, concerns, or complaints about your rights as a research participant or the research in general and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the University Park Institutional Review Board (UPIRB), 3720 South Flower Street #301, Los Angeles, CA 90089-0702, (213) 821-5272 or [upirb@usc.edu](mailto:upirb@usc.edu)

**SIGNATURE OF RESEARCH PARTICIPANT**

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

**AUDIO/VIDEO/PHOTOGRAPHS** (If this is not applicable to your study and/or if participants do not have a choice of being audio/video-recorded or photographed, delete this section.)

- I agree to be audio/video-recorded /photographed (remove the media not being used)*
- I do not want to be audio/video-recorded /photographed (remove the media not being used)*

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

**SIGNATURE OF INVESTIGATOR**

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

\_\_\_\_\_  
Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

# APPENDIX E IRB Minutes: A Sample

## MEETING MINUTES

Friday, XX/XX/2012

**Credit Union Building (CUB) 3<sup>rd</sup> Floor,**

10:00 a.m. – 12:00 p.m.

Meeting Start Time: 10:25am

**Meeting End Time: 11:31am**

Meeting Chaired by: XXXXXXXXX, Ph.D., Chair of UPIRB

Minutes Prepared by: XXXXXXXXXXXXX, IRB Program Specialist, UPIRB

XXXXXXXXXX, M.A. Psy., IRB Program Specialist, UPIRB

### **Members in Attendance:**

XXXXXXXXXXXX, M.D.

XXXXXX, PsyD., (Community Member)

XXXXXXXX, Ph.D.

XXXXXXXXXXXX, Ph.D.

XXXXXXXXXX, MSW (Non-Scientific, Community Member)

XXXXXX, Ph.D.

XXXXXXXXXXXX, IRB Student Mentor (Non-Scientific, Affiliated Member)

XXXXXXXXXXXX, Ph.D.

### **Alternates in Attendance:**

XXXXXXXX, B.Sc., CIP (Alternate for XXXXXXX, MPH, CIP)

8 members were present, a quorum was maintained throughout the meeting and alternate members were not needed.

Community members were present during all study discussions and votes.

### **Members Absent:**

XXXXXXXX, M.P.H. CIP (Non-Scientific, Affiliated Member)

XXXXXXXX, Ph.D.

### **Alternates Members Absent:**

XXXXXXXXXXXX, M.D.

XXXXXX, Ph.D.

### **Non-members in Attendance:**

XXXXXXXX, OPRS, Program Administrator

XXXXXXXXXXXX, IRB Program Specialist, UPIRB

XXXXXXXX, Ph.D., Executive Director, OPRS.



XXXXXXXXXX, IRB Administrative Assistant, UPIRB

Statement read to members:

Dr. XXXX discussed the member conflict of interest and reminded members of their voting restrictions should they have a potential conflict of interest. Members with a potential conflict of interest must leave the room during the discussion and vote or abstain from voting on a study, as appropriate.

### **1. Minutes from Previous Meetings**

The Minutes of the UPIRB meeting dated XX/X/2012 were confirmed by the Chair and sent out electronically on XX/XX/2012 to all IRB members. These minutes were reviewed and voted for approval by the UPIRB on XX/XX/2012. Minutes were approved, without revisions

The expedited and exempt actions, dated XX/X/2012 – XX/XX/2012 were previously sent out electronically to all IRB members on XX/X/2012. The expedited exempt actions are also included in the Agenda and were ratified by the members.

### **2. Discussion/Education Items**

What IRBs Could Learn from Corporate Boards-Saver

Power Politics and IRB's-Meyers

Qualitative Inquiry-2007-Boser-1060-74

Group Dynamics articles

IRB Ethics & Human Research November-December Vol.34 No.6

IRB Advisor December 2012 Vol.12 No.12

#### **Discussion:**

Portions of the above items/topics were covered with minimal questions from the board.

### **3. New Studies**

**i. UPIRB#:** UP-XX-XXXXXX “[Social Networking Study]”

**Funding Source:** XXXXXXXXX

**PI:** XXXXX XXXXXXX

**Reviewers:** XXXXXXXXX & XXXXXXX

#### **Discussion:**

The community members were present during the discussion and vote. A quorum was maintained.

The Primary and Secondary Reviewers submitted a written evaluation in iStar, which was available to all Committee Members. The IRBA staff member’s review and comments were also shared with the members.

The primary reviewer explained that this study is essentially an extension of a longitudinal study. She then provided a brief breakdown of the previous research: a study of maltreated adolescents' substance abuse and sexual behavior. She noted that this current study aims to follow peer interactions online to determine how it affects these subjects' substance abuse and sexual behavior patterns.

[details omitted]

There were concerns in regards to consent (written versus verbal) including the absence of discussing/acknowledging any detail in regards to secondary subjects who will not be aware that anything they have posted onto the subject's pages could be collected without their knowledge or consent. There really is no mention about how the secondary subjects and or their data will be handled. In addition to this issue, the study team also does not mention how they will handle suicidal or homicidal (etc.) ideation for the secondary subjects.

The primary review later pointed out that researchers are also lacking any mention of the [Social Networking Site] privacy policy (or terms of use). This is important, because [Social Networking Site] policies need to be adhered to.

A brief discussion ensued in regards to the CoC and whether it covers this study as an extension of the study listed on the CoC. The CoC does not expire until 20XX, but the board members agreed that the study team will need to contact the NIH and possibly submit an amendment for their CoC to ensure it covers this study as well, because research are collecting new data.

The primary reviewer did not have any issues with the compensation amounts and stated that the subjects clearly have willingly stayed enrolled in this study for quite some time.

One member mentioned that some of the secondary subjects may be minors. The board acknowledged that while this may be true, there is likely no way for anyone, including the researchers, to know if an individual/secondary subject is a minor or not.

The chair acknowledged some of the reasons that this study is being considered greater than minimal risk and informed the board that studies like this one will likely be seen by the board more often in the future. He also suggested that UPIRB develop its own guidelines and policies for online research.

The staff member's main concern focused on the surrounding issue of secondary subjects, including how suicidal ideation will be managed. The IRBA also questioned whether or not a waiver of signed consent was warranted. After some discussion, the board agreed that a waiver could be granted as long as certain aspects were mandated, such as requiring this information to appear in writing before the survey and before downloading the app.

One member suggested that perhaps a disclaimer be placed on each subject's [Social Networking Site] page, to notify secondary subjects, but the concern was that this may cause the primary subjects

to violate their own confidentiality and would likely change the nature of the interaction/data collected.

The members then discussed privacy issues and ethical concerns regarding online research in general. The legal perception is moving towards the thought that anything posted on a website is public and not protected; it's fair game for anyone to use the information in any way they like. Of course, this is different than requesting private access, such as obtaining someone's [Social Networking Site] password or downloading an app. This called into question the method that researchers want to use to access this information, because it is more covert, not data that are publicly available. Thus, there are still concerns of ensuring that certain individuals, such as secondary subjects, are being protected, yet there is likely no feasible way to consent or inform these secondary subjects.

The members all seemed to agree that a primary concern was the fact that the study team did not acknowledge certain issues such as the implication for secondary subjects. One member noted that the following language should also be included in the info sheet/consent form:

[details omitted]

After the board voted on the deferral, the members briefly rehashed all of the stipulations that they wanted to be clarified before it was reviewed again at the January board meeting.

**Motion:**

Defer

**Stipulations:**

- 1) Section 12.1: The board would like the information sheet to be presented in writing as well. Please indicate how you would best be able to do this. Suggestions: Include a written copy along with the mailed instructions, include the information sheet electronically as a part of/prior to the app installation instructions, or prior to the display of survey questions. Other? If not at all feasible, please explain why.
- 2) Section 12.1: The [Social Networking Site] app subjects are to download, will collect data from secondary subjects who will not be informed that their information will be collected. The board felt that the issue regarding secondary subjects (SS) was not adequately addressed. Please include detail in regards to the SS by responding to the following instructions/questions:

[details omitted]

- 3) Section 12.1: Researcher's should address the [Social Networking Site] privacy policies and any terms of use, and include a statement explaining how/why this research will not violate these policies and terms.

- 4) Section 24.7: The board has requested that you add additional language in the information sheet. Please also describe data the app will not collect (private e-mails, photos, etc.). In the same section, please include the following (or similar) statement: “data collected from this app could impact the privacy of your friends without their knowledge.”
- 5) Even though this study is an extension of prior research, the methodology and data to be collected differ in some ways; thus, researcher’s will need to check with the NIH and possibly submit an amendment to the NIH for their CoC to ensure it will cover this particular research study.

**Vote:**

8 for, 0 against, 0 abstain

**ii. UPIRB#:** UP-XX-XXXXX

“XX”

**Funding Source:** Departmental

**PI:** XXXXXXXXXXXX

**Reviewers:** XXXXXXXX & XXXXXXXX

**Discussion:**

**a. UPIRB#:** UP-XX-XXXXX-CR002 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX -  
Continuing Review: 2012

Funding Source: No Funding

PI: XXXXXXXXXXXX

Reviewers: XXXXXX & XXXXXXXXXXXX

**Discussion:**

The community members were present during the discussion and vote. A quorum was maintained.

The Primary and Secondary Reviewers submitted a written evaluation in iStar, which was available to all Committee Members. Both reviewers were present.

The primary reviewer gave a detailed description of the study, aims, procedures, subject population, potential risks and precautions taken to limit risks, especially to hearing. The members agreed that the subjects and their parents were fully informed of anticipated risks.

The reviewer provided a detailed description of some of the procedural aspects; including definitions of a few highly technical and/or medical terminology used within the study application.

The members agreed that the devices used would be classified as a non-significant risk device.

The waiver of HIPAA authorization for recruitment was approved.

The members agreed that minors qualified for inclusion under 45CFR46.406.

The members agreed that the IRBA could revise the application, moving the BAD and HAT-D instruments from section 20.1 to section 21.2.

The researchers will be reminded in the approval notice that only those persons listed in section 2.1, who are CITI compliant, can conduct study related activities. The members were informed that the UPIRB does not have access to CHLA personnel CITI certificates.

**Motion:**

Approved

**Stipulations:**

No stipulations

**Vote:**

The members voted 8 for, 0 against, 0 abstained.

**Language for Approval Notice:**

The following materials were reviewed and approved by the members:

Approved Informed Consent Form, dated XX-XX-2012

Approved Addendum Consent, dated XX-XX-2012

Approved Assent Form, dated XX-XX-2012

Approved Youth Assent Form, dated XX-XX-2012

Approved Recruitment Email, dated XX-XX-2012

Approved Recruitment Script, dated XX-XX-2012

HIPAA Form, dated XX-X-2011

Minor revisions were made to the application, recruitment and consent documents by the IRB Administrator (IRBA). The IRBA revised documents have been uploaded into the relevant iStar section. Please use the IRBA revised documents if an amendment is submitted and future revisions are required.

Note: The application has been revised by the IRB Administrator at the request of the board members in order to expedite the approval process. The BAD and HAT-D are not psychophysiological measures; they have been removed from Sections 20.1 Section 20.1.1. Both are psychometric scales and have been uploaded to Section 21

This study has been categorized as a “medical experiment” under the California Health and Safety Code (24174) which requires the California Bill of Rights (CBOR) to be provided to research subjects. Subjects, or their parents must review, sign and be given a signed copy of the CBOR. The

CBOR has been incorporated into the Informed Consent Forms and Informed Consent Form for Parents.

The IRB (designee) reviewed the request for waiver of Partial HIPAA authorization for screening, recruiting and identifying participants and determined that the above study met the regulations outlined in 45 CFR 164.512 (i)(2)(A-C) and granted approval of the partial waiver of authorization. Note: only those persons with HIPAA Certification can access PHI.

Researchers are reminded that all personnel must be CITI compliant; please note that XXXXXXXX's CITI and GCP expired XX/XX/2012.

#### **4. Continuing Reviews**

**a. UPIRB#:** UP-XX-XXXXX-CR002 XXXXXXXXXXXXXXXXXXXXXXXXXXXX - Continuing Review: 2012

Funding Source: No Funding

PI: XXXXXXXXXXXX

Reviewers: XXXXXXXXXXXX & XXXXXXXX

#### **Discussion:**

The community members were present during the discussion and vote. A quorum was maintained.

The Primary and Secondary Reviewers submitted a written evaluation in iStar, which was available to all Committee Members. The secondary review was read to the members.

A brief description of the study, aims, procedures, subject population and study status, including the adverse events, and amendments, was given to the members.

The primary reviewer noted one minor adverse event which was a protocol deviation. The only comment was that the researchers are way behind their target accrual (goal of 80 and enrollment of 9). The reviewer wondered why this wasn't addressed, but did not push for clarification from the study team. Other than this comment, there were no other specific concerns.

The secondary reviewer did not have any additional comments and agreed with approval.

#### **Motion:**

Approve

#### **Stipulations:**

None

#### **Vote:**

8 for, 0 against, 0 abstain

**b. UPIRB#:** UP-XX-XXXXX-CR002 XXXXXXXXXXXXXXXXXXXX- Continuing Review:  
Continuing Review 2013

**Funding Source:** XX

**PI:** XXXXXXXX

**Co-PI:** XXXXXXXXXXX, XXXXXXXX & XXXXXXXXXXX

**Reviewers:** XXXXXXX & XXXXXXXXXXX

**b. UPIRB#:** UP-XX-XXXXX-CR002 XXXXXXXXXXXXXXXXXXXX-  
Continuing Review: 2013

**Funding Source:** XXXXXXXXXXX

**PI:** XXXXXXXXXXX

**Co-PI:** XXXXXXXXXXX, XXXXXXXXXXX & XXXXXXXXXXXXXXXXXXXXXXXX

**Reviewers:** XXXXXXXXXXX & XXXXXXXXXXXXXXXX

**Discussion:**

The community members were present during the discussion and vote. A quorum was maintained.

The Primary and Secondary Reviewers submitted a written evaluation in iStar, which was available to all Committee Members. The secondary review was read to the members.

A brief description of the study, aims, procedures, subject population and study status, including the adverse events, and amendments, was given to the members.

There was some discussion regarding the study status; the members were informed that the CR application was returned to the PI by the IRBA for clarification. It was confirmed by the IRBA that the study status remains “enrolling new subjects...”

The researchers will be instructed to remove any personnel no longer working on the application.

**Motion:**

Approved

**Stipulations:**

No stipulations

**Vote:**

The members voted 8 for, 0 against, 0 abstained.

Language for Approval Notice:

The following materials were reviewed and approved by the IRB:

[hyperlinks removed]

- Approved Informed Consent Form for Parents with fMRI, dated XX-XX-2012
- Approved Informed Consent Form for Parents-non-fMRI dated XX-XX-2012
- Approved Informed Consent Form with fMRI, dated XX-XX-2012
- Approved Informed Consent Form-non fMRI dated XX-XX-2012
- Approved Youth Assent Form with fMRI, dated XX-XX-2012
- Approved Youth Assent Form-non fMRI dated XX-XX-2012

- Approved fMRI FAQ Sheet, dated XX-XX-2011
- Approved Parent Recruitment Letter, dated XX-XX-2011
- Approved Permission to Use Video Tapes, dated XX-XX-2011
- Approved Recruitment Email, dated XX-XX-2011
- Approved Recruitment Phone Script for Child, Updated XX-XX-2011
- Approved Recruitment Phone Script for Parent, updated XX-XX-2011
- Dornsife Incidental Findings Form - updated XX-XX-2011
- Dornsife Screening Form

The IRB Office has moved; the consent documents have been revised to reflect the updated address by the IRB Administrator (IRBA). The IRBA revised documents have been uploaded into the relevant iStar section. Please use the IRBA revised documents if an amendment is submitted and future revisions are required. The “date of preparation” in the footer should be revised accordingly; this maintains an audit trail and makes sure the latest versions are revised/used.

Persons no longer working on the study should be removed using the updated “edit study personnel function” Please see the attached screenshot for instructions on how to use this function.

**c. UPIRB#:** UP-11-XXXXXX-CR001 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX - Continuing Review: XXXXXXXX 2013

**Funding Source:** XXXXXXXX

**PI:** XXXXXXXXXXXX

**Co-PI:** XXXXXXXXXXXX, XXXXXXXXXXXX, Ph.D., XXXXXXXX

**Reviewers:** XXXXXXXXXXXX & XXXXXXXX

**Discussion:**

The community members were present during the discussion and vote. A quorum was maintained.

The Primary and Secondary Reviewers submitted a written evaluation in iStar, which was available to all Committee Members. The secondary review was read to the members.



A brief description of the study, aims, procedures, subject population and study status, including the adverse events, and amendments, was given to the members.

The primary reviewer was absent so the chair read his review. Comments were very brief and there were no issues hindering re-approval.

The secondary reviewer rehashed a few items in regards to the research progress; the study team is waiting until funding before enrolling any subjects. Thus, there are no significant changes in regards the study and none involving any research subjects.

In hindsight, this study probably did not need to come back to the board because there is has been zero subject enrollment.

**Motion:**

Approve

**Stipulations:**

None

**Vote:**

8 for, 0 against, abstain

Meeting adjourned 11:31am

**-END OF MEETING MINUTES-**