#3: SAMPLE CONSENT FORM

[Key Element #3: Who is conducting the study]
UPMC | University of Pittsburgh Medical Center
Western Psychiatric Institute and Clinic

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

[Key Element #3: Who is conducting the study & Key Element #8: Who to contact]
INVESTIGATORS:

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University of Pittsburgh
Principal Investigator
[redacted]

Stephen Thomas, Ph.D.
Maryland Center for Health Equity
Co-Investigator

SOURCE OF SUPPORT: National Center for Minority Health and Health Disparities and National Institute of Mental Health

[Key Element #1: Purpose]

Why is this research being done?

The purpose of this research study is to learn if teaching problem-solving skills or teaching improved dietary practices can help to prevent someone who has mild symptoms of emotional distress (such as feeling sad, gloomy, anxious, or having trouble sleeping) from developing a clinical depression. Your participation in the study will last up to 24 months or until you notify the study staff that you no longer wish to participate in the study.

[Key Element #2: Why you are asked to join]

Who is being asked to take part in this research study?

You are being invited to participate in this study because you are age 50 or above, and are suffering from mild symptoms of emotional distress. Three hundred six people, aged 50 and older, of both sexes and all races, will be asked to participate in this study, which will be conducted in our specialty mental health research clinic in Bellefield Towers, in our primary care practice satellites at UPMC St. Margaret Hospital and Fort Pitt Senior Health Care Assoc. at UPMC Mercy Hospital, in the primary care practices of Community Medicine Incorporated, and Co-ordinated Care Network, in the Hill House, at the Kingsley Center, in the University of Pittsburgh Physicians/Ophthalmology Clinic, at the Centers for Healthy Hearts and Souls, and at Hosanna House.

[Key Element #6: What you will be doing]

What procedures will be performed for research purposes?

If you decide to take part in this research study you will undergo the following procedures that are not part of your standard medical care:

Screening Procedures: Procedures to determine if you are eligible to take part in a research study are called “screening” procedures. For this research study, the screening procedures include first a brief questionnaire for symptoms of emotional distress. If you screen positive, then you will be offered a comprehensive clinical evaluation.

Comprehensive Clinical Evaluation: During this evaluation, a study psychiatrist or study clinician will ask you to provide information regarding any past or present psychiatric symptoms you are having, any past or present medical illnesses, and any medications you have been taking (including over the counter medications). This evaluation will last 2 to 3 hours. The purpose of this evaluation is to determine if you qualify to be in this study. The evaluation will diagnose if you are experiencing the symptoms of emotional distress that may lead to the development of a clinical depression. If it is determined that you are experiencing a clinical depression or another mental health condition, you will not be eligible to participate but will be referred for treatment.

If you participated in another research study during the last six months, the results of the psychiatric assessment of past or present mental health symptoms obtained in the other research study may be used in this study and you will not need to have this evaluation repeated before beginning participation this study. A comprehensive clinical evaluation is usually done prior to the start of depression or anxiety treatment, as part of routine clinical care, regardless of study participation. All other procedures in this study are research related. The results of research evaluations obtained in another research study within the past 3 months may also be used in this study and you will not need to have these evaluations repeated before beginning participation this study.

Experimental Procedures: If you qualify to take part in this research study, you will undergo the following experimental procedures: **Begin Problem-Solving Therapy (PST)** or **Education in Health Dietary Practice (DIET).** You will be randomly assigned (like a flip of the coin) to receive either Problem solving Therapy (PST) or Education in Health Dietary Practices (DIET)

Problem solving Therapy (PST)
PST will focus on helping you to develop more productive ways to deal with the social and interpersonal problems associated with emotional distress. The PST sessions will be conducted by a study clinician trained in this form of therapy. If you are assigned to receive PST, you will meet with a study clinician for 6 to 8 sessions. These sessions are spread out over 6 to 16 weeks, and depending on your schedule, will preferably take place every 2 weeks. The first PST session lasts 1 hour and the subsequent sessions last 45 minutes each for a total of 6 to 8 PST sessions or about 4.75– 7.25 hours total time. You may have 2 extra 30 minute visits during the course of the study if you begin to develop a worsening in your symptoms of emotional distress. It is important that you have 6 therapy sessions. Therefore, if you are unable to come in for a study appointment, the therapy may be conducted over the telephone. Or, if you are unable to participate in a therapy session (for instance, due to illness or vacation), the session will be conducted as soon as you are able to participate. For example, if you miss a session at week 6 of the study, we would ask you to come in for a therapy session later that same week or the following week.

You will also meet with a study assessor 8 times during the course of the study for monitoring evaluations which will be conducted: after your last PST session, 6 months after entering the study, and then every 3 months until the end of the study. During these visits, the study assessor will ask you questions about your symptoms, memory, daily functioning, social supports, stressful life events, problem solving skills, medical illnesses and medications, and any mental health treatment you may have received since your last contact with the clinician. We will also obtain your vital signs (e.g., blood pressure and weight) at 2 of these visits: 12 and

24 months after entering the study. If you are unable to come in for a study visit, the evaluations may be conducted over the telephone. If you are unable to participate in the visit (for instance, due to illness, vacation), the evaluation will be conducted as soon as you are able to participate. These visits will last approximately 30 to 45 minutes except for the visits done at the end of your last PST or DIET session and at the end of your study participation. During these 2 visits, which will last approximately 1 ½ hours, you will also be asked to participate in some cognitive (thinking) tests of your memory, concentration, attention, and ability to solve problems.
You will also be asked to come in for a 30 minute therapy session at the following time points: 6 months, 12 months, and 18 months after starting the study. For your convenience, we will try to schedule these on the same day that you have your monitoring evaluation.

Education in Health Dietary Practices (DIET)
You will receive education in healthy eating practices if you are assigned to DIET. DIET will entail six to 8 sessions, conducted over 6 to 16 weeks, lasting a total of 4.75-7.25 hours in which you will receive information about the food pyramid, the types of food and calories recommended for people aged 50 and above, tips on shopping for healthy food, and tips on food preparation and healthy eating behavior.

The first DIET session lasts one hour and the subsequent sessions, which are spread out over the following 5-16 weeks, lasts 45 minutes each. If assigned to DIET, we will inform your primary care physician of the results of your mental health evaluations, and you and your doctor can then decide if you should receive any treatment for your feelings of emotional distress. You will be assigned to a study clinician whom you can call during the course of the study if you develop a worsening in your symptoms, or if you have any questions or concerns. You will meet with a study assessor 8 times during the course of the study for follow-up evaluations which will be conducted: after your last DIET session, then again 6 months after entering the study, and then every 3 months until the end of the study.

During these visits, the study assessor will ask you questions about your symptoms, memory, daily functioning, problem solving skills, medical illnesses and medications, and any mental health treatment you may have received since your last contact with the clinician. We will also obtain your vital signs (e.g., blood pressure and weight) at 2 of these visits: 12 and 24 months after entering the study. If you are unable to come in for a study visit, the evaluation may be conducted over the telephone. Or, if you are unable to participate in the visit (for instance, due to illness, vacation), the evaluation will be conducted as soon as you are able to participate. These visits will last approximately 30 to 45 minutes. You will also be asked to come in for a 30 minute Diet session at the following time points: 6 months, 12 months, and 18 months after starting the study. For your convenience, we will try to schedule these on the same day that you have your monitoring evaluation.

Both PST and DIET

The frequency of your visits could be increased temporarily if you develop a worsening in your symptoms. At all points during the study, your study clinician will be the primary person for you to contact should the need arise. If you develop a clinical depression or some other mental illness during the course of this study, the study will end and we will refer you for continued treatment based on your needs and preferences.

[Key Element #10: Privacy and Data Management]

Monitoring Procedures: Procedures performed to evaluate the safety and effectiveness of the experimental procedures are called monitoring or follow-up procedures. For this research study, the monitoring or follow-up procedures include:

Your PST and DIET sessions will be audio-taped. A recording device (similar to a tape recorder) will record your conversation with your study clinician during your clinic visit, and the recording will then be transferred into a computer for storage. Once the recording is transferred into the computer, the recording will be erased from the recording device. These recordings will be reviewed by your study clinician, by his or her supervisor for the purpose of assuring that your study clinician is providing high-quality treatment, and rated to ensure your clinician is sticking with your assigned study treatment (PST versus DIET). The audio recordings will be identified by a code number (and not by your name), and the information linking these code numbers to your name will be kept in a separate, secure location. These coded recordings will be kept indefinitely. The principal investigator, listed on the first page of this consent form, will assume overall responsibility for the storage of the recordings. The audio recordings may be listened to by investigators, not listed on the first page of this consent form, who are involved in other research projects about depression. However, the audio recordings will continue to be identified by code number and nothing that links your name to the tapes will be given to them.

[Key Element #6: More of what you will be doing]

Study Evaluations: As noted earlier, you will meet with a study assessor 8 times during the course of the study for follow-up evaluations. These visits will last approximately 30 to 45 minutes. The study clinical assessors will not know your therapy assignment and we request that you not tell them which study treatment you are receiving (PST or DIET). If we have concerns about your emotional distress or symptoms of a memory problem, we will inform your primary care doctor. At each PST or DIET session, you will be asked to complete a questionnaire that asks questions about symptoms of depression that you may or may not be experiencing.

Opinions about Ways to Reduce Stress: At the beginning of the study before you are assigned to either PST or DIET, we will ask you to answer a few questions about ways people sometimes cope with stress and to tell us how useful or successful you think these ways may be.

Suicide Assessment: At each assessment time point, you will be asked if you are having any suicidal thoughts. If you make a suicide attempt during the study, a study assessor will meet with you for an additional 30 minutes to get more information about the suicide attempt, what you were thinking at the time of the attempt, and the circumstances of the attempt. If you become suicidal we may take steps to protect your life. These steps will involve removing you from the study to enable you to receive an alternative treatment, informing your family members, and possibly taking steps to hospitalize you.

Cognitive Tests: You will be asked to participate in some cognitive (thinking) tests of your memory, attention, concentration, and ability to solve problems. The cognitive tests, which will be done by study staff, will take place at the beginning of the study before you are assigned to either PST or DIET, after your last PST or DIET session, and then again at one year of study participation, and at the end of your study participation. These tests take approximately 40 to 45 minutes to complete.

Social Support Assessment: We will ask you to answer some questions to get your opinion on if you think you have an adequate support system in your life. Examples of this would be people to help you if you were sick, people you can call with problems, or if you have friends to do things with. These questions take approximately 3 minutes to answer.

Stressful Life Events Assessments: We will give you a list of problems and complaints that people sometimes have in response to stressful life experiences. We will ask you to tell us if, in the last month, any of these bothered you, and if so, how much it bothered you. These questions take approximately 2 to 3 minutes to answer.

Functional Status Assessment: We will give you a list of activities and ask you to tell us how often you do them and ask if you feel limited in your ability to do them. These questions take approximately 3 to 5 minutes to answer.

Medical Monitoring: If you are hospitalized or become physically ill, we will access your medical records and/or consult with your PCP in order to obtain your diagnosis, results of your lab tests, and the treatment you receive. If your records are in a non-UPMC facility, we will ask you to sign a separate consent permitting us to do this. If we have concerns about your physical and emotional health, we will share these concerns with your PCP.

Reliability Testing of Staff: You may be asked if you would be willing to allow us to audiovideotape one of our staff asking you the questions on the various research assessments we use in this study and in other studies that the staff work in. The audio-videotapes will then be reviewed and rated by investigators and staff who work in our Center, some of whom may work in other research projects about depression, for the purpose of assuring that they are rating the

assessments in the proper manner. To protect your confidentiality, the audio-video recordings will be identified by a code number (and not by your name or other personal information), and the information linking these code numbers to your identity will be kept in a separate, secure location. The principal investigator listed on the first page of this consent form, will assume overall responsibility for the storage of the recordings. These coded recordings will be kept indefinitely and will continue to be identified by code number. You may still participate in this study if you decide not to do this.

[Key Element #4: Possible risks]

What are the possible risks, side effects, and discomforts of this research study?

All forms of therapy, including PST or DIET, may be associated with some emotional discomfort. There is a possibility that PST or DIET will not work and you may not improve. As with any investigational study, there may be adverse events or side effects that are currently unknown and it is possible that certain of these unknown risks could be permanent, serious or life-threatening.

The following measures will be taken to detect and treat the occurrence of illness or injury. You will be assessed for the occurrence of depressive symptoms or a worsening of your symptoms at each study assessment. Suicide is a possible risk of depression. If you become depressed and suicidal or if you experience psychosis (such as hearing voices that others do not hear, beliefs that others do not share), the research team may take steps to protect your life. These steps will involve removing you from the study to enable you to receive an alternative treatment, informing your family members, and possibly taking steps to hospitalize you.
In addition, to ensure your safe participation in this study, you are being asked to designate someone whom the research team can contact about your symptoms and participation in the study, and who the research team can contact if they have questions about/are concerned about your health and/or are unable to reach you. You are being asked to write below the name, address, and phone number of a relative, friend, or someone who can contact the study staff in case of emergencies.

_____ _____

Name Address

_____ _____

Telephone Number Alternate Telephone Number

Throughout the course of the study your care will be supervised at all times by the study investigators and the Medical Director of the clinic. **[Key Element #8: Who to contact]** The late-Life Depression Clinic has a 24- hour answering service with the study investigators and staff on-call. The phone number for the answering service is (412) 246-6006. If you are unable to reach research staff through the answering service, you may also contact the emergency room of Western Psychiatric Institute and Clinic at (412) 624-2000. The emergency room staff will then put you in touch with a study investigator or research staff member.

Some inconvenience and or anxiety may occur due to time required to complete formal rating scales and questionnaires. The cognitive assessments impose some risk of emotional discomfort.

Risks of breach of confidentiality of research data: There is a possibility that if your study research data were to become generally known, this knowledge of your research data could potentially impact your future insurability, employability, or reproduction plans: or have a negative impact on family relationships; and/or result in shame or embarrassment

There is also a risk of detecting a previously unrecognized medical or psychiatric problem. If this happens, you will be referred for appropriate treatment based on your needs and desires.

[Key Element #5: Possible benefits]

What are the possible benefits from taking part in this research study?

There is no guarantee that you will receive any benefit from participating in this research study. Your symptoms may improve but there is no guarantee that they will. You may benefit from the screening procedures that include a careful examination of your mental health condition. You may also benefit from the ongoing close mental health evaluation during the course of the study, as well as the extent that PST or education in dietary practices may improve your overall functioning. You may also benefit from careful assessment of cognition if areas of impairment are detected that could be improved by other treatment. The results of this study may help other older individuals who are suffering from depressive symptoms.

What treatments or procedures are available if I decide not to take part in this research study?

You can receive Problem Solving Therapy or Education in Healthy Dietary Practices outside of this study. Other treatments can involve the use of other types of therapy, such as cognitive therapy.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any new information develops during the conduct of this research study which may cause you to change your mind about continuing to participate.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?

The study will pay (you and your insurance company will not be billed) for the cost of the study therapy, study evaluations, and for your study visits. If you require medical care outside of the study, you will be billed in the standard manner for any procedures performed for your routine medical care, including any applicable co-pays, coinsurances, and deductibles. If you need to be hospitalized due to a worsening of your depressive symptoms, you or your insurance provider will be billed for the costs associated with this hospital stay.

[Key Element #7: Incentives]

Will I be paid if I take part in this research study?

You will be paid $25 for each of the two screening assessments and 8 follow-up assessments and $20 for each of the PST or Diet education sessions that you complete during your participation in this research study. Thus, you may earn up to $435 for your study participation.

Who will pay if I am injured as a result of taking part in this research study?

University of Pittsburgh investigators and their associates who provide services at the UPMC recognize the importance of your voluntary participation to their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research.

If you believe that you are injured as the result of the research procedures being performed, you should **[Key Element #8: Who to contact]** contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form. Emergency medical treatment for injuries solely and directly relating to your participation in this research will be provided to you by hospitals of the UPMC. It is possible that the UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

[Key Element #10: Privacy and data management]

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All data obtained from this research will be kept in a locked file cabinet and secured password database. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician or psychologist office) records. The information that will be recorded will be limited to information concerning your demographics (such as your age, sex, date of birth, education, employment status, occupation, religion, race, type of insurance you have, marital status, and living arrangements). We will also record information about your mental health that we are unable to obtain during your interviews, and physical health such as diagnosis, medical exams, laboratory and cognitive tests that might influence the state of your emotional health. This information is useful in gaining a better understanding of your mental health history and determining if you should be in the study. This research study will result in identifiable information that will be placed into your medical records held at UPMC. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes progress notes (information about your diagnosis, symptoms, treatments, and response) from your research psychiatrist(s)and research clinician(s), and results from your medical evaluations and memory and alertness tests). In addition, if we become concerned about your psychiatric condition (for example, you become more depressed, suicidal, experience psychosis or another psychiatric problem), we will inform your primary care physician and/or the person you identified as your emergency contact person.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the sponsor of this research study, the National Institute of Mental

Health (NIMH), will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.
Authorized representatives of the UPMC hospitals or other affiliated health care providers (such as neuropsychological staff) may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) conducting neuropsychological testing; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e., quality assurance).

Your data (information about your diagnosis, symptoms, study treatment, study evaluations, and results from your medical evaluations and memory and alertness tests) will be shared with John Kasckow M.D., Ph.D., Principal Investigator of “Primary Prevention of Major Depression in Later Life” research project occurring at the VA Medical Center. To protect your confidentiality, all personal identifiers (such as your name, social security number, birth date) will be removed (deidentified) and replaced with a specific code number. The information linking this code number to your identity will be kept in a separate, secure location. The investigators on this study and the VA Medical Center study will keep the data indefinitely.

There may be future analyses of the research data conducted by the study investigators, as yet unplanned, dealing with other aspects of late-life mental health illnesses. Your research data (which will be identified by a code number and not by your name or other personal information) may be provided to secondary investigators for the purpose of conducting additional analyses about late-life mental health illnesses, such as depressive disorders, bipolar disorders, anxiety disorders, insomnia, and Alzheimer’s disease.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research for at least 10 years. The University of Pittsburgh requires that all research records be kept for at least five years after the study ends.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in the research study) contained within your medical records filed with your health care provider.

[Key Element #9: Voluntary participation and right to withdraw]

Is my participation in this research study voluntary? Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study? You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, including the therapy and inter-rater reliability testing audiotapes, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. If you decide to end your study participation, or if the study investigators decide to end your study participation, your audio recordings will continue to remain the property of the investigators and will continue to be stored with a linkage code to your name.

To formally withdraw your consent for participation in this research study you can inform the research team verbally; or, if your desire to do so, you can provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future

medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you withdraw consent from participation in this research study, we will refer you for appropriate treatment based on your needs and preferences and assist you in making an appointment for your continued care.

Your doctor may be an investigator in this research study, and as an investigator, is interested in both your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

If I agree to participate in this research study, can I be removed from the study without my consent? You understand that you may be removed from the study at any time by the investigators if you are determined by the research team to be unable to follow the study requirements, such as attend study clinic appointments, participate in therapy sessions, become suicidal, or develop a depression or another psychiatric illness. We will refer you for appropriate treatment based on your needs and preferences and assist you in making the appointment for your continued care.

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VOLUNTARY CONSENT: The above information has been explained to me and all of my current questions have been answered. Any future questions I have about this research study will be answered by one of the investigators listed on the first page of this consent document at the telephone numbers given. I understand that I may always request that my questions be answered by a listed physician investigator involved in the conduct of this research study. Any questions I have about my rights as a research participant, will be answered by the Human Subjects Protection Advocate of the University of Pittsburgh IRB Office 1-866-212-2668.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

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CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation.

Any questions the individual had about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date