

10 Key Elements of the Informed Consent Process

During the informed consent process, there are some key elements you will always be given and that you should make sure you understand. These key elements should be discussed during your meeting with the research team member and included in the informed consent document you receive.

1. **Purpose of the study**
2. **Why you were asked to join the study**
3. **Who is conducting the study (names of the institution and researchers)**
4. **Possible or anticipated risks**
5. **Potential benefits**
6. **What you will be doing during the study**
7. **What incentives, if any, there are for volunteering**
8. **Information about who you can contact during the study if you have any questions or concerns**
9. **Statement that participation is voluntary and that if you join the study, you can quit at any time**
10. **Privacy and Confidentiality**

How to Identify the Key Elements

Sometimes, a study you want to join is fairly simple. It may involve taking a survey or participating in an interview. In these cases, the informed consent process will probably be short and the information straightforward and easy to understand. Other times, however, if a study is more complicated, involves more steps, or has a higher risk of negative side effects, there will be a large amount of information given during the informed consent process, and the consent document may be long and the material difficult to understand. But, all 10 key elements **MUST** be present in both simple and complicated research studies.

You should ask questions if there is anything you don't understand or would like to know more about. You should also expect to have time to make your decision. This may mean going home to discuss the information with your family, if desired, and joining the study after you have had a chance to think about the decision