

Institutional Review Board

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The IRB Quick Reference Guide:

Consent Process and Procedures

How to Use This Guide

This *IRB Quick Reference* guide provides basic tips on the consent process. This guidance should be used in conjunction with information regarding the review process and protocol development found at <http://gra.sdsu.edu/research/irb>.

What is informed consent?

The informed consent process involves providing understandable information about study procedures to enable an individual to make an informed decision about participation in an environment free from any undue influence or coercion.

Informed consent is a process, not just a signature on a form.

Regulations and Federal Guidance

For more information on the consent process see the "Guidance by Topic" section at: <http://www.hhs.gov/ohrp/> and federal regulations 45 CFR 46.116 and 45 CFR 46.117.

REVIEW LEVELS & CONSENT

In **Exempt** research a formal consent form is not required.

- Obtaining a signature is not necessary.
- The language used during this process is less formal.
- Often using an entirely verbal process is acceptable; however, the IRB will still need to be provided with a copy of the language planned for use with participants.
- This informal consent form can be used as both a recruitment script and to obtain consent if appropriate.

In **Expedited** or **Full Committee** research, regulations require that the following information be described within a more formal signed consent document:

- A statement that the study involves research
- The purpose of the research
- The procedures to be followed during participation
- The potential risks/discomforts
- The confidentiality of research records
- Whom to contact with questions
- A statement that participation is voluntary

After receiving this information individuals are offered the choice to participate in the research.

PROVISION OF STUDY INFORMATION

When obtaining consent, it is important to consider the language used. The consent process should be carried out in simplified language that will be understandable to the population under study.

- When including an average adult population in research, the IRB recommends that consent documents be written at a 6th - 8th grade reading level to increase the likelihood that individuals will understand what is involved in study participation.
- Any complex procedures should be described in lay language and jargon should be avoided or explained.

- When individuals who are not English speakers are included in the research, it is important to provide them with consent documents that are written in their primary language in order to ensure that all aspects of study participation are understandable.

It is also important to consider whether the setting and timing for explaining the research is conducive to good decision-making.

For example:

- It may be culturally appropriate to give a potential participant time to discuss his/her participation in the study with family members before making a decision.
- Individuals who are invited to participate in research in the hospital waiting room may not be in the right frame of mind to fully consider participation.

SPECIAL POPULATIONS

Special procedures are required when involving special populations in research activities.

Children in Research

- When minors are included in research, parental permission must be obtained before assent is obtained.
- Written assent is obtained for children 7 and older.
- Verbal assent is obtained from younger children.
- However, determination of an individual child's ability to assent will depend upon the child's age and maturity.
- When child participants are also wards of the court, regulations require that an **Advocate**, who is not affiliated with the research or guardian organization, is selected to act in the best interest of the child throughout the study.
- The **Advocate's role** is to ensure that the child understands what will occur during participation and can assent to participate.

Cognitively Impaired Populations

- Cognitively impaired individuals must have a **Legally authorized representative (LAR)** who can provide permission for that individual to participate in the research.
 - The **LAR** is an individual, judicial, or other body authorized under law to consent on behalf of a prospective participant.
 - In cases of temporary impairment should the participant regain the ability to consent, he/she should then be asked to provide consent for the remainder of research activities.
 - Should research involve a population that is expected to become impaired during the study (e.g., progressive disorders, aging populations), individuals may initially consent for themselves. However, it is recommended that individuals are asked to consider establishing a **LAR** who will provide consent should capacity to consent diminish.
 - When a mildly impaired population will be included in research it may necessary to include procedures in the consent process by which individuals are asked to summary each section of the consent form. (*Note that it still may be necessary to include a **LAR** in the consent process.)
- ⇒ This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process occurs (e.g., After the *Description of the Study* section, individuals can be asked: *What will you be asked to do if you decide to participate in this study?*).

HIPAA

If using/accessing **PHI (Protected Health Information)** either a **HIPAA authorization** or a **Waiver of HIPAA authorization** is necessary. This means:

- Consent is required to access **PHI**. The consent form must address the types of **PHI** accessed, the purpose for obtaining **PHI**, and who will have access to **PHI**.
- **OR** the institution housing the **PHI** has provided a waiver such that **PHI** can be obtained without consent if certain criteria apply.

For more information on HIPAA: www.hhs.gov/ocr/hipaa/

SPECIAL PROCEDURES

When research involves multiple activities (e.g., interviews, videotaping focus group discussions, etc.) consider including check boxes within the consent form so that individuals may elect to participate only in those activities they feel comfortable with.

For longitudinal studies, consider re-consenting individuals at each new session to ensure that they still understand what participation involves and to ensure they still agree to participate.

- This can be done by asking them to re-sign a single consent form at each new session, or verbally going over the consent form again and obtaining verbal agreement to continue to participate.

Waivers-Expedited and Full Committee Research

- The requirement to obtain signatures on consent forms can be waived if the only record linking the participant and the research is the consent document and the main risk is harm resulting from a breach of confidentiality - **or**- the research involves minimal risk of harm to subjects and involves no procedures for which written consent is normally required
- The requirement to use a written consent process can be waived if **(1)** The research involves no more than minimal risk to the subjects **(2)** The waiver will not adversely affect the rights and welfare of the subjects **(3)** The research could not practicably be carried out otherwise

For more information on waivers: [link]

NOVEL METHODS

An audiotaped consent process can be used for illiterate populations or populations where no written language exists. The text of the consent document can be played for individuals.

Similarly, videotape can be used to present study information to individuals, such as examples of how a blood pressure monitoring device should be worn.

CONSENT DOCUMENTS:

Templates for the forms listed below are located under "Human Research Protection Program" at: gra.sdsu.edu/research.php

Please use the available templates when developing forms for use in your study.

- Consent form
- Exempt Consent Script
- Videotape/Audio/Photo Release form
- Parental Permission form
- Assent form
- Consent for cognitively impaired population

OTHER TIPS

In **Expedited and Full Committee** research, participants and the investigator should sign two copies of the consent form—the investigator retains one copy in his/her records for a minimum of three years and the participant is given a copy to keep.

Passive or implied consent (e.g., asking individuals to sign and return a consent form only if they **do not** want to participate in research) is not permitted. This practice is not consistent with the regulatory requirement for seeking and obtaining consent.

Consent documents should be written in second person as the use of "I" throughout the document can be unduly coercive.

The Main IRB Site contains helpful hints and important guidance.

FAQ's, sample protocols, SDSU Research guidebook, and other helpful guides, templates and forms can be found here.

<http://gra.sdsu.edu/research/irb>