Assent and Consent from Human Participants

Before embarking on research involving human participants, you must obtain *informed consent*. If the potential participant is over the age of 18, and can make a decision about his or her willingness to participate (or not) in a research study a written consent form must be reviewed and signed. If the participant is under the age of 18 and old enough to understand what is happening, but does not have the authority or ability to consent to participation in a research study, he or she needs to give their *assent* to be part of the study and a LAR (legally authorized representative) must give full informed consent.

Assent is an agreement to participate in a research study based on what is usually a simplified description of what is involved. It is important to note that *failure to object* is not considered assent. Informed consent or assent does not waive any rights. As a general rule, many IRBs use the age of *seven* as the approximate time when it becomes appropriate to seek assent. Complex decision making, especially that including altruistic motivation and personal autonomy, is believed to take shape in many children by age seven. However, it is more important to look at the child than his or her birth certificate. A bright child who is asking questions should provide assent even if he or she is only 5. A child who's more sluggish and passive may be hard to provide assent until a later age. A child with mental retardation may not be capable of assent until much later. The IRB will usually expect seven-year-olds to provide assent unless there's a documented good reason otherwise.

An oral assent process with less detailed documentation may also be acceptable, especially in studies of very low risk. Researchers may wish to propose this option if the situation warrants.

Note: Permission is usually not necessary when the research involves the observations of public behavior and the investigator does not participate in the activities being observed.

The special vulnerability of children makes consideration of involving them in a research study particularly important. To safeguard their interests, and protect them from harm, special ethical and regulatory considerations are in place through Federal Regulations. In addition, at most universities this usually involves the approval from the entire or full board. Thus studies with children participants often take longer to review and are more difficult to receive approval than studies that do not contain children. An explanation of the study must include a discussion of any potential risks including discomforts and even inconveniences the child may experience if he or she agrees to participate.

Consent and assent documents have to contain sufficient information written in language easily understood by the intended audience, and an opportunity for the potential participant or LAR to consider whether to take part in a research study. In addition, some assurance needs to be provided to protect from coercion or undue influence. If the IRB determines your study is high risk or deals with sensitive subjects, the consent form must be signed by both parents/guardians unless only one has legal responsibility for, and care of, the child.

A potential participant needs to be able to make a reasonable decision about participation, based on an understanding of the potential risks and anticipated benefits (if any) of the study. Signed consent of all participants or LAR is required unless a waiver of signed consent is granted by the IRB. The IRB may waive the need for formal informed consent if obtaining this would jeopardize performing the study and the potential risks are minimal (such as confidentiality). The researcher must provide the participant with two copies of the consent and assent documents to be signed. One signed copy is kept by the participant and the other by the investigator. There are, however a few exceptions…

Anonymity

For some studies, a cover letter can be used when a signed consent form is either not needed or would, by its use, compromise the anonymity of participants. The IRB may grant a waiver of signed consent and decide that a cover letter is acceptable. In this case the identity of the participants will not be known to the researcher.

Online Surveys

When a participant is asked to complete an online survey, the IRB may grant a waiver of signed consent due to the impracticality of obtaining the participant's signature. The consent document must appear as the first page of the online survey, contain a statement regarding collection of Internet Protocol addresses, and contain participation agreement statements at the bottom of the consent document. If you do not wish to collect the IP addresses of potential participants; thereby keeping responses to your study completely anonymous, some online

survey services like Survey Monkey, allow you to select the “No” radio button in the “Save IP Address in Results?”

For Children Participants

Studies involving participants under the age of 18 require that researchers obtain both parental (or LAR) consent as well as child assent for minors capable of providing assent. Since all consent documents need to be written in language easily understood by the intended audience, careful attention should be given when constructing forms for use in obtaining the assent of minors.

Please note that consent documents may vary in design between different universities but most contain similar information. Kennesaw university contains a particularly user friendly checklist of what needs to be included in a consent and assent form.

http://www.kennesaw.edu/irb/documents/consent_checklist.html

Appropriate Language

It is important to write in lay language suited to the age and educational level of the participants, that you use a font size large enough to enable the participants to read the form easily, and avoid the use of jargon and technical terms. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate. Thus a child needs to receive a simple and lay explanation of the study and be told what will happen to me. The following templates could help you design your assent letter.

A Template for use with a Young Child (7-10)

I, _____know that my parents (mom and dad)/guardian have/has said it’s okay for me to take part in a project about _____done by _____.

I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.

_____

Signature

A Template for a Pre-teen or Teenager:

I, _____ understand that my parents/guardian have/has given permission for me to participate in a study concerning _____ under the direction of _____.

My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time without penalty and loss of benefit to myself.

_____

Signature

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Most Consent Forms Include

TITLE OF PROJECT: _____

RESEARCHER'S NAME(S), TELEPHONE NUMBER(S), CONTACT INFORMATION:

INTRODUCTION:

PURPOSE:

DURATION AND LOCATION OF STUDY:

PROCEDURE:

POTENTIAL RISKS AND DISCOMFORTS:

POTENTIAL BENEFITS

CONFIDENTIALITY/ANONYMITY/ VOLUNTARY PARTICIPATION:

WHAT WILL BE DONE WITH THE RESEARCH RESULTS

RIGHT TO REFUSE AND TO WITHDRAW:

OFFER TO ANSWER ANY QUESTIONS:

A PLACE TO SIGN INDICATING AGREEMENT TO PARTICIPATE IN THIS RESEARCH STUDY

Name_____ Date_____