IRB Guidelines 1.4

Informed Consent Procedures

Version 1.1: Created 4/20/2016

Overview

Informed consent is a continual process not a document or piece of paper titled consent form (see 45 CFR 46). The concept is situated in respect for persons, voluntary participation, and the obligation to obtain legally effective informed consent of participants or their legally authorized representatives. Both written and oral forms of consent must involve an information exchange in which the researcher informs potential participants among other things about the nature of study, the risks and benefits and the rights of the subjects. In short, unless informed consent is waived or altered by the IRB, researchers may NOT involve human subjects in research project without having first obtained the legally effective informed assent/consent of the participant and/or the participant legally authorized representative.

Guidelines

The following tripartite section will discuss the specific requirements for informed acquiring informed assent/consent for different subpopulations.

Part I: Standard Adult Consent

Every informed consent needs to be (1) documented (e.g., signed), (2) conveyed in a language understandable to the participant (e.g., a rule of thumb for the general public: 6th-8th grade level), and (3) free of any exculpatory language (exculpatory language is any language through which the participant is made to waive or appear to waive any of her/his legal rights, and/or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence). The standard informed consent can be obtained via two different routes: written or oral procedures (variations in application requirements discussed below).

Important: Unless the researcher applies for (and is being granted) a waiver and/or alteration (see next section), however, every informed consent (oral or written) needs to include the following eight standard elements, five institutional requirements, and - if necessary additional research-specific information.

Standard Elements: According to 45 CFR 46.116(a), the informed consent needs to have the following standard components for adult populations:

__ (1)(a) A statement that the study involves research;
__ (1)(b) An explanation of the purposes of the research;
__ (1)(c) A statement of the expected duration of the subject's participation;
__ (1)(d) A description of the procedures to be followed;
__ (1)(e) Identification of any procedures which are experimental, if applicable;
__ (2) A description of any reasonably foreseeable risks or discomforts to the subject;
__ (3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
__ (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
__ (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
__ (6) For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
__ (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
__ (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Informed Consent Alterations and/or Waivers

The standard informed consent process may be under certain circumstances altered or waived. The

the specific criteria for granting waivers and/or alterations.

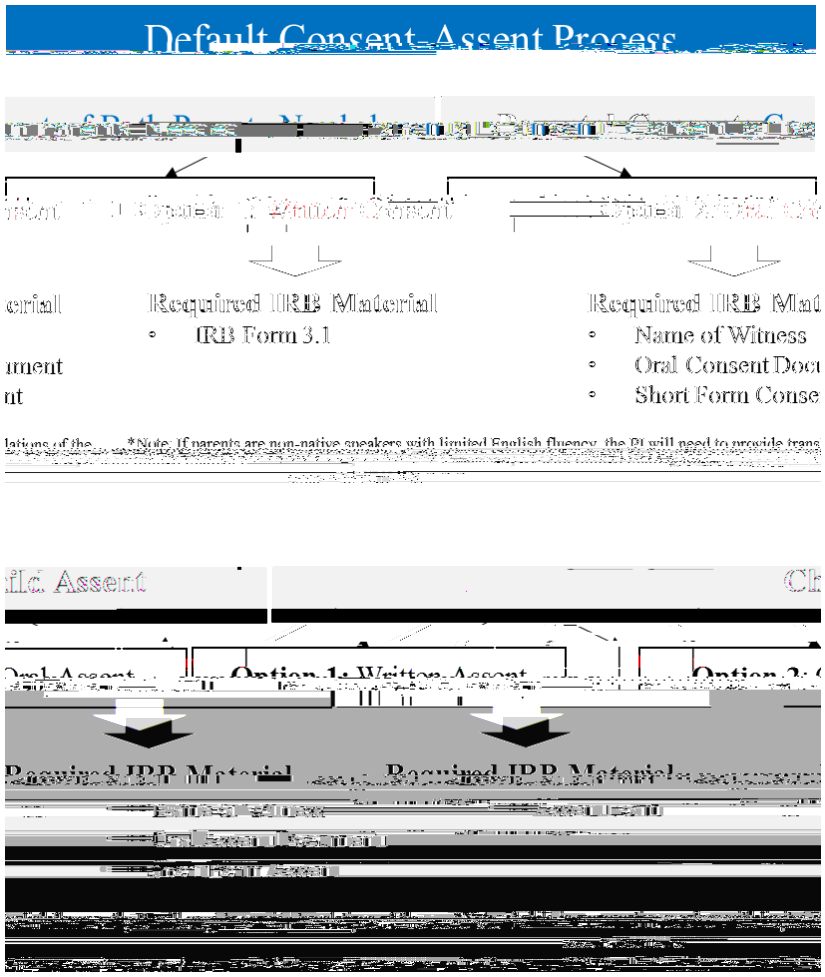
Step 1: Determining Basic Eligibility

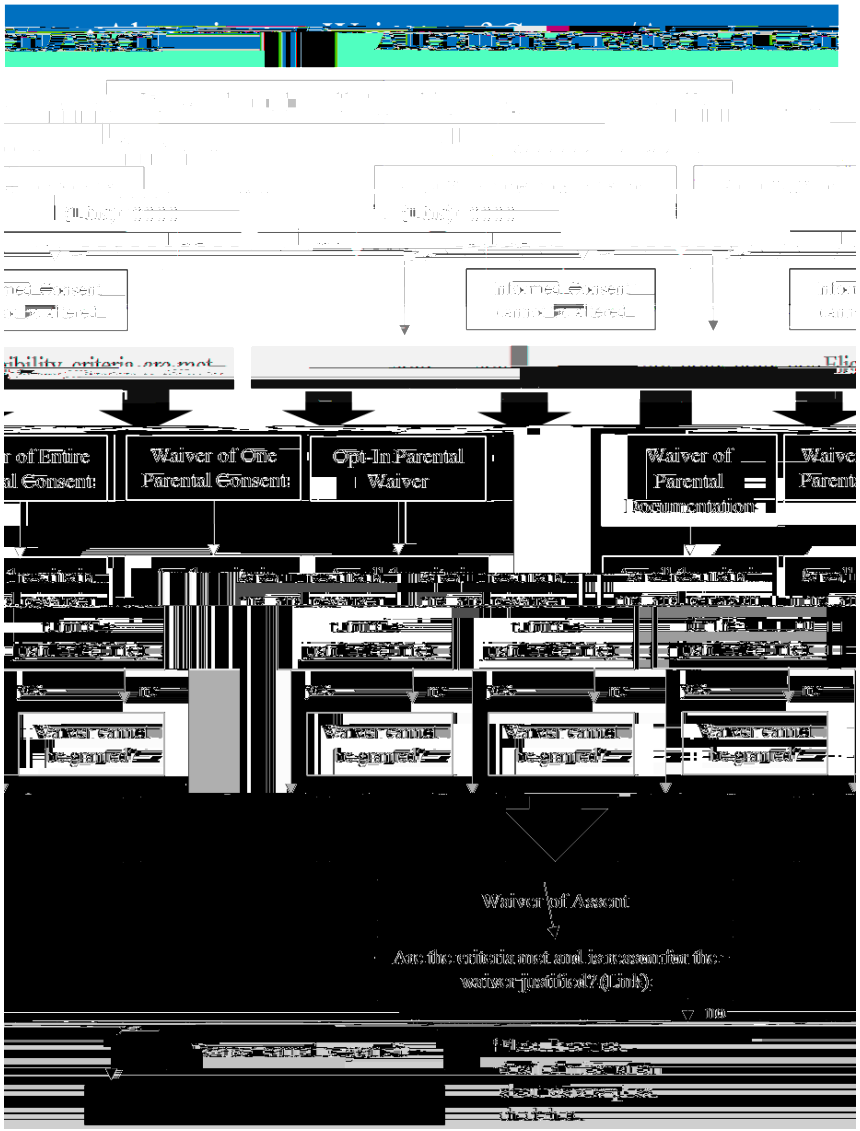
To determine eligibility for waiver or alteration of informed consent, all applications will be assessed

alterations requested, referencing the appropriate requirement of informed consent from the

Minor Assent and Guardian Consent

It must not be practicably possible to conduct the research without the waiver or alteration.


Default Consent-Assent Process
Required IRB Material
IRB Form 3.1
Required IRB Mat
Name of Witness
Oral Consent Doc
Short Form Conse
*Note: If parents are non-native speakers with limited English fluency, the PI will need to provide trans
Option 1: Written Assent
Required IRB Material
Required IRB Material

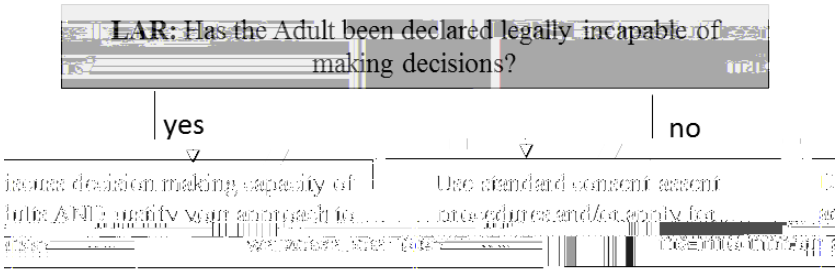

Waiver of One Parental Consent:
Opt-In Parental Waiver
Waiver of Assent

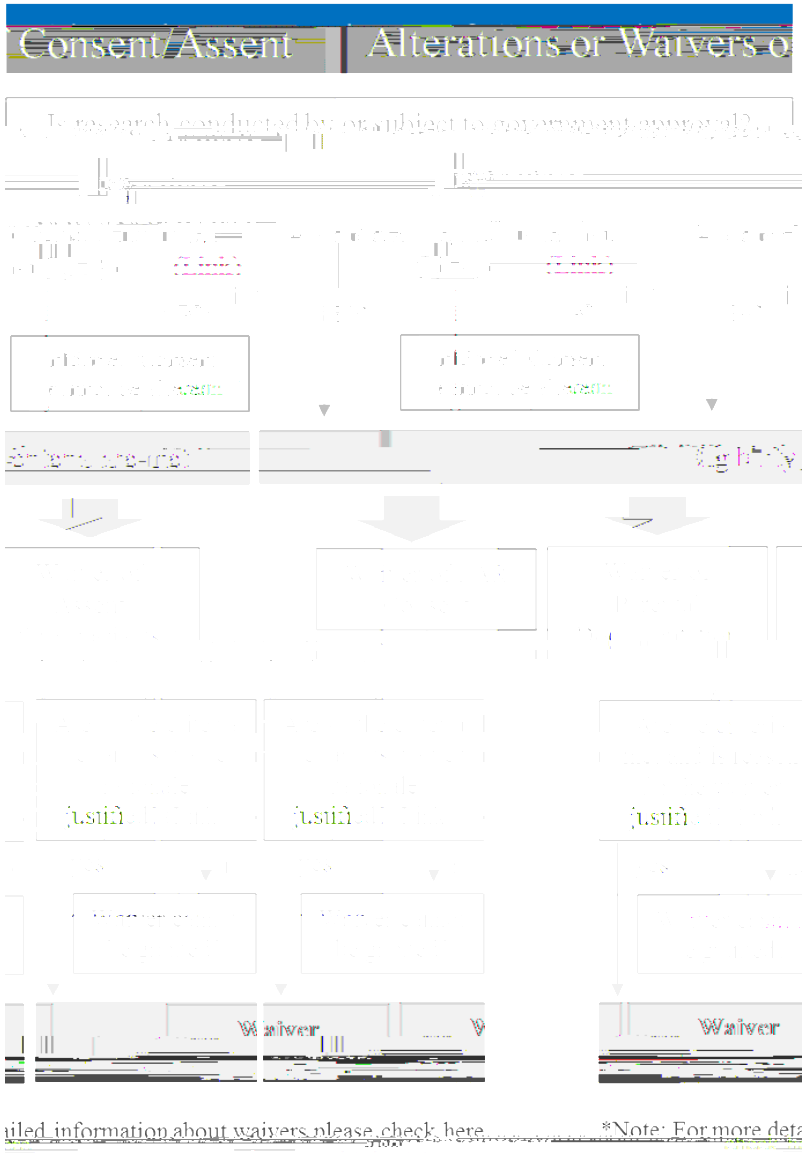
All Other Research

For all other research, the following four conditions need to be met:

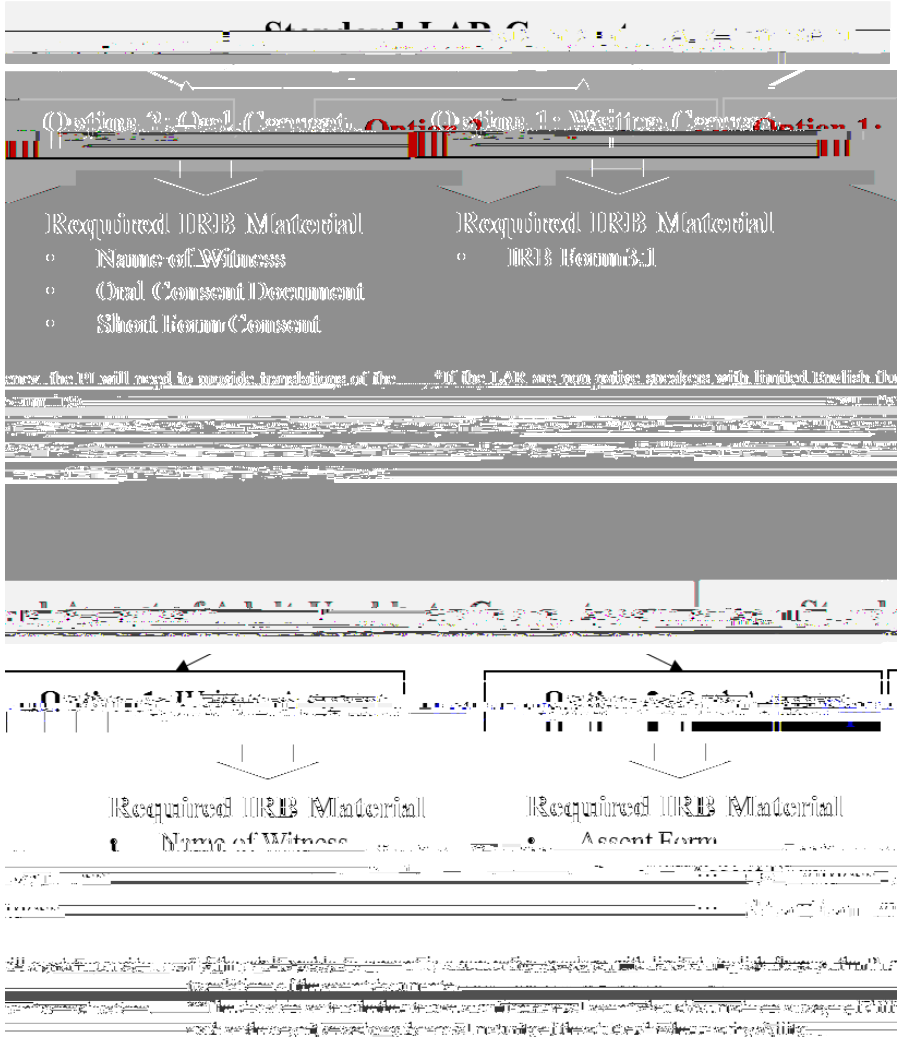
the research is designed to study conditions in minors for which parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused

Part III: Adults with Limited Decision-Making Capacity


LAR: Has the Adult been declared legally incapable of making decisions?
yes
no



iled information about waivers please check here *Note: For more deta



All Other Research

For all other research, the following four conditions need to be met:

The research must not involve greater than minimal risk;

The research must not be practicably possible to conduct without the waiver or alteration;

welfare; and

When appropriate, pertinent information will be provided to the subjects at a later date.

Step 2: Wt

Waiver II: If the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the participants and is available only in the context of the research; and

Waiver III: If the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults.

An application for any of these three waivers requires a reasonable justification and/or documentation.

If you need this document in another format, please email irbchair@ung.edu or call 706-867-2969.