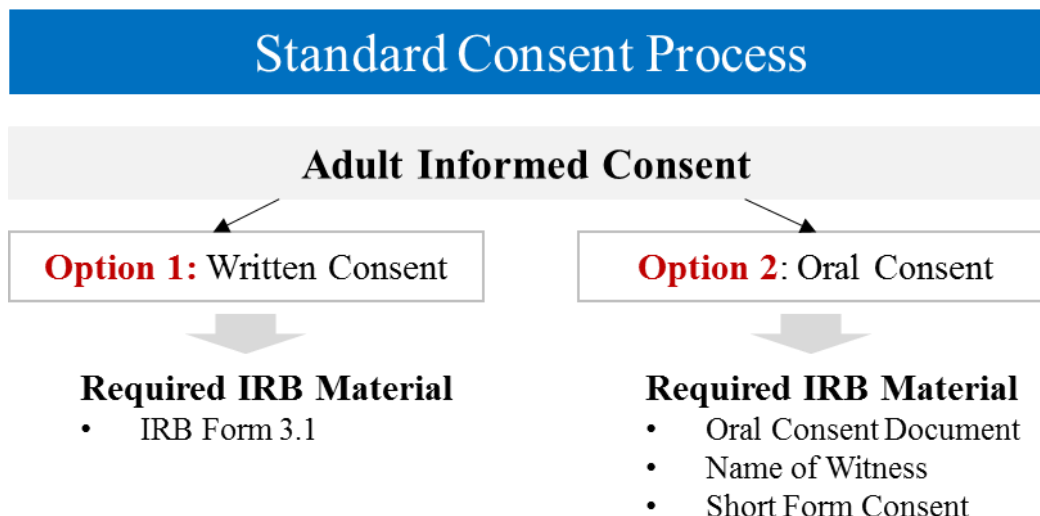


Overview

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.



*Note: If adults are non-native speakers with limited English fluency, the PI will need to provide translations of the consent documents.

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.

Institutional Requirements: The IRB of the University of North Georgia also requires the following additional information to be part of the informed consent form:

- ___ title of the study, exactly as it appears on the IRB application;
- ___ a statement of affiliation with the University of North Georgia;
- ___ investigator contact information (and/or faculty advisor contact information); and
- ___ documentation of informed consent (e.g., signatures, recordings of consent).

Research-Specific Informed Consent Requirements: Depending on the nature of the research, additional policies (e.g., FERPA, other 45 CFR 46 stipulations) may apply necessitating one or more of the following information to be included in the informed consent.

FERPA-Related Issues

applies when PI tries to access FERPA-protected data via informed consent (also see [FERPA FAQs](#))

When utilizing student educational records, including grades, coursework, or other personally identifiable information for research purposes, the following additional information must be included in the informed consent form ([for alternatives see FERPA FAQs](#)):

- ___ a specification of the records that may be disclosed,
- ___ the purpose of the disclosure, and
- ___ the identification of the part of class or parties to whom the disclosure may be made (99.30).

Extra 45 CFR 46.116(b) stipulations

only applies to certain types of research

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- (3) Any additional costs to the subject that may result from participation in the research
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- (5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- (6) The approximate number of subjects involved in the study

Route 1: Standard **Written** Consent

If a written consent is used, the researcher needs to submit IRB Form 3.1 with all the required elements of informed consent to the IRB (see above). Participants must be given adequate time to read and understand the document. Unless a waiver and/or alteration of documentation is sought (see below), the document needs to contain a signature line for both the participant's and the researcher's signatures. The IRB also asks PIs to include the following information at the bottom of the document: "Research at the University of North Georgia that involves human participants is overseen by the Institutional Review Board. Questions or problems regarding your rights as a participant should be addressed to _____ (add the following information here: IRB Chair, Department, address, phone, e-mail IRBchair@ung.edu)." **Here is a Sample IRB Form 3.1**

***Note:** Written documents such as the informed consent may be signed by the participant's legally authorized representative (e.g., via a power of attorney).

Route 2: Standard **Oral** Consent

In certain circumstances (e.g., participants cannot read), researchers may want to use an oral rather a written informed consent process. To use an oral consent procedure, the researcher will need to submit the following information with their IRB application (45 CFR 46.117):

- **name of a witness:** The witness – who needs to be free of any conflicts of interest – is responsible to oversee the presentation of the oral consent form and sign the consent form as well as the oral consent short form (see below).
- **an oral consent statement:** The oral consent statement is the statement that the researcher will read to the participant (and thus represents the document based on which the person will decide as to whether she/he wants to consent to the research). Unless the researcher also applies for waivers and/or alterations (see below), the oral consent statement – like the written consent - needs to include all eight standard elements, five institutional requirements, and – if appropriate/necessary – additional research-specific information (see section on standard written consent for more info). In addition to the witness, this statement also needs to be signed by the researcher. [Example of an Oral Consent Statement.](#)
- **an oral consent short form:** This document states that the required elements of informed consent have been presented orally to the research participant. Unless an alteration to this procedure becomes necessary (e.g., subject is unable to sign due to physical disability and/or cultural norms prohibit signing documents), the witness and the participant need to sign this document. [Example of an Oral Consent Short Form.](#)

Informed Consent Alterations and/or Waivers

The standard informed consent process may be – under certain circumstances – altered or waived. The following section is based on 45 CFR46 and specifies how the IRB will determine “eligibility” and details 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 based on criteria specific to the nature of proposed research.

Research Conducted by or Subject to Government Approval

If the research is conducted by or subject to the approval of state and/or local government officials, the following conditions must be met:

- The project must be designed to study, evaluate, or otherwise examine at least one of the following:
 - public benefit of service programs,
 - procedures for obtaining benefits or services under those programs,
 - possible changes in or alternatives to those programs or procedures, or
 - possible changes in methods or levels of payment for benefits or services under those programs.
- It must not be practicably possible to conduct the research without the waiver or alteration.

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;
- Waiving or altering the informed consent must not adversely affect the subjects’ rights and welfare; and
- When appropriate, pertinent information will be provided to the subjects at a later date.

Step 2: Waiver, Alteration, or Waiver of Documentation

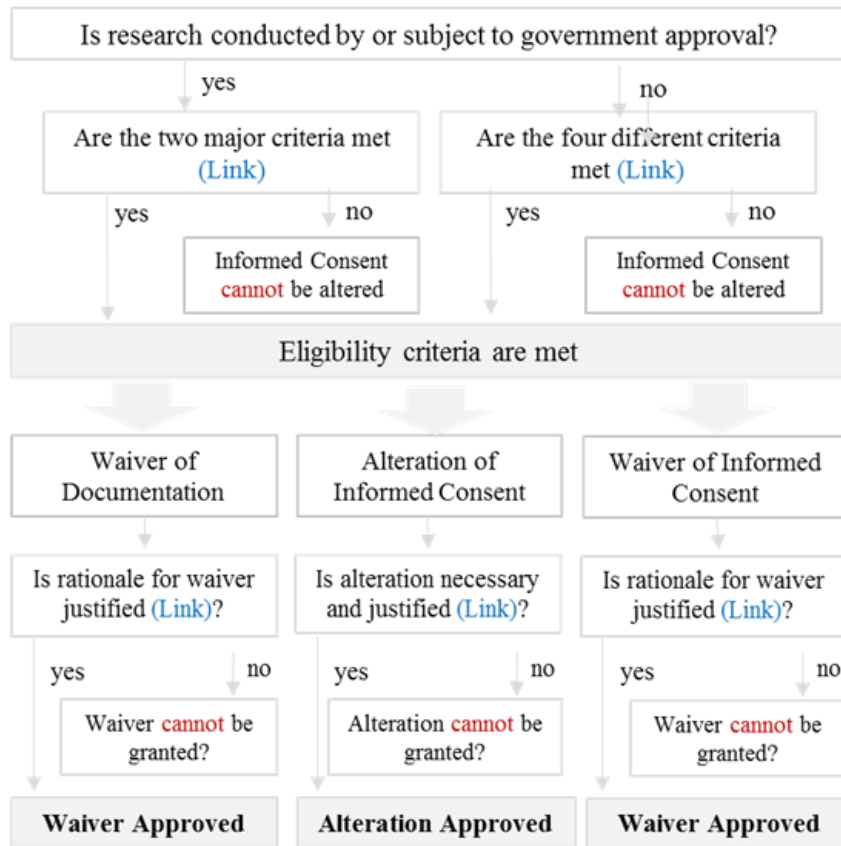
If the research meets the eligibility conditions from step 1, the researcher must determine whether to seek an alteration of the requirements for informed consent, a waiver of *documentation* of informed consent, and/or a waiver of informed consent.

- **Waiver of Documentation:** A waiver of documentation of informed consent is appropriate when the following conditions are met:
 - The consent document would be the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality, and
 - The research involves no more than minimal risk and involves no procedure for which written consent is normally required outside the research context.
- **Waiver of Informed Consent:** If a waiver of consent is requested, the researcher must provide an argument for the necessity and acceptability of a waiver. The IRB will check for the following requirements:
 - The argument for a waiver of informed consent supports the conditions for eligibility from step 1 (e.g., the alteration will not adversely affect the subjects' rights and welfare, etc.).
- **Alteration of Informed Consent:** If the researcher is seeking alteration of informed consent (if, for example, deception is necessary), then he/she must completely describe the specific

alterations requested, referencing the appropriate requirement of informed consent from the document, “Informed Consent: Research Involving Adults.” He/she must also provide an argument for the necessity and acceptability of the alteration. The IRB will check for the following requirements:

- The requested alteration is adequately described, and
- The argument for alteration of informed consent supports the conditions for eligibility from step 1 (e.g., the alteration will not adversely affect the subjects' rights and welfare, etc.).

Alterations or Waivers of Consent



*Note: For more detailed information about waivers and/or alterations please [check here](#).

Additional Considerations

The following section provides further information on how to deal with specific informed consent conditions/scenarios.

Risks of Injury

- Include an injury clause if any risk of injury exists (physical or psychological). Sample statement:

"I understand that medical care is available in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. I also understand that I am not waiving any rights that I may have against the university for injuries resulting from negligence of the University or investigators."

- Referral information (including a phone number) for those who wish to seek assistance should also be included (e.g., Counseling and Psychological Services).

Issue with Anonymity and Confidentiality

- For surveys that are anonymous, also known as passive consent, the informed consent form does not need to be signed. The researcher should apply for a waiver of documentation in this case. If passive consent is used, a statement like the following must be included;

“Completion and return of the survey, questionnaire, etc. implies that you agree to participate and your data may be used in this research.”
- NOTE: If there is any means of identifying a participant, a signed consent form is required (unless a complete waiver of consent has been approved)
- If surveys are to be administered electronically, but not anonymously,
 - state that there is only limited assurance of confidentiality due to the technology of the Internet; and
 - provide a space for participants to type their names and the date → this will replace the signature lines on the paper consent
- If audio- or videotaping will be used, state:
 - where tapes will be stored,
 - when tapes will be destroyed (within a definitive time frame such as “by the year 2014” or “tapes will be destroyed immediately following transcription”), and
 - who will have access to the tapes.

Use of Deception

- If deception is involved and the full purpose of the study will not be disclosed to participants until their participation has ended, a statement such as this needs to be included:

“Because the validity of the results of the study could be affected if the purpose of the study is fully divulged to me prior to my participation, I understand that the purpose of the study cannot be explained to me at this time. I understand that I will have an opportunity to receive a complete explanation of the study's purpose following the completion of the study.”
- If the consent statement will affect the outcome of the research, a thorough description of the debriefing as well as justification statement should be inserted in the methodology section of the proposal.

Use of Compensation

- If extra credit or course credit is offered as compensation for participation, the consent form must state what the alternatives to participating are to earn equivalent extra credit or course credit.
- If compensation is offered, the following statement may need to be included in the consent form,

“If you are an employee of University of North Georgia, the compensation you receive for participation will be treated as taxable income and therefore taxes will be taken from the total amount. If you are not employed by University of North Georgia, total payments within one calendar year that exceed \$600 will require the University to annually report these payments to the IRS. This may require you to claim the compensation that you receive for participation in this study as taxable income.”

Minor Assent and Guardian Consent

Researchers must provide the IRB a complete description of how they will obtain consent from the participant's legal guardian(s) and assent from the participant (the minor). Unless the researcher seeks a waiver and/or alteration of the consent procedure (see below), BOTH the guardian consent and assent by the minor must be obtained and documented.

Guardian Consent

If the participant is a child, defined as persons who have not attained the legal age for consent under the applicable law of the jurisdiction in which the research will be conducted, the Common Rule (45 CFR 46, Subpart D, section 408) stipulates that the researcher – for the standard consent process – needs to obtain informed consent from BOTH parents. However, there are certain exceptions to this rule, as outlined below:

Exceptions:

- The minor has only one guardian (examples: one parent is deceased, unknown, incompetent or not reasonably available; or only one parent has legal responsibility for the care and custody of the child); or
- If the research is of minimal risk or the benefits outweigh minimal risks, permission from one parent or guardian may be sufficient.
- The informed consent guidelines may be waived or altered under the conditions listed in 45 CFR 46, Subpart A, 46.116c&46.116d, as outlined in the section waiver and/or alternation of standard guardian consent.

Standard Guardian Consent

The standard guardian consent form needs to contain all the required consent elements and information (see here for more information). The only difference between standard guardian consent and standard consent is that the researcher will obtain the consent and signature of the guardian, rather than the participant.

Waiver and/or Alteration of Standard Guardian Consent

The standard consent process may be – under certain circumstances – altered and/or waived. The following section is based on 45 CFR 46, Subpart A, 46.116c&d and specifies how the IRB will determine whether a waiver or alternation is viable as well as detail 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 based on criteria specific to the nature of proposed research.

Research Conducted by or Subject to Government Approval

If the research is conducted by or subject to the approval of state and/or local government officials, the following two conditions must be met:

- The project must be designed to study, evaluate, or otherwise examine at least one of the following:
 - public benefit of service programs,
 - procedures for obtaining benefits or services under those programs,
 - possible changes in or alternatives to those programs or procedures, or
 - possible changes in methods or levels of payment for benefits or services under those programs.

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

Default Consent-Assent Process

Parental Consent: Consent of Both Parents Needed

Option 1: Written Consent

Required IRB Material

- IRB Form 3.1

Option 2: Oral Consent

Required IRB Material

- Name of Witness
- Oral Consent Document
- Short Form Consent

*Note: If parents are non-native speakers with limited English fluency, the PI will need to provide translations of the consent documents.

Child Assent

Option 1: Written Assent

Required IRB Material

- Assent Form

Option 2: Oral Assent

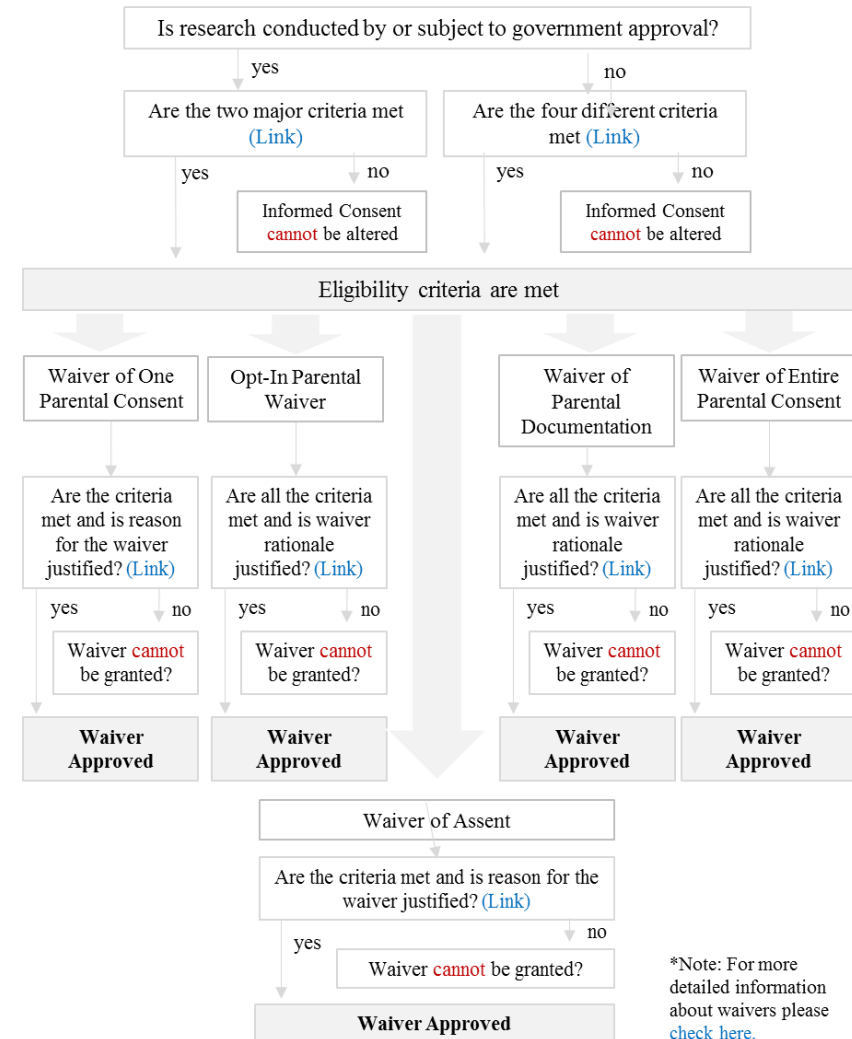
Required IRB Material

- Name of Witness
- Oral Assent Document
- Short Form Assent

*Note: If child is a non-native speakers with limited English fluency, the PI will need to provide translations of the assent documents.

**Note: The decision as to whether to use a written or oral assent should be made on a range of different considerations such as the cognitive and psychosocial maturity of the child or his/her reading ability.

Alterations or Waivers of Consent/Assent



*Note: For more detailed information about waivers please [check here](#).

All Other Research

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

- The research must not involve greater than minimal risk or involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.
- The research must not be practicably possible to conduct without the waiver or alteration;
- Waiving or altering the informed consent must not adversely affect the subjects' rights and welfare; and
- When appropriate, pertinent information will be provided to the subjects at a later date.

Step 2: Waiver, Alteration, or Waiver of Documentation

If the research meets the eligibility conditions from step 1, the researcher must determine which of the following waivers and/or alterations applies, based on 45 CFR 46 Subpart A, 46.116 and 45 CFR 46, Subpart D, 46.404&405.

- **Waiver of One Guardian Consent:** This waiver (if granted) allows the researcher to obtain informed consent requirement from only ONE of two legal guardians. There are two variations of this waiver (with the last technically not being a waiver).
Researcher must meet one of the following conditions to be eligible (check one):
 - **Variant 1:** Consent of only one legal guardian may be sufficient for research not involving greater than MINIMAL RISK, as long as adequate provisions are made for soliciting the assent of the minors and the permission of their legal guardian.
 - **Variant 2:** Consent of only one guardian may also be sufficient for research that involves GREATER THAN MINIMAL RISK in cases where the research presents the prospect of direct benefit to the minor. The following criteria, however, needs to be met:
 - The risk is justified by the anticipated benefit to the subjects,
 - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and
 - Adequate provisions are made for soliciting the assent of the children and permission of their parents.
 - **Variant 3:** While technically not a waiver, consent by only one guardian can be approved if the researcher can – convincingly – demonstrate that the minor – for all intents and purposes – has only one guardian (examples: one parent is deceased, unknown, incompetent or not reasonably available; or only one parent has legal responsibility for the care and custody of the child).
- **Opt-In Waiver:** In some cases, it may be difficult to get guardians to actively opt in the research. In cases where the research involves MINIMAL RISK, the researcher may apply for an opt-in waiver. If granted, the waiver would allow the researcher to alter the consent process by giving parents the option to “opt-out” from the research. Parents that do NOT make use of this option then are considered to have passively consented to have their minors participate in the research. The PI needs to justify the use of an opt-in waiver and the IRB must approve it.
- **Waiver of Documentation of Consent:** A waiver of documentation of consent may be granted when the following conditions are met:
 - The consent document would be the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality,
 - The research involves no more than minimal risk and involves no procedure for which written consent is normally required outside the research context, and
 - The research cannot be reasonably done without the waiver of documentation.
- **Waiver of Guardian Consent:** This waiver – if granted – would remove the requirement of obtaining consent from the minor's guardian/s. The waiver may be granted if the following conditions are 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 children), and
- an appropriate mechanism (for example, appointing a child advocate or an assent monitor) is in place to protect the children.

Assent (Minor)

The researcher must provide the IRB with a complete description of the procedure for obtaining assent. Assent – like adult consent – can be obtained via oral or written consent procedures (please check here for more information on adult written and oral consent).

Standard Assent

Alongside the assent documentation, the researcher may wish to provide the IRB a description of the cognitive and social disposition of the subjects to enable the IRB to determine if all of the following [assent requirements](#) are met:

- The assent procedure is appropriate for the age, maturity, and psychological state of the subjects;
- The assent procedure provides an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort); and
- The assent procedure reflects a reasonable effort to enable the child to understand, to the degree they are capable, what her/his participation in research would involve.

Note: In other words, for example, an assent form for an elementary school student should look different than that of a high-school student (i.e., the high school student consent being closer to that of an adult → for more information on adult consent procedures check here).

Waiver of Child Assent

There are three types of circumstances in which a waiver of participant assent may be approved:

- **Waiver I:** If the capability of some or all of the participants is so limited that they cannot reasonably be consulted;
- **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.

Part III: Adults with Limited Decision-Making Capacity

Adults with conditions that affect their ability to provide informed consent are considered a vulnerable population. This includes people who are cognitively impaired or who have Alzheimer's disease, dementia, mental illness, or any other condition resulting in limited or fluctuating decision-making capacity. In such cases, researchers must describe how the subject's capacity to consent will be assessed. For research involving adults who have been legally declared incapable of making informed decisions, the researcher must obtain the consent of the legally authorized representative (LAR) of the subject. Researchers must consult and cite applicable state law(s) regarding LARs in the description of the consent process. In all cases, the assent of the participant must be obtained.

LAR Consent

If the participant is an adult who had been legally declared unable to consent (e.g. cognitive impaired adults), the researcher must obtain informed consent from the LAR as outlined in the standard consent procedures for adults (link?). However, the informed consent guidelines may be waived or altered under the conditions listed in 45 CRF 46, Subpart A, 46.116c&46.116d, as outlined in the section waiver and/or alternation of standard guardian consent. The LAR consent form needs to contain all the required consent elements and information (see here for more information). The only difference between the LAR consent and standard consent is that the researcher will obtain the consent and signature of the LAR, rather than the participant.

Waiver and/or Alteration of LAR Consent

The LAR consent process may be—under certain circumstances—altered and/or waived. The following section is based on 45 CRF 46, Subpart A, 46.116c&d and specifies how the IRB will determine whether a waiver or alternation is viable as well as details 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 based on criteria specific to the nature of proposed research.

Research Conducted by or Subject to Government Approval

If the research is conducted by or subject to the approval of state and/or local government officials, the following two conditions must be met:

- The project must be designed to study, evaluate, or otherwise examine at least one of the following:
 - public benefit of service programs,
 - procedures for obtaining benefits or services under those programs,
 - possible changes in or alternatives to those programs or procedures, or
 - possible changes in methods or levels of payment for benefits or services under those programs.
- It must not be practicably possible to conduct the research without the waiver or alteration.

LAR: Has the Adult been declared legally incapable of making decisions?

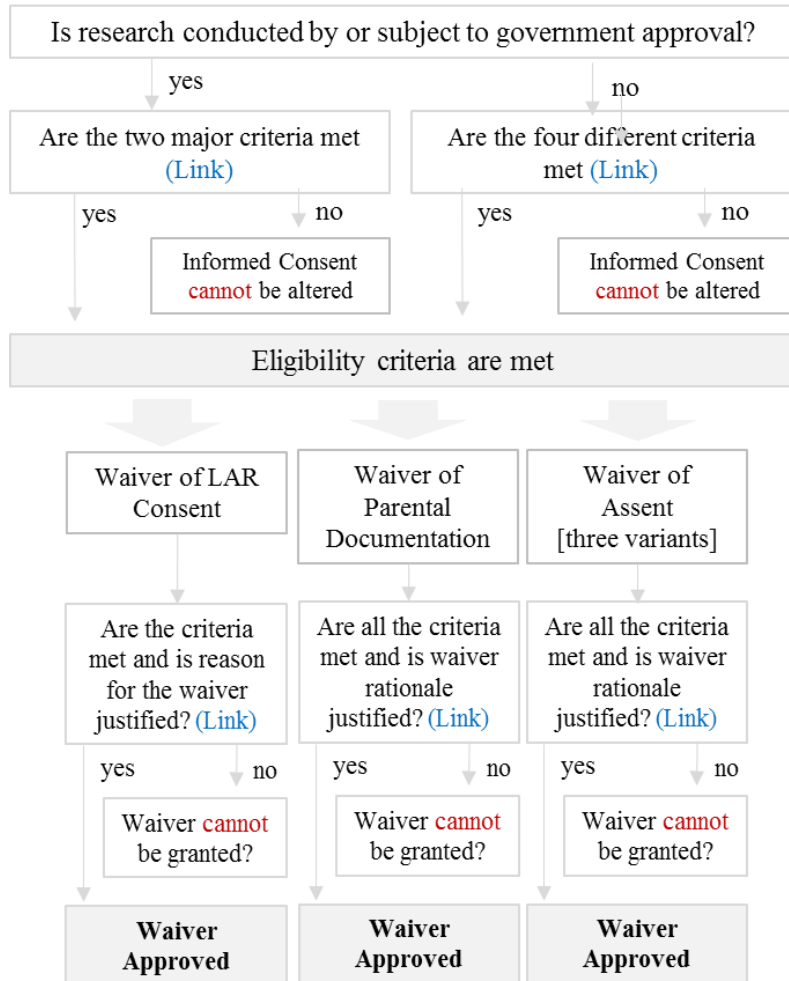
yes

Use standard consent-assent procedures and/or apply for waivers/alterations

no

Discuss decision making capacity of adults AND justify your approach to the informed process

Alterations or Waivers of Consent/Assent



*Note: For more detailed information about waivers please [check here](#).

Standard LAR Consent

Option 1: Written Consent

Required IRB Material

- IRB Form 3.1

Option 2: Oral Consent

Required IRB Material

- Name of Witness
- Oral Consent Document
- Short Form Consent

*If the LAR are non-native speakers with limited English fluency, the PI will need to provide translations of the consent documents.

**If the adult with decision-making capacity has NOT been declared legally incapable of making decisions, the PI will need to provide sufficient information about the adult's capacity to consent and the steps that will be taken to assure the integrity of the informed consent process.

Standard Assent of Adult Unable to Consent

Option 1: Written Assent

Required IRB Material

- Assent Form

Option 2: Oral Assent

Required IRB Material

- Name of Witness
- Oral Assent Document
- Short Form Assent

*If the adult unable to consent is a non-native speakers with limited English fluency, the PI will need to provide translations of the assent documents.

**The decision as to whether to use a written or oral assent should be made on a range of different considerations such as the cognitive and psychosocial maturity of the adult or his/her reading ability.

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;
- Waiving or altering the informed consent must not adversely affect the subjects' rights and welfare; and
- When appropriate, pertinent information will be provided to the subjects at a later date.

Step 2: Waiver, Alteration, or Waiver of Documentation

If the research meets the eligibility conditions from step 1, the researcher must determine which of the following waivers and/or alterations applies, based on 45 CFR 46 Subpart A, 46.116 and 45 CFR 46, Subpart D, 46.404&405.

- **Waiver of Documentation of Consent:** A waiver of documentation of consent may be granted when the following conditions are met:
 - The consent document would be the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality,
 - The research involves no more than minimal risk and involves no procedure for which written consent is normally required outside the research context, and
 - The research cannot be reasonably done without the waiver of documentation.
- **Complete Waiver of LAR Consent:** This waiver – if granted – would remove the requirement of obtaining consent from the LAR. The waiver may be granted if the following conditions are met:
 - the research is designed to study conditions in adult unable to consents for which guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or an abused adult unable to consent), and
 - an appropriate mechanism (for example, appointing an adult unable to consent advocate or an assent monitor) is in place to protect the adult unable to consent.

Assent of Adults with Limited Decision-Making Capacity

The researcher must provide the IRB with a complete description of the procedure for obtaining assent. Assent – like adult consent – can be obtained via oral or written consent procedures (please check here for more information on adult written and oral consent).

Standard Assent

Alongside the assent documentation, the researcher may wish to provide the IRB a description of the cognitive and social disposition of the subjects to enable the IRB to determine if all of the following [assent requirements](#) are met:

- The assent procedure is appropriate for the cognitive and psychological state of the subjects;
- The assent procedure provides an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort); and
- The assent procedure reflects a reasonable effort to enable the subject to understand, to the degree they are capable, what her/his participation in research would involve.

Waiver of Assent

There are three types of circumstances in which a waiver of participant assent may be approved:

- **Waiver I:** If the capability of some or all of the participants is so limited that they cannot reasonably be consulted;

- **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.