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The HSPPO has developed Informed Consent Document templates that provide investigators with guidance in developing this form. The template prompts the investigator to add details about the study, levels of risk, and other issues as indicated. The format and language in the template have been approved by the IRB.

Informed consent is a continuing process whereby the investigator and research participant have an on-going dialogue about all aspects of a research study that might inform a participant’s decision to take part in the study and their decision to continue their involvement as a participant. The purpose of the consent process is to assure knowledgeable decision-making and voluntary participation.

This process generally includes:
   1. Bringing the research study to the notice of potential participants;

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2. Presentation and explanation of the study activities to the participant or their legally authorized representative (LAR);
3. Documentation of the informed consent via a signed and dated written consent document;
4. Ongoing discussions between the investigator and the participant regarding continued participation in the study.

The consent process must:
1. Provide sufficient opportunity for the participant, or the participant’s legally authorized representative (LAR), to consider whether to participate;
2. Minimize the possibility of coercion or undue influence;
3. Be free of exculpatory language; and
4. Be in language understandable to the participant or their representative.

The IRB also requires that the circumstances of the consent process be culturally and linguistically appropriate for the intended participants.

Refer also to Chapter 14.6 for more information on the consent document, and Principal Investigator responsibilities in the informed consent process.

### 12.1 Requirements for Informed Consent

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Unless waived by the IRB, legally effective informed consent must be obtained from participants or their LARs as a condition for protocol approval. All relevant requirements in OHRP in 45 CFR 46.111 and 46.116, and in the FDA regulations in 21 CFR 50.20, 50.25, 50.27 and 56.111 that are applicable to the consent process and the consent document must be satisfied.

**IRB Evaluation of Compliance with Informed Consent Requirements**

The evaluation of compliance is achieved by:
1. IRB review of the informed consent process information and document(s) provided by the PI.
2. Consent form reviews at the time of continuation comparing signed and dated consent forms with the IRB approved versions.
3. Observation of the consent process, performed either as a periodic review function of the HSPP Compliance Auditors, or as requested by the convened IRB. See Chapter 12.7.

### 12.1.1 Elements of Informed Consent

Legally effective informed consent includes the eight basic required elements and the six additional elements specified in 45 CFR 46.116 and 21 CFR 50.25. Informed consent requirements for vulnerable and other special populations are addressed in Chapter 12.2. [Guide 022 IRB Approval of Research Criteria](#).
12.1.2. Additional Consent Requirements

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<td>The University of Louisville has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.</td>
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University legal counsel can provide assistance to investigators and the IRB in resolving any conflicts among applicable laws.

1. HIPAA
2. HIV Testing or Research on AIDS
3. Genetic Testing
4. Data and Tissue Repositories
5. International research
6. Other Federal Agencies

1. Health Insurance Portability and Accountability Act (HIPAA)

If the study application involves protected health information (PHI) as defined by HIPAA, then HIPAA authorization may be included in the consent process. HIPAA authorization is an authorization to use or disclose PHI, and must be executed by signature, date, and relationship of LAR (if applicable). Consent templates incorporating HIPAA authorization language are provided on the Human Subjects Protection Program Office website.

2. HIV Testing; Research on AIDS

**Public Health System (PHS) Funded Research**

If the protocol is supported by funding from the Department of Health and Human Services and includes testing for HIV, the consent documentation must state that identifiable participants will be informed of their results and provided with the opportunity for counseling. The IRB requires this except in cases where it is not required by PHS policy.

**HIV testing and disclosure:**

Individually identifiable research records of AIDS-related research and/or HIV testing are confidential and may only be disclosed with the prior written consent of the participant and may be subject to Kentucky Legislature 214.181.

Additionally, the following language must be inserted into the informed consent document:

“This study involves testing for ______. If you have a positive test, we are required by Kentucky law to report the results to the local Health Department nearest where you live or to the Kentucky Department for Public Health.”

3. Genetic Testing

If a protocol includes genetic testing, the IRB requires that the informed consent information disclose the risks specific to this type of testing. Genetic testing includes research that studies the characteristics, genes, and gene versions that are transmitted by parents to offspring. This may include many types of information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual or family medical histories, reactions to medication, and responses to treatment. The IRB includes detailed provisions and issues in its informed consent template that should be considered by the Principal Investigator when the research includes genetic testing. The template is also used by IRB staff and members as a guide for their review of such a consent document.
As required by federal regulations, any study that involves genetic information must include the following statement as written within the informed consent:

“Research Involving Genetic Information
A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

1. Health insurance companies and group health plans may not request your genetic information that we get from this research or use your genetic information when making decisions regarding your eligibility or premiums.
2. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Employers with 15 or more employees, health insurance companies, and group health plans must follow this law. This new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.”

4. Data and Tissue Repositories
The NIH guidance on Data and Tissue Repositories is of interest to investigators who collect data or tissues of participants for repositories, and IRB staff and members who review such protocols.

When such repositories collect individually identifiable health information of participants, the HIPAA privacy regulations in 45 CFR Parts 160 and 164 must also be satisfied. This may require either a written HIPAA authorization from the participants or a waiver of authorization by the IRB. These requirements are discussed in Chapter 11.

4. International Research
When conducting research in certain communities or social contexts, whether in the U.S. or abroad, it may be inappropriate to document consent by using the standard written and signed consent document. Other consent procedures may be more culturally or socially sensitive and may afford better protection to participants.

Investigators may ask the IRB to consider a waiver or alteration of some of the mandatory elements of consent [45 CFR 46.116(d)], or a waiver of documentation of consent [45 CFR 46.117(c); 21 CFR 56.109(c)]. See Chapter 12.5.

5. Requirements - Other Federal Agencies
Additional requirements might apply, depending on the source of support/funding (e.g., Department of Defense, Department of the Navy, Department of Justice): see Guide-014 - Other Federal Agencies - Additional Requirements

Consult Legal Counsel If Necessary: PIs should contact the legal advisor to the IRBs in the Office of University Counsel to assist in determining who under local law may serve as a legally authorized representative, if children or adults who are unable to consent may be enrolled as participants.
12.1.3. Consent Templates and Glossary of Lay Terms

The Human Subjects Protection Program website provides consent form templates, in which certain additional information may need to be provided to participants. For research involving children, an assent template is also provided.

To assist PIs in preparing consent documents comprehensible to lay persons (i.e., at approximately 8th grade level) a glossary of lay terms is also available on the HSPPO website.

12.1.4. Short Form Consent Process

Federal regulations permit the use of a short form consent process (45 CFR 46.117(b)(2)) with the prior approval of the IRB. However, the IRB encourages the use of a full consent form translated into the participant’s language whenever possible.

The short form consent process may be approved by the IRB, on a protocol-specific basis, for use with participants who are non-English speaking. The IRB considers the study complexity and the amount and duration of participant involvement when determining if using the short form consent process is appropriate and can be approved. See section 12.2.5 for information on consenting non-English speaking participants. Information on the requirements for use of a short form consent process is available on the OHRP website.

12.1.5 Re-consenting Study Participants

Consenting is an ongoing process. When changes to the informed consent are made, it may be necessary to re-consent subjects. All applicable criteria below would trigger re-consenting a subject:

1. The investigator of the study changes.
2. The contact information in the Informed Consent for the subject to reach a member of the study team changes.
3. Any change to the informed consent that would affect the subject’s willingness to continue participation (e.g. changes to risks, procedures, new findings, etc.).
4. Research related injury payment changes.
5. Subject previously signed an assent and turns 18 years old while participating in the study. They must be re-consented to the most current informed consent and research authorization (if applicable).
6. Compensation to the subject is changed.
7. A subject who regains the cognitive ability to consent as determined by the PI, must be re-consented using standard consenting procedures.
8. In the event a subject has been initially consented by a LAR, and a LAR of higher priority subsequently notifies the investigator of that relationship to the subject, the investigator must defer to the higher priority LAR’s decision regarding whether the subject will continue to participate or to withdraw from the study.
9. Investigators shall describe to potential LARs the nature of ongoing decisions during the study regarding the subject’s participation, decision to participate in certain procedures, changes to the study, etc., in order to ensure that the LAR will be willing to undertake these on-going responsibilities.
10. In the event that the LAR dies, the subject must be re-consented subsequently upon any event that would otherwise trigger re-consenting the subject.

Additional criteria not mentioned above may also require re-consent. How participants will be notified of the changes above, will depend on the nature of the study and where subjects fall within the protocol schedule of events. The IRB will notify the researcher on the approval letter if re-consenting is necessary.
If no changes are made to the consent at time of continuing review, active participants do not need to be re-consented.

12.2 Consent Procedures for Vulnerable and Other Special Populations Including Consent by a Legally Authorized Representative

“Surrogate” and “legally authorized representative” have the same meaning when used in this Chapter 12 and the HSPP.

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</tr>
<tr>
<td>II.4.B</td>
<td>The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.</td>
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Determining the decision-making capacity of the subject

Whenever possible, investigators will attempt to obtain informed consent directly from the subject.

The application reviewed by the IRB must detail a protocol-specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may qualify for LAR consent. While there are no standardized measures for determining capacity to consent, subjects may be assessed on their ability to understand and to express a reasoned choice concerning the:

1. Nature of the research and the information relevant to his/her participation;
2. Consequences of participation for the subject’s own situation, especially concerning the subject’s health condition; and
3. Consequences of the alternatives to participation.

The capacity to understand all of these concepts may not be necessary in order to consent to participate in a particular research protocol – greater capacity is required for higher-risk protocols. This standard should be used for determining the capacity of the LAR as well, if necessary.

In protocols in which a LAR’s consent has been approved by the IRB, assessment of the decision-making capacity of the LAR should be implemented only when the investigator has reason to believe that the LAR’s decision-making capacity may be impaired.

If the investigator determines that the subject lacks decision-making capacity, the investigator shall inform the subject of the investigator’s intent to seek LAR consent and shall document this discussion in the research file. If the subject is unconscious due to trauma or due to medication administered to treat that trauma, the investigator shall document that condition in the research file and the above described required discussion regarding intent to seek LAR consent shall be waived. If the subject expresses resistance or dissent to participation or to the use of LAR consent, the subject shall be excluded from the research study.

LAR consent for participation in a research study should be employed only to the extent that it is consistent with the intent of 45 CFR 46, 45 CFR 46 and 21 CFR 50 and all other federal and state laws and regulations pertaining to protecting human subjects participating in research.
IRB Review Criteria for use of LAR

While no specific set of criteria can encompass all conceivable situations in which the use of LAR consent complies with the intent of 45 CFR 46 and 21 CFR 50, the following criteria should be viewed as fundamental guidelines to be used by the UofL IRBs when determining whether to permit the use of LAR consent for participation in a research study.

1. LAR consent should be considered only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research subject.
2. LAR consent is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB.
3. LAR consent is requested through the application process for new research studies or through the modification process for an existing protocol.
4. As in all human subjects research, the IRB must consider carefully the risk/benefit ratio of the particular study for the targeted population.
5. As with all mental health research conducted by the University, subject confidentiality and privacy must be protected.
6. The IRB may consider whether the frequency of a specific protocol’s review cycle should be reasonably modified when LAR consent is implemented.
7. The IRB application/amendment form should detail the criteria under which LAR consent may be sought.

The IRB may consider additional safeguards to protect participants, such as:

- Requiring the involvement of participant advocates
- Requiring independent monitoring
- Requiring waiting periods
- Appointing a monitor to supervise the informed consent process.

Such decisions may be based on the amount of risk involved in the research and the likelihood that participants will derive health benefits from their participation.

Determination of who may act as a LAR

In a non-emergency room environment, LAR consent may be obtained from any of the following potential LARs who has reasonable knowledge of the subject, in the following descending order of priority:

1. The judicially-appointed guardian of the person, if the guardian has been appointed and (for biomedical research) if medical decisions are within the scope of the guardianship;
2. The attorney-in-fact named in a durable power of attorney, if the durable power of attorney (for biomedical research) specifically includes authority for health care decisions;
3. The spouse of the person;
4. If the person is incompetent, an adult child of the person, or if the person has more than one (1) child, the majority of the adult children who are reasonably available for consultation;
5. The parent(s) of the person;
6. The nearest living relative of the person, or if more than one (1) relative of the same relation is reasonably available for consultation, a majority of the nearest living relatives.
In non-emergency room research settings, no LAR consent may be utilized if there is a disagreement whether to consent among the members of the highest available priority class of LARs, (e.g., where two members of persons in the highest of categories, 6, disagree and there is no person in categories 1-5 available.

In non-emergency room research settings only, the investigator is responsible for ensuring that the LAR:
1. Has reasonable knowledge of the subject;
2. Is familiar with the subject’s degree of impairment;
3. Is willing to serve as the legally authorized representative;
4. Understands the risks, potential benefits, procedures and available alternatives to research participation;
5. Makes decisions based on the subject’s known preferences, and where the subject’s preferences are unknown, makes decisions based upon the LAR’s judgment of what the subject’s preferences would be.

In an emergency room setting, the order of priority does not apply. LAR consent may be obtained from a
1. LAR decision maker who is any of the following:
2. The judicially-appointed guardian of the person, if the guardian has been appointed and (for biomedical research) if medical decisions are within the scope of the guardianship;
3. The attorney-in-fact named in a durable power of attorney, if the durable power of attorney (for biomedical research) specifically includes authority for health care decisions;
4. The parent or spouse of the person;
5. If the person is incompetent, an adult child of the person, or if the person has more than one (1) child, the majority of the adult children who are reasonably available for consultation;
6. The nearest living relative of the person, or if more than one (1) relative of the same relation is reasonably available for consultation, a majority of the nearest living relatives.

In emergency room research settings, no LAR consent may be utilized if there is a disagreement whether to consent among any available LARs.

In both a non-emergency room and an emergency-room setting:

1. LARs are prohibited from receiving any financial compensation for providing consent. This does not prohibit the LAR from being reimbursed for expenses the LAR may incur related to the LAR’s participation in the research.
2. In protocols in which a LAR’s consent has been approved by the IRB, assessment of the decision-making capacity of the LAR should be implemented when the investigator has reason to believe that the LAR’s decision-making capacity may be impaired.

12.2.1 Adults with Impaired Decision-Making Capacity - “Cognitively Impaired”

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Special consideration is given to protecting the welfare of vulnerable participants, such as children, prisoners, pregnant women, fetuses, and mentally disabled persons, handicapped persons, or economically or educationally disadvantaged persons (45 CFR 46.111(b) and 21 CFR 56.111(b)). There are specific regulatory provisions for research involving pregnant women, fetuses, and neonates (45 CFR 46, Subpart B), prisoners (45 CFR 46, Subpart C), and children (45 CFR 46, Subpart D and 21 CFR 50 Subpart D). Special considerations for providing legally effective informed consent for these participants are discussed in the following sections.

Also see Chapter 9.3 concerning determination of the risks to vulnerable populations as defined in applicable federal regulations, and specifically for determining the required risk categories in protocols involving children and prisoners.

**Cognitively Impaired Participants**

The IRB will determine that adequate provisions are made for seeking the assent of the cognitively impaired person, as well as the informed consent of the person’s LAR when in the judgment of the IRB the person is capable of providing assent. In determining whether the cognitively impaired person is capable of assenting, the IRB will take into account the age, maturity, and psychological state of the person involved. This judgment may be made for all cognitively impaired persons to be involved in research under a particular protocol, or for each individual, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the cognitively impaired persons is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the individuals and is available only in the context of the research, the assent of the persons is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

**Assessment and Determination of Incompetence**

If it is believed that the prospective participant is not competent to consent for him or herself, competency must be determined by a physician (generally an investigator on the protocol). A determination of incompetence shall be made after an appropriate medical evaluation that concludes there is little or no likelihood that the participant will regain competence in a reasonable period of time, or as established by legal determination. This definition of incompetence is not limited to the legal definition but also may be a clinical judgment that a person lacks the capacity to understand the circumstances of participating in research and to make an autonomous decision to take part.

Competency should be evaluated on an individual basis to avoid incorrect assumptions as to an individual’s ability to make decisions. Criteria for determining competence might vary according to the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gain can be anticipated.

Some approaches to this assessment include:

- A post-consent quiz documenting the participants’ knowledge of critical elements in the informed consent document - i.e., nature of the illness being studied, voluntary nature of participation, ability to withdraw at any time, consequences of withdrawing, possible risks and benefits of participation, procedures involved, time required, confidentiality, and whom to call with any questions.

- The study investigators may ask a physician/psychologist outside the research team to evaluate the potential participant’s decisional capacity.
Protocols submitted to the IRB should describe how capacity to consent will be determined, by whom it will be done, and what procedures will be in place to assure that legally effective informed consent is provided for all individuals found to lack decision-making capacity.

### 12.2.2. Pregnant Women, Fetuses and Neonates

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In accordance with OHRP, the IRB requires that additional protections be provided to pregnant women, fetuses and neonates involved in research. General considerations related to research involving pregnant women, fetuses and neonates are set out in Chapter 9. The special informed consent requirements are specified in 45 CFR 46, Subpart B (OHRP).

**Pregnant Children**

If the pregnant person is under the age of 18 and is not emancipated, the IRB generally requires, consistent with OHRP, that parental permission and child assent be obtained. If the research is therapeutic, and the PI believes that the child’s participation in the research falls into one of the categories under Kentucky law where an un-emancipated minor is permitted to consent to her own medical care, the PI should confirm this with IRB staff or the IRB legal advisor in the Office of the Legal Counsel.

**Nonviable Neonates**

Consent may not be obtained from a legally authorized representative of either or both of the parents of a nonviable neonate. The IRB will not permit elements of the informed consent process to be altered or waived in research involving nonviable neonates, even if the general requirements for waiver are satisfied. *When it has been determined that the neonate is viable*, the neonate is considered a child and the consent requirements laid out below apply.
12.2.3. Children and Consenting Minors

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The IRB imposes additional protections on research involving children, in accordance with 45 CFR 46, Subpart D and 21 CFR 50, Subpart D.

Children in Kentucky under age 18 (unless Emancipated) must have consent given by a LAR. The LAR may be determined by the following:

1. The judicially-appointed guardian of the child, if the guardian has been appointed and if medical decisions are within the scope of the guardianship;
2. The attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for health care decisions;
3. The parent or parents of the child;
4. An adult sibling of the child, or if the child has more than one (1) sibling, the majority of the adult siblings who are reasonably available for consultation;
5. The nearest living relative of the child, or if more than one (1) relative of the same relation is reasonably available for consultation, a majority of the nearest living relatives

Eligibility for Emancipation

Although there’s no law specifying an emancipation procedure in Kentucky, it’s still possible to become emancipated before 18. This can happen in any of the following ways:

- **Marriage:** A child can marry before 18 and be considered a legal adult, this requires parental consent or a court order granting the marriage license.
- **Self-Support:** Moving out of a parent’s home and becoming self-supporting will impliedly emancipate the child, if the parent doesn’t try to get the child back to the home
- **Court Order –** A minor can petition the court for emancipation and, possibly, be granted it by court order.

Assent

When, in the judgment of the IRB, the children are capable of providing assent the IRB may determine that assent is required, that adequate provisions are made for soliciting the assent of the children, and whether and how assent must be documented. Generally, children aged 7 and above may be asked to give their assent to participation. The IRB has developed assent templates for PI use when developing these documents.

The assent form does not replace a thoughtful discussion with the child regarding participation in the research. Investigators should remember that the assent process should take into account, in oral and written communication, the child’s experience and level of understanding. Ultimately, the assent process should illustrate respect for the child and convey the essential information the child requires, in a manner the child can understand, in order to make a decision about participating in the research.
Parental Permission

Parents or legal guardians grant “permission” for children to participate in research. The “permission” form is in essence a consent document and should follow all applicable requirements for informed consent as outlined in this guide. This document should be written to the parent(s) who will give permission for the child.

Whenever possible, the permission of both parents should be obtained; however, current Federal regulations do not require permission from both parents in all research situations. In general, the risk to the child and the prospect of direct benefit for the child as a research subject determine whether single parent/guardian permission may be permitted. If the research involves no greater than minimal risk, permission of one parent is sufficient. If the research involves greater than minimal risk, consent of both parents must be obtained, unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Investigators must have signed permission from parents before contacting children for participation in research.

A child under the age of 18 is not required to sign the parental permission form, however, they must sign the assent form if seven years of age or older.

Conditions of Confidentiality for Parental Permission

The Commonwealth of Kentucky mandates that investigators and their staff report a reasonable suspicion of known abuse or neglect of a child. When research is likely to reveal possible child abuse, such as interviews about personal behavior, child-rearing practices, discipline or when talking to others about the child or specific familial relationships, or when the research is conducted in the subject’s home, a medical facility, or a doctor’s office, the parental permission from should clearly state that the investigator is required to report a reasonable suspicion or known abuse or neglect of a child. The following statement is required for parental permission forms when investigators conduct research with children that requests information regarding sensitive personal or family behavior or is conducted in the subject’s home:

Under Kentucky statute the privilege of confidentiality does not include information about sexual or physical abuse of a child. If a member of the research team has or is given information, she or he is required by law to report it to the authorities. The obligation to report includes alleged or probable abuse as well as known abuse.

12.2.4. Illiterate Participants

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The IRB allows individuals who speak and understand English, but who cannot read the consent materials due to illiteracy, to enroll in a study by “making their mark” (e.g., signing or marking an “X”) on the consent document, after going through the informed consent process.

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study.
An impartial third party should witness the entire consent process and sign the consent document. A video tape or audio tape recording of the consent interview is recommended. Witness signature can be documented using the supplemental signature page located at http://louisville.edu/research/humansubjects/templates/links-to-forms.

**12.2.5. Non-English Speaking Participants**

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<th>AAHRPP Std./Element</th>
<th>Description</th>
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<tr>
<td>II.4.B</td>
<td>The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.</td>
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</table>

Investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English. Participants who do not speak English should be presented with a consent document written in a language understandable to them, and which embody all the elements necessary for legally effective informed consent.

The University of Louisville HRPP and OHRP strongly encourage the use of a full consent form translated into the participant’s language whenever possible. When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is required. In addition, a person fluent in both the participant’s language and English needs to available for research visits.

When a full-length form embodying all elements of consent is required by the IRB to document consent, the IRB requires that appropriately translated consent documents be submitted to the IRB for review and approval prior to their use in enrolling participants.

Investigators may use language translators or interpreter services to obtain consent in a language understandable to the participant or the participant's legally authorized representative. The researcher must document the consent process including who served as a translator. The IRB may utilize expedited review procedures in approving such documents if the English language consent document has already been approved.

Development of non-English language consent forms will typically necessitate translation of the original consent from English to the second language. A certificate of accuracy from the qualified translator should be submitted.

**Short Form Consent Process**

Federal regulations permit the use of a short form consent process (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)) with the prior approval of the IRB; for more information see Chapter 12.1.4 above.


If a non-English speaking subject is encountered unexpectedly, investigators may rely on an oral translation of the English language consent form but should take extra care in the informed consent process to ensure that the subject has understood the study procedures, risks, benefits, etc.

The research subject should be provided with a short form consent document, written in the subject’s native language that summarizes the basic elements of the informed consent.
Consent procedures:

a. The standard (i.e. IRB approved, full description) informed consent document should be presented verbally to the subject in his/her native language and all questions must be answered.

b. With the agreement to participate in the research study, the subject should sign and date the translated “short form” consent document and the witness to the informed consent process should sign and date the “short form” consent document and the standard consent document. The investigator or person obtaining informed consent should sign and date the standard informed consent document.

c. Copies of the signed “short form” consent document and the standard informed consent should be given to the subject with the originals of both documents retained in the investigator’s research records.

d. A statement in the research records should indicate that the translation took place; the name of the translator; and the translator’s belief that the subject understands the study and the consent process.

e. Investigators should consider that in obtaining clinical consent, family members most often shield their loved ones from bad news (i.e. risks of study). A proper medical translator is an important safeguard that should not be set aside lightly.

f. Subsequent modifications of the informed consent document should be fully translated to a language understood by the participant. This could be as an addendum to the consent form.

When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

Who can serve as a translator/interpreter?

- an officer or employee of an official translation bureau or agency
- professor or instructor who is teaching the translated language in an accredited college or university in the United States
- interpreter services provided by the medical facility
- a family member of the participant, only if the participant has declined the use of the above mentioned interpreter.
- If a member of the study staff speaks the participant’s language, the staff member can act as the interpreter and Person Obtaining Consent (POC), but cannot also act as a witness.

Who can be the witness?

- A person who attests to the oral presentation and is conversant in both English and the participants language.
- The witness may be the interpreter

To request the use of a Short Form, submit an amendment in the ESS with the following:

- Explain the intention to use the short form consent process and how the consent will take place.
- Provide the IRB with the plan for ensuring ongoing communication with the participant in a language understandable to the participant.
- Provide certified translations of all documents the participant will be required to complete (surveys/questionnaires).
- Attach the translated Short Form in the participant’s native language.
- Attach the English version of the Short Form.
- Attach the revised English consent form adding witness signature lines as indicated below.

Note: If the English version of the Short Form has not been approved previously by the convened IRB, the amendment will be assigned to a full board meeting per §46.117(b)(2).

“The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.”

________________________________   ______________________ __________
Signature of Witness     Printed Name of Witness Date

12.2.6. Prisoners

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<tr>
<td>II.4.B</td>
<td>The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.</td>
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The IRB considers prisoners to be a vulnerable population because both their incarceration and the constraints imposed on them during their incarceration may render them unable to make a truly informed and voluntary decision regarding whether to participate in research. The IRB imposes additional protections pertaining to biomedical and behavioral research involving prisoners, limits the types of research that can be approved, and requires special consent information as specified in OHRP in 45 CRF 46 (Subpart C). See Chapter 9 and Guide-004-Additional Protections for Research Involving Prisoners. If the Principal Investigator (PI) is not familiar with these legal requirements, the PI who proposes to involve prisoners in research (or who has a participant become incarcerated after enrollment) should contact IRB staff for additional guidance.

12.3 IRB Review of the Consent Process, including Consent Documents

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<tr>
<td>II.3.F</td>
<td>The IRB has and follows written policies and procedures to evaluate the consent process and to require that the Researcher appropriately document the consent process.</td>
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Principal Investigators should refer to Chapter 14 for information regarding the development of an informed consent process and method of documentation appropriate to the type of research and the study population.

PIs must submit for IRB review any consent document(s) and explanation of the circumstances under which informed consent will be sought for new protocols, at continuing review, and whenever a modification to the consent process or documents is requested.

The Protocol Application solicits the information necessary for the IRB to evaluate whether the informed consent process will be appropriately conducted given the protocol-specific circumstances (e.g., level of risk, inclusion of special participant populations) and adequately protects participants, considering issues such as whether:

1. Participants have sufficient time to discuss concerns and decide whether to participate in the research;
2. The possibility of coercion and undue influence is minimized;
3. Communications to the participant or their LAR are in a language understandable to them; and
4. Consent process communications do not include any exculpatory language through which the participant or their LAR is made to waive, or appear to waive, any of the participant’s legal rights, or which releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

The same evaluation criteria apply to review and approval of the consent process and consent document(s) when reviewed by the expedited process, as by regular review.

The IRB staff review the consent document(s) and consent process information. For continuing review or modifications, any new information that could impact participants’ risks (e.g., adverse events) or procedure changes are also examined to ensure the consent document is appropriately updated. Consent process requirements are discussed in Chapter 12.1 above.

The IRB considers the relationship between the person(s) who will solicit, obtain consent, and explain the consent document and the potential participant. The person obtaining consent must be approved personnel on the study and have the required Human Subjects Protections training. The IRB requires that the circumstances of the consent process be culturally and linguistically appropriate for the intended participants, and protects participants by minimizing the possibility of coercion and undue influence and allowing adequate time for them to discuss and decide whether to participate in the research.

The IRB also reviews any direct advertising (e.g., newspaper, TV or radio ads, posters, flyers, letters or postcards, emails, postings on bulletin boards/ internet/ web), since it is considered by the FDA “to be the start of the informed consent and subject selection process.” In order to approve advertisements, the IRB must determine that the direct advertising is not unduly coercive and does not promise a certainty of cure or favorable outcome or other benefits beyond what is outlined in the consent and the protocol. (See Chapter 10.)

**Consideration at an IRB Convened Meeting**

The IRB determines that all basic, and all additional elements appropriate to the research, are included in the consent process. All the relevant requirements in OHRP in 45 CFR 46.109(b) and 46.116, and in the FDA regulations in 21 CFR 56.109(b), 50.20 and 50.25, that are applicable to the consent process and the consent document, must be satisfied for IRB approval. See [Guide-022-IRB Research Approval Criteria](#).

The IRB may require revisions to the consent document as a condition for approval. If the revisions are minor and can be dictated verbatim at the meeting, the protocol may be approved contingent upon the revisions being made. An IRB member must confirm that the revisions have been implemented as specified before the contingency can be removed. If revisions are greater than minor or cannot be dictated verbatim at the convened meeting, the protocol is deferred, and the consent document is referred back to the PI for the drafting of the revisions and submission at a future convened meeting. If the PI objects to the revisions specified by the IRB, the PI must submit a new consent document for future consideration.

The approval date and the expiration date must be added to the consent document(s). (See Chapter 14.6).

**12.4 Documentation of Informed Consent – Signature Requirements**

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II.3.F  The IRB has and follows written policies and procedures to evaluate the consent process and to require that the Researcher appropriately document the consent process.

**Documentation of informed consent** refers to a participant, or their legally authorized representative (LAR), signing and dating an IRB stamped approved, dated consent document, which includes the basic elements of informed consent and the additional elements of informed consent, when appropriate (45 CFR 46.116; 21 CFR 50.25(a),(b)).

When a person agrees to be a participant in a research study, signing the consent document indicates that they have participated in the consent process, and understand the information provided to them.

Documentation requirements for informed consent are specified in OHRP in 45 CFR 46.117(a),(b) and FDA 21 CFR 50.27(a),(b).

In order to approve research, the IRB must determine that informed consent will be appropriately documented, unless the IRB waives documentation under OHRP or FDA regulations (see Chapter 12.5.2.). If a participant lacks the capacity to consent, then consent for research must be obtained from their LAR. See Chapter 12.2 above.

Consent is documented through use of a written consent document signed and dated by the participant or their legally authorized representative that embodies all of the required elements of informed consent (see Chapter 12.1). Only the IRB approved informed consent document may be used, and unless the requirement is waived by the IRB, the document must be signed by the participant (or the participant’s LAR), and a copy must be given to the person signing the form. FDA regulations require that the signature be dated. As a local requirement, the Principal Investigator or Sub-Investigator(s) on the study must also sign and date the consent within 14 days of subject signature.

In certain cases, it may be necessary for the subject or parent(s) of children who are subjects to email/fax a signed copy of the consent or permission form to the investigator. The subjects or parents need not provide the investigator with the original signed consent. The subjects cannot participate in the research until the signed, emailed/faxed, consent is in the possession of the investigator.

**Short Form Consent Process – Additional Signature Requirements**

Subject to prior approval of the IRB, consent may be documented through use of a short form written consent document with the requirements and process specified in OHRP 45 CFR 46.117(b)(2) and the FDA regulations in 21 CFR 50.27(b)(2). The short form consent process is generally applicable to situations involving non-English participants. If the participant agrees to take part in the study, the following signatures are required:

- **On the short form consent document (translated):**
  - i. Participant or the participant’s legally authorized representative [LAR]
  - ii. Witness (the interpreter may act as the witness)

- **On the summary form (English Consent Form):**
  - i. Person obtaining consent
  - ii. Witness (the interpreter may act as the witness)

For information on using the short form consent process see Chapter 12.1.4.

**Children Participants, Documentation of Informed Consent, and Assent**

Since children cannot legally give consent, informed consent must be obtained from parents (“parental permission”), or the legally appointed guardian. When, in the judgment of the IRB, the children are capable of providing assent, the IRB
may determine whether and how assent must be documented. See the Assent Template and Chapter 12.2.3. For additional information on the requirements for documentation of consent for children participants, see guidance Informed Consent of Minors.

12.5 Waiver or Alteration of Informed Consent Requirements

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<th>AAHRPP Std./Element</th>
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<tr>
<td>II.3.G</td>
<td>The IRB has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.</td>
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- Waiver or alteration of the consent process
- Waiver of documentation of informed consent – (“waiver of signature”)

12.5.1 Waiver or Alteration of the Consent Process

Under OHRP 45 CFR 46.116(c) (d), and (e), IRBs have authority to alter or waive the requirement to obtain informed consent.

FDA regulations do not provide for a waiver or alteration of the informed consent process. The only exceptions to the informed consent requirements are for clearly defined circumstances of emergency use of a test article (see Chapter 5.8), and waivers granted for planned emergency research (see Chapter 12.6). Thus, the information below in this Chapter 12.5.1 applies only to non-FDA-regulated research.

The IRB may approve an investigator’s request to waive or alter the requirement to obtain informed consent if the investigator demonstrates with specificity that the criteria under 45 CFR 46.116(c) or 46.116(d) are met. To approve such a request under 46.116(d), the IRB must find and document the following:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, subjects will be provided with additional pertinent information after participation.

Also, under 45 CFR 46.116(c) the IRB may waive or alter the consent process; however this is rarely applicable.

To request a waiver or alteration of the informed consent process the investigator must demonstrate that each of the criteria under Section 46.116(c) or (d) is met for the given protocol.

To approve a waiver or alteration of the informed consent process the IRB must find and document that all regulatory criteria under 45 CFR 46.116(d) (OHRP) are met and that the research is not subject to FDA regulations.

Special Considerations for Research Involving Deception

In research involving deception, the investigator may, with protocol-specific justification, request an alteration of the consent process. The IRB may approve the research, including the request to alter the requirement for informed consent if the investigator demonstrates that deception or incomplete disclosure is necessary and addresses concerns relating to participant protection; e.g., debriefing.
In order for the IRB to adequately review the research, investigators should justify, in detail, in the protocol, the reasons for deceiving or withholding information from subjects, including an explanation of: (a) the necessity for deceiving subjects; (b) how potential benefits of the research justify the use of deception; and (c) how the investigators will conduct the debriefing. In addition, investigators should include a debriefing script or statement that indicates the information subjects will receive regarding their participation in the research.

Research Involving Children: Waiver of Parental Permission/Guardian Consent

Research regulated by the FDA is not eligible for waiver of parental permission, except for the use of an FDA test article meeting the emergency exception (see Chapter 12.6).

The IRB will often consider a request for a waiver or partial waiver of parental permission for minimal risk research to be conducted in a classroom.

The IRB may waive parental permission by determining that the criteria for waivers or alterations are met. However, research is ordinarily not suitable for a waiver of parental permission if it involves any of the following issues:

1. Parental political affiliations or beliefs
2. Mental or psychological problems
3. Sexual behavior or attitudes
4. Illegal, antisocial, or self-incriminating behavior
5. Appraisals of other individuals with whom the minor has a familial relationship
6. Relationships legally recognized as privileged (lawyers, doctors, clergy), and
7. Religious affiliations or beliefs.

If the IRB waives the requirement for parental permission, it may require an alternative mechanism to protect the child participants (e.g., appoint a qualified child advocate).

12.5.2. Waiver of Documentation of Consent – (“waiver of signature”)

As allowed by OHRP (45 CFR 46.117(c)) and FDA regulations (21 CFR 56.109(c)), the IRB may waive the requirement to obtain written documentation of informed consent. This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of the consent process itself. A waiver of documentation of consent does not mean that requirements of the consent process are removed.

Even if a waiver of documentation is granted by the IRB, permitting the investigator to forego obtaining the participant’s signature on a written consent document, the investigator still must provide the participant with all of the information described in Chapter 12.1 required to constitute a complete and appropriate consent process, through an information sheet, or through an oral script in a language understandable to the participants. In all cases in which the requirement for documentation of consent is waived, the IRB may require the PI to provide participants with the written consent document with an option to sign the consent document, or with a written statement regarding the research.

To approve a waiver of documentation, the IRB must find that the protocol-specific justification for waiving documentation satisfies regulatory criteria. Specifically, the IRB must determine the regulatory basis for the waiver as one of the following (note that (a) does not apply for FDA-regulated research):

(a) Under OHRP (45 CFR 46.117(c)(1) the IRB must find and document either:
   i. the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked
whether he/she wants documentation linking the participant with the research, and the participant’s wishes will govern; or

ii. the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context;

or

(b) For research subject to OHRP and FDA regulations, the IRB must find and document that the research involves no more than minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context. (45 CFR 46.117(c)(2), 21 CFR 56.109(c)(1)).

Waiver or Alteration of HIPAA Authorization
In order to waive or alter an authorization, the investigator must provide sufficient information on which the IRB may make the following three findings specified by the Privacy Rule (45 CFR 164.512(i)(2)(ii):

A. The use or disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals based on;
   1. An adequate plan to protect the identifiers from improper use and disclosure;
   2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
   3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;

B. The research could not be practically conducted without the waiver or alteration; and

C. The research could not be practically conducted without access to and use of the protected health information.

12.6 Exceptions to Informed Consent in Emergency Planned Research

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<td>II.4.C</td>
<td>The IRB has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.</td>
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</table>

Note: “Planned emergency research “is not synonymous with” emergency use of a test article”, which is addressed in Chapter 5.8.

Planned emergency research refers to research planned for emergency settings, including the planned use of a test article.

Planned emergency research involves an extensive approval process, including FDA approval, prospective IRB review, and approval and consultation with representatives of the communities where the research will be conducted and from where participants will be drawn. Investigators must submit a protocol application including a description of the informed consent process or a request to waive informed consent; often in emergency settings it is not possible to obtain informed consent from a potential participant when there is insufficient time and a legally authorized representative (LAR) is not available.
The IRB may waive the requirement for informed consent in accordance with an exception under 21 CFR 50.24 (FDA) or 45 CFR 46.101(i) or 45 CFR 46.116(f) (OHRP), depending on whether or not the research is subject to FDA regulation, given that all required IRB determinations under these provisions can be made. Under these regulations, the IRB may permit planned research in an emergency setting without the informed consent of the participants or their legally authorized representatives in a limited class of emergent situations where the participant is in need of an emergency experimental intervention, but cannot give informed consent due to a life-threatening medical condition and there is not sufficient time to obtain consent from the participant’s legally authorized representative.

In addition, advance notice of such planned emergency research protocols will be provided to the Office for Human Research Protections pursuant to 45 CFR 46.101(i).

See also:
- Informed Consent Requirements in Emergency Research [OHRP]
- Exception from Informed Consent for Studies Conducted in Emergency Settings [FDA]
- HRPP Chapter 8.7

### 12.7 Observation of the Consent Process

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<tr>
<td>I.1.C</td>
<td>University of Louisville has and follows written policies and procedures that allow the Institutional Review Board to function independently of other organizational entities in protecting research participants.</td>
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As part of the IRB oversight options, the IRB may require that a staff member or an outside third party observe the consenting of research participants to determine:

- Whether the informed consent process has been appropriately completed and documented;
- Whether the participant has had sufficient time to consider study participation, that no coercion has been used by the consenting staff; and
- That the information presented to the participant reflects the content of the consent form and is conveyed in understandable language.

The IRB may require that one or more informed consent process situations be observed for selected protocols. IRB considerations used to choose such protocols include:

- High risk studies
- Studies that involve particularly complicated procedures or interventions
- Studies involving potentially vulnerable populations (e.g., ICU patients, children)
- Studies involving study staff with minimal experience in administering consent to potential study participants, or
- Situations when the IRB has concerns that the consent process is not proceeding well.