

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 10-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 11-06-09

## **OBJECTIVE**

To describe policies and procedures for obtaining and documenting informed consent/assent and for reviewing and requesting waiver of informed consent or waiver of documentation of informed consent for non-exempt human research

## **GENERAL DESCRIPTION**

### *Informed Consent/Assent Permission: Process and Documentation*

A major requirement of research involving human subjects is that investigators must obtain the informed consent of prospective subjects before they include these subjects in research. Informed consent is an ongoing educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation or of the process.

The consent document is not a substitute for discussion among investigators and research subjects. To ensure an effective informed consent process, the Institutional Review Board (IRB) and investigators comply with all applicable federal regulations (e.g., 21 CFR 50, 45 CFR 46.116, 117, and 38 CFR 16.116, 117). These regulations mandate the inclusion of eight basic informed consent elements. Six additional elements may be required, depending on the nature of the research. IRB policy also specifies the information to include in the consent process. The informed consent template included in the full and expedited IRB application forms outlines the required elements of informed consent. The investigator may use a short form if approved by the IRB in accord with applicable federal requirements.

### *Definitions*

*Assent* is defined as affirmative agreement of a child or an individual with impaired consent capacity to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

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*Permission* is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

In Kentucky, the terms *child* or *children* refer to all individuals under 18 years of age unless the individual(s) is legally emancipated. (See section *Emancipated Individuals* for details of Kentucky state law.) Individuals under 18 years of age who are not emancipated meet the federal definition for “child” [e.g., Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education].

*Legally Authorized Representative (LAR)* is an individual who has the authority to make research participation decisions on behalf of another. In accord with state law and federal regulation, individuals who can serve as legally authorized representatives are as follows:

1. Permission and/or authorization by a legally authorized representative for children: Consistent with Kentucky health care decision statutes for choosing an LAR for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child: (a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the parent of the child.
2. Permission and/or authorization by a legally authorized representative for individuals with impaired consent capacity: Consistent with Kentucky health care decision statutes for choosing a legally authorized representative for adult subjects unable to consent, one of the following responsible parties, in the following order of priority (if no individual in a prior class is reasonably available, willing, and competent to act), is authorized to make research participation decisions on behalf of the person: (a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for the decisions to be made under the consent; (c) the spouse of the person; (d) 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; (e) the parents of the subject; (f) the nearest living relative, or if more than one of the same relation, a majority of the nearest living relatives.

Consent by an LAR should involve all the same considerations that informed consent from a competent subject involves.

3. Permission and/or authorization for decisionally challenged/subjects with impaired consent capacity in Veterans Affairs Medical Center (VAMC) research: Consistent with VA regulations, a health care agent appointed by the subject in a Durable Power of Attorney for Health Care or similar document; court-appointed guardians of the person; or from next-of-

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kin in the following order of priority, unless otherwise specified by applicable state law: spouse, adult child (18 years or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older). These individuals are the only surrogate entities allowed to provide consent for research purposes.

In Kentucky, a *guardian* is an individual who may serve as an LAR as defined above. These individuals meet the federal definitions for guardian.

*Waiver of Informed Consent Process*

The IRBs have the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations. The FDA and DHHS/VA requirements for waiver differ. Consequently, the investigators and IRB must comply with the applicable regulations, which differ depending upon study sponsor or regulatory status of the proposed research. A summary of applicable waiver federal regulations and University requirements is as follows:

1. Non-FDA regulated studies: to waive informed consent requirements, the IRB must find and document that the study meets the requirements in 45 CFR 46.116(c)(d) and 38 Part 16.116(c)(d).
2. Non-FDA or DHHS funded or regulated studies involving planned emergency research: the University of Kentucky (UK) does not accept proposals that require a waiver of informed consent for planned emergency research for non-FDA/DHHS regulated research.
3. FDA regulated and/or DHHS funded planned emergency research: the IRB approves exceptions for informed consent requirements if the study meets all of the requirements specified in 21 CFR Subpart B 50.24 and/or 45 CFR 46.101(i).
4. VAMC research/waiver in planned emergency research: the VAMC does not allow planned emergency research.
5. Single subject emergency use of a FDA regulated test article: the UK policy is more stringent than the FDA requirements outlined in 21 CFR 50.23. UK requires investigators to consult with the IRB Chair or designee before using the test article in a single subject without informed consent. The IRB may allow an exception to consultation, consistent with 21 CFR 50.23.
6. Waiver of parental or guardian permission in non-FDA regulated studies: when consent of parents or guardians is not a reasonable requirement because it poses additional risk to the potential subject or the parents' interest may not adequately reflect the child's interest (e.g.,

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neglected or abused children), the IRB may waive parental or guardian permission in accord with 45 CFR 46 Subpart D and 46.408(c) and Subpart A 46.116.

*Waiver of Documentation of Informed Consent*

Federal regulations permit an IRB to waive the documentation requirements for obtaining informed consent under special circumstances.

1. FDA regulated studies: IRB may waive documentation for some or all of the subjects if the study meets the conditions listed in 21 CFR 56.109(c).
2. Non-FDA regulated studies: the IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if the study meets the requirements in 45 CFR 46.117(c) and 38 CFR Part 16.117(c).

**RESPONSIBILITY**

Execution of SOP: Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff, IRB, UK Legal Counsel, Quality Improvement Program (QIP) Coordinator, Veterans Affairs Medical Center (VAMC) Associate Chief of Staff (ACOS)

**PROCEDURES**

*Informed Consent Process and Documentation*

1. The PI submits a proposed informed consent procedure and written form with his/her IRB application prior to initiation of research, except in situations such as research proposals that meet exempt criteria (although informed consent(s) may be included). The PI indicates in the IRB application the study personnel who will participate in the informed consent process or individuals the PI will authorize to obtain informed consent on his/her behalf.
2. The UK IRB has an informed consent template, available in the full and expedited review applications on the ORI website. Investigators use this template as a guide unless the IRB grants exceptions or a waiver. The consent template contains the eight required elements, the six additional elements of informed consent, and additional IRB requirements for UK research involving human subjects. Investigators conducting research that recruits subjects from the VAMC use the VA informed consent template which contains additional VA requirements. See *Additional Elements Where Appropriate* below.
3. At a minimum, the proposed consent process and form include the following eight federally required elements and additional elements where appropriate:

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- Research statement: a statement that the study involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures which will be experimental.
- Reasonably foreseeable risks or discomforts: a statement that describes foreseeable risks or discomforts associated with the research, the likelihood of their occurrence, and the ramifications associated with the risks (e.g., decreased blood count may result in need for a blood transfusion).
- Reasonably expected benefits to subjects or others: a statement that describes benefits to subjects or others that may reasonably be expected from the research including no benefit, if this is applicable. Payment for participation in a research project is not considered a benefit.
- Appropriate alternatives: a statement that describes with enough detail any alternative procedures or course of treatment that may benefit the subject. If no alternatives exist, the consent form must state that there are no alternatives except not to participate.
- Extent of confidentiality: a statement that describes the extent to which the investigator/study personnel will maintain or not maintain confidentiality of records identifying the subject (e.g., law requires reporting child abuse, etc.) and describes how the research team will protect subjects' private records during and after the conclusion of proposed research studies. Any research that is subject to audit or inspection must identify who will have access to the subject's record (e.g., FDA, National Institutes of Health (NIH), UK, VA, Government Accounting Office, sponsors, or contract research organizations).
- Compensation or treatment for injury: for studies with greater than minimal risk, a statement explaining any compensation and an explanation of any medical treatments available if injury occurs or where the subject may obtain further information. The IRB informed consent template contains standard statements in accordance with UK policy. The VA informed consent template contains standard statements in accordance with VA requirements.
- Contact information: a statement that describes contact information details, including telephone numbers, and whom to contact for the following situations: questions about the research (e.g., investigator and other team members), questions about subjects' rights, comments, suggestions, or input (e.g., the ORI), and in the event of a research-related injury (depending on the nature of the research, the PI or a physician on the research team).

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- Voluntary participation statement: a statement that describes clearly that participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
  - Additional elements where appropriate: The IRB requires the additional elements unless the item(s) does not apply given the nature of the research or the proposed procedures (e.g., subjects will not receive remuneration for participation).
    - Unforeseeable risks to subjects, embryos, or fetuses: a statement warning subjects that some risks are currently not known or foreseeable, when applicable;
    - Investigator-initiated termination of participation: a statement that describes the instances in which an investigator may terminate a subject's participation (e.g., subject noncompliance, subject not benefiting from research, etc);
    - Additional costs: a statement that describes any additional costs a subject may encounter such as transportation, time away from work, parking, health costs, etc.;
    - Early withdrawal/procedures for termination: a statement that describes a subject's right to withdraw from the study and any procedures that may be necessary after an early withdrawal for subject's safety;
    - Significant new findings: a statement that subjects will be told of any new findings which may affect willingness to continue in the research;
    - Approximate number of subjects: a statement that explains the approximate number of subjects to be enrolled in the study, nationwide and locally;
    - Disposition of subject's blood samples: DNA testing, cell lines, development of future products;
    - Payment: a statement which includes all information concerning the amount and schedule of payment for participation.
4. If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The investigator may consult the IRB Survival Handbook, which includes Protocol Specific Training (PST), or ORI staff for guidance. The vulnerable populations and sensitive issues include, but are not limited to:
- Research involving the participation of children;
  - Research involving individuals with impaired consent capacity;
  - Research involving HIV screening and/or AIDS research;

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- Research involving DNA banking, genetic research, or gene therapy;
  - Research activities directed toward pregnant women;
  - Research involving prisoners.
5. The investigator also must address the following issues, if applicable to the proposed research:
- DHHS/NIH-sponsored multicenter clinical trial: the investigator must include a copy of the DHHS/NIH-approved sample informed consent document in the application. The investigator must justify in writing any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document, and the IRB must approve these deletions or modifications. For trials sponsored by the National Cancer Institute, investigators must forward copies of such IRB-approved changes, with their justifications to the appropriate Cooperative Group headquarters;
  - Investigational drugs, devices, or biologics: the investigator must inform the subject in the purpose that the study includes evaluation of both safety and effectiveness of the test article and state the test article is investigational, and, if applicable, not approved by the FDA;
  - The process of dose escalation;
  - The possibility of risk for an unborn child, a man or woman’s ability to procreate, or a woman’s ability to conceive or carry a child will include the statement listed in the Instructions for Documentation of Informed Consent, which may be revised to meet the needs of the study;
  - Additional requirements as specified in the IRB full and expedited review; applications/informed consent template.
6. If the research involves genetic testing or DNA banking the PI must address, in the informed consent process and form, the applicable issues discussed in the Issues to be Addressed in Obtaining Informed Consent in DNA Banking and Genetic Research document.
7. If the research involves establishing a specimen/tissue repository, the PI must address, in the informed consent process and form, the applicable issues discussed in the Issues to be Addressed in Obtaining Informed Consent Involving Specimen Collection for Tissue/Specimen Repositories document.
8. The IRB assesses the PI’s description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject or subject’s legally authorized representative; be in language understandable to the subject; be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate and that minimize coercive influences; does not include language through which the subject is made to waive his/her legal rights or releases

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the investigator, sponsor, or institution from liability for negligence). The IRB uses the Criteria for IRB Approval: Reviewer Checklist in conducting this assessment.

9. The IRB determines whether disclosure of any investigator conflict of interest is warranted in the informed consent process and document.
10. The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal, VAMC, and UK requirements are met.
11. Once the IRB approves the study, ORI staff affix an approval stamp to every page of the approved informed consent document, the first page of which includes the approval and expiration dates. ORI staff then forward the form to the investigator. Investigators may only enroll subjects using informed consent/assent forms which have a valid "IRB approval" stamp unless the IRB grants a waiver from the requirement for informed consent or documentation.
12. If the study includes documents approved by the IRB for use in the informed consent process which are not signed by subjects under waiver of documentation, (e.g., survey cover letters, web page cover letters, telephone scripts), ORI staff affix an approval stamp to the document which includes the approval and expiration dates. The investigator removes the approval stamp and produces a clean copy of the approved version to post or disseminate to potential subjects.
13. The investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her LAR after the subject or the subject's LAR has had an adequate opportunity to read the form and prior to subject participation in any part of the study, using the process and form approved by the IRB.
14. The subject or the subject's LAR and the person providing the information to the subject sign and date the informed consent document at the time of consent. Only individuals authorized (in the IRB approved protocol) to obtain informed consent sign on the line entitled "Name of [authorized] person obtaining consent from the subject."
15. The investigator's signature on the informed consent document verifies that the person who explained the study and obtained informed consent is qualified and that the IRB has approved him/her to do so (may not be applicable for informed consent document for nonmedical protocols). The subject or LAR signing on the subject's behalf receives a copy of the signed form.

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*Use of the Short Form Written Consent Document*

1. The PI may request to use a short form written consent document stating that study personnel have presented the elements of informed consent (as required by 45 CFR 46.116) orally to the subject or the subject's LAR.
2. The IRB reviews the request and may approve the short form option for documentation only if the study meets all of the requirements outlined in 45 CFR 46.117(b), and as applicable, 21 CFR 50.27(b) and/or 38 CFR 16.117(b).
3. When the IRB approves use of the short form method:
  - The PI must ensure there will be a witness to the oral presentation. For participants who do not speak English, the PI must ensure the witness is conversant in both English and the language of the participant.
  - The IRB must approve a written summary of the oral content presented to the subject or the subject's LAR, which embodies the basic and appropriate elements of disclosure.
  - The subject or the subject's LAR signs the short form. For FDA-regulated research the subject or the subject's LAR signs *and* dates the short form.
  - The witness signs both the short form and a copy of the summary.
  - The person actually obtaining consent signs a copy of the summary.
  - The person obtaining consent gives a copy of the summary to the subject or the subject's LAR, in addition to a copy of the short form.

*Veterans Affairs Medical Center Research--Informed Consent Process and Documentation*

1. Investigators conducting VAMC research and the VAMC are responsible for ensuring compliance with special VA requirements as outlined in the applicable Veterans Health Administration (VHA) Handbook.
2. The VHA Handbook requires the use of VA Research Consent Form 10-1086 or an electronic version of VA Form 10-1086, as the consent form for both the long and short forms of documentation of the informed consent process. The informed consent form must contain elements required by the VHA Handbook and 38 CFR 16.116., including the following disclosures:
  - In the event of a research-related injury, the VAMC must provide necessary medical treatment to the research subject injured by participation in a research project approved by the VA Research and Development Committee and conducted under the supervision of one or more VA employees in accordance with 38 CFR 17.85.
  - Except in limited circumstances, the necessary care must be provided in VA medical facilities. In cases of exceptions, the VAMC Director may contract for such care. Exceptions include:

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- Situations where VA facilities are not capable of furnishing economical care;
  - Situations where VA facility are not capable of furnishing the care or services required;
  - Situations involving a non-veteran research subject.
  - The requirement to provide medical treatment for a research-related injury does not apply in cases where injuries result from noncompliance by a research subject with study procedures.
  - The informed consent form also includes statements:
    - Explaining the VA’s authority to provide medical treatment to research subjects injured by participation in a VA research project;
    - Stating that a veteran-subject will not be requested to pay for care received as a subject in a VA research project except as follows: in accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g) certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not part of the VA-approved research study must pay any applicable co-payment for such care and services.
3. The IRB VA members use the VA Research: Reviewer Checklist for VAMC research protocols as a guide to ensure review and approval in accord with special VA informed consent requirements. The VAMC ACOS or his designee also uses the checklist as a guide in conducting his/her administrative review of VA studies.
  4. The IRB approves the wording of the consent. ORI staff document the approval through the use of a stamp on the first page of the VA Form 10-1086 that indicates the date of the most recent IRB approval of the document.
  5. If the investigator amends the consent form for VAMC research during the protocol approval period, the first page of the form bears the approval date of the amendment rather than the date of the approved protocol.
  6. The investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her LAR after the subject or the subject’s LAR has had an adequate opportunity to read the form and prior to subject participation in any part of the study, using the process and form(s) approved by the IRB.
  7. The subject or the subject’s LAR signs and dates the informed consent document at the time of consent.
  8. A witness must be present for and attest to the subject’s or the LAR’s signature by also signing the consent document.
  9. The person authorized by the investigator to obtain the informed consent from the subject signs and dates the informed consent document at the time of consent. Only individuals

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authorized (in the IRB approved protocol) to obtain informed consent sign on the line entitled “Name of [authorized] person obtaining consent from the subject.”

10. In cases where the sponsor or the IRB requires a witness to the consenting process in addition to the witness to the participant’s signature and the same person serves both capacities, the informed consent form contains a note to that effect below the witness’s signature line.
11. The person authorized by the investigator to obtain the informed consent provides a copy of the signed informed consent form to the subject or the subject’s LAR
12. The PI complies with the VHA Handbook and VAMC procedures for filing the original signed consent form in the subject’s case history, flagging the medical record, and making progress note documentation unless the IRB waives the requirement.

*Veterans Affairs Medical Center Research -- Use of the Short Form Written Consent Document*

1. The PI may request to use a short form written consent document stating that the elements of informed consent (as required by VHA Handbook and 38 CFR 16.116) will be presented orally to the subject or the subject’s LAR.
2. The IRB reviews the request and may approve the short form option for documentation only if the study meets all of the requirements outlined in 45 CFR 46.117(b), 38 CFR 16.117(b), and as applicable, 21 CFR 50.27(b).
3. When the IRB approves use of the short form method:
  - The PI must ensure there is a witness to the oral presentation.
  - The IRB must approve a written summary of what is to be said to the subject or the subject’s LAR.
  - The subject or the subject’s LAR signs the short form.
  - The witness must sign both the short form and a copy of the summary. The person actually obtaining the consent must sign a copy of the summary. Study personnel file the original short form and summary. The original short form and summary must be filed, per institutional requirements.
  - The person obtaining consent gives a copy of the summary to the subject or the subject’s LAR, in addition to a copy of the signed short form.
  - Study personnel place a progress note documenting the informed consent process in the subject’s medical record.
  - The progress note, at a minimum, must include:
    - a. The name of the study;
    - b. The person obtaining the subject’s consent;
    - c. A statement that the subject or the subject’s LAR was capable of understanding the consent process;
    - d. A statement that the study was explained to the subject; and

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- e. A statement that the subject was given the opportunity to ask questions.
- Study personnel must also place an entry in the progress note when the subject actually enters into the study and when the subject’s participation terminates. (Study personnel may combine consent and entry notes when both occur at the same visit.)

*University of Kentucky Research Involving Individuals with Impaired Consent Capacity*

1. The PI completes the IRB application, including forms, and after obtaining IRB approval implements the research in accordance with the requirements for assessing consent capacity specified in the UK Impaired Consent Capacity Policy. See this policy and the IRB application for details on the procedure.
2. In conducting the review, the IRB uses the recommendations for assessing consent capacity as a guide to ensure additional safeguards are in place. (See Impaired Consent Capacity Policy for details.)

*Veterans Affairs Medical Center Research Involving Mentally Disabled/Decisionally Impaired Subjects*

1. Before an investigator may consider persons with impaired decision-making capacity for participation in any VA research, the IRB must find that the proposed research meets all of the conditions contained in VHA Handbook. Persons with impaired decision-making capacity must not be subjects in research simply because they are readily available. Persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.
2. The PI may obtain consent by an LAR only in situations where the prospective subject is incompetent or has impaired decision-making capacity, as determined and documented in the person’s medical record in a signed and dated progress note. The determination that a subject is incompetent or has an impaired decision-making capacity must be a legal determination or a determination by the practitioner, in consultation with the chief of service after appropriate medical evaluation that the prospective subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
3. In cases where the determination that a prospective subject lacks decision-making capacity is based on a diagnosis of mental illness, the investigator consults with a psychiatrist or licensed psychologist in accord with VA or IRB requirements.
4. The investigator advises the LAR of his/her role and responsibilities in serving as the decision-maker for the subject. The investigator also advises the LAR that it is his/her

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obligation to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what he/she thinks is in the incompetent person's best interest.

5. If feasible, the investigator explains the proposed research to the prospective subject even when the LAR gives consent. No one may, under any circumstances, force or coerce prospective subjects to participate in a VA research study.
6. For subjects whose decision-making capacity may fluctuate or those with decreasing capacity to give consent, the PI may use a re-consenting process with surrogate consent necessary. (See Veterans Health Administration Handbook, - Research Involving Human Subjects with Surrogate Consent.)

#### *Assent*

1. The PI must develop processes and forms consistent with guidance provided in a number of IRB policies including but not limited to: UK Impaired Consent Capacity Policy, applicable sections of the Protocol Specific Training materials; UK IRB Policy on Children in Research; Assent Form Template; and requirements found in the IRB full and expedited review applications related to assent.
2. The PI is responsible for including in the IRB application a description of the process/procedure for obtaining and documenting assent when research includes:
  - Children and/or;
  - Individuals with impaired consent capacity.
3. The IRB reviews the proposed process and, if applicable, the assent form to ensure compliance with IRB guidance and federal requirements.

#### *Emancipated Individuals*

1. Under Kentucky state law, absent a court order, there are no classes of individuals under the age of eighteen who are named as emancipated for all purposes. Consequently, if the PI would like to enroll some or all prospective subjects as emancipated, the PI consults with UK legal counsel when preparing the IRB application and prior to submitting the application to the IRB. He/she includes legal counsel's recommendations in the IRB application.
2. Under Kentucky state law, in general, individuals under the age of eighteen who are living on their own, have borne a child, or are married are viewed as emancipated and are able to consent to participate in some research studies. Legal counsel reviews the studies on a case-by-case basis to determine whether the subjects are legally emancipated. If pregnant individuals under the age of eighteen are neither married nor living on their own (i.e., living at home under the care of their parents or some other adult), they are not legally emancipated, and both parental permission and subject assent are needed.

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3. When conducting the study, given the variety of living situations that an individual may find him or herself living in, investigators may need to make decisions on a subject-by-subject basis regarding the applicable state statutory requirements. If there are questions relating to whether an individual meets the state statutory requirements to be emancipated, the investigator consults UK legal counsel.
4. If a child or a class of subjects is deemed to be emancipated, then 45 CFR 46 Subpart D and 21 CFR 50 Subpart D do not apply, and the subject may provide informed consent as an adult.

*Obtaining Informed Consent outside the State of Kentucky*

1. If the PI conducts the research outside the state of Kentucky and the research involves children, an LAR, or a guardian, the investigator must follow the requirements of the state/country in which he/she will conduct the research. The PI must also determine which individuals meet the federal definitions for child/children, LAR, or guardian in the location outside the state of Kentucky.
2. The PI identifies the state law(s) applicable to the determination of legally authorized representative and contacts UK legal counsel for review and determination prior to approval by the IRB. If the PI is unable to identify applicable state law(s), the PI contacts UK legal counsel for assistance prior to approval by the IRB.

*Non-English Speaking Subjects*

1. Investigators must deliver all information regarding informed consent/assent to potential subjects or their LAR in the subject's native language(s) or one that the subject understands. The investigator must provide the IRB and prospective subjects a translated version of the consent/assent form.
2. ORI staff identify a cultural consultant to review the study and informed consent/assent document for accuracy and cultural appropriateness. If ORI staff are unable to identify an individual to serve as a cultural consultant, the investigator provides a cultural consultant for review of accuracy of the informed consent form and cultural appropriateness.
3. ORI staff ensure that the consultant does not have a conflict of interest. (See IRB Member and Consultant Conflict of Interest SOP)
4. The IRB may use expedited review procedures in approving such documents if the IRB has already approved the English language consent/assent document, and the cultural consultant attests to the accuracy of the translation.

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*Research that Requires Monitoring of Informed Consent/Assent Process and Procedures*

1. The IRB determines which research requires monitoring of the informed consent/assent process and the procedure and frequency with which such monitoring will occur based on the degree of risk to subjects, the need for protection of vulnerable subjects, or concerns related to an incident of noncompliance.
2. A designated IRB member(s), the QIP Coordinator (see QIP Directed On-Site Review SOP), or other designee (as determined by the IRB) may monitor the informed consent/assent process. The monitoring may involve direct observation, interviews of subjects, surveys of subjects, or other means as deemed appropriate by the IRB for the circumstances.

*Recordkeeping*

1. For studies which recruit subjects from the VAMC, the PI places an original signed consent form or, if applicable, assent form in the subject's medical record unless the IRB waives the requirement. The PI must also keep a copy of the signed consent/assent document in his/her research records in accord with the IRB-approved protocol.
2. For studies conducted at a UK hospital or clinic, the PI places a copy of the signed consent form or, if applicable, assent form in the medical record unless the IRB waives the requirement. The PI must also keep the original signed consent/assent document in his/her research records in accord with the IRB-approved protocol.
3. For studies conducted in other settings (i.e., not conducted in UK/VAMC hospital/clinic), the PI keeps the original signed informed consent form and, if applicable, assent in accord with the ORI/IRB Recordkeeping SOP and the study procedures as approved by the IRB.
4. The IRB documents its review as delineated in the applicable procedures for a particular review mechanism (e.g., initial full review, expedited review, modification review, etc.) and the ORI/IRB Recordkeeping SOP.

*Waiver of Informed Consent for Non-FDA Regulated Studies*

1. The PI makes a preliminary decision to seek waiver of informed consent and submits a justification for the request in the IRB application.
  - The IRB may waive the requirements or alter elements if it finds and documents:
    - The research involves no more than minimal risk to the subjects;
    - The research will not adversely affect the rights and welfare of subjects ;
    - The investigator could not practicably conduct the research without the waiver or alteration.
    - Whenever appropriate, study personnel provide subjects additional pertinent information after participation.

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2. The IRB may also waive the requirement to obtain informed consent or alter some of the elements if the IRB finds and documents that:
  - The research or demonstration project is to be conducted by or is subject to approval of state or local government officials and is designed to study, evaluate or examine public benefit of service programs, procedures, methods or levels of payment; AND
  - The investigator could not practicably conduct the research without the waiver or alteration.
3. If the IRB reviews the protocol at a convened meeting, ORI staff document the waiver of informed consent approval in the IRB meeting minutes.
4. If the protocol is eligible for expedited review, the expedited reviewer documents on the expedited review approval signature page whether the study meets each of the criteria.

*Waiver of Informed Consent for FDA Regulated and/or DHHS Funded Planned Emergency Research (Excluding VAMC Research)*

1. The PI completes the IRB application following the procedures outlined in the Initial Full Review SOP. The ORI staff screen the application using procedures outlined in the Initial Full Review SOP. ORI staff send the PI a copy of the 21 CFR 50.24 and a copy of the summary of the rule in the “Overview of Basic IRB Regulations” document. ORI staff ask the PI to address any additional issues not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.
2. At the convened meeting, the ORI staff provide the IRB Chair or designee with a copy of 21 CFR 50.24 and/or 45 CFR 46.101(i). The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. The outcomes of the review are the same as those listed in the Initial Full Review SOP. ORI staff record the discussion in the minutes, following the procedures in the Minutes of IRB Meetings SOP.
3. Planned emergency research is not allowed at the VAMC.

*Exception from Informed Consent Requirement for Use of FDA-Regulated Test Articles in a Single Subject*

1. The PI must obtain informed consent, even in an emergency use situation, unless the study meets certain conditions. (See Emergency Use SOP.)

*Waiver of Parental or Guardian Permission for Research Involving Children in Non-FDA Regulated Research*

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1. The PI makes a preliminary decision to seek waiver of parental or guardian permission for participation of children in accord with 45 CFR Subpart D 46.408 (c) or 45 CFR 46.116(c)(d). The PI includes justification for the waiver and a description of a substituted appropriate mechanism for protecting the children who will participate in the research.
2. The IRB may approve the request provided the study meets the conditions outlined in 45 CFR Subpart D 46.408(c) or 45 CFR 46.116 (c)(d).
3. If the IRB reviews the research at a convened meeting, ORI staff record the discussion on each criterion in the minutes.
4. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review signature page whether the research meets the criteria.

*Waiver of Documentation of Informed Consent for FDA-Regulated Research*

1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.
2. The IRB may waive the documentation requirement to obtain a signed consent if the research presents no more than minimal risk and involves no procedures for which the IRB normally requires written consent.
3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will give to the subjects.
4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
5. If the IRB reviews the request at a convened meeting, ORI staff include the discussion on each of the criteria in the IRB minutes.
6. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited reviewer approval signature sheet whether the research meets each of the criteria.

*Waiver of Documentation of Informed Consent for Non-FDA Regulated Studies*

1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.
2. The IRB may waive the documentation requirements to obtain a signed consent if:
  - The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of

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- confidentiality. Study personnel must ask each subject whether the he/she wants documentation regarding the research; or
- The research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required (i.e., a cover letter or a phone script).
3. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
  4. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that subjects will receive.
  5. If the IRB reviews the request at a convened meeting, ORI staff include the discussion on each of the criteria in the meeting minutes.
  6. If the IRB reviews the protocol using expedited procedures, the expedited reviewer documents on the expedited reviewer approval signature sheet whether the research meets each of the criteria.

## **REFERENCES**

21 CFR 50.20  
21 CFR 50.23-25  
21 CFR 50.27  
21 CFR 56.109 (b),(c)  
38 CFR 16.116  
38 CFR 16.117  
45 CFR 46.101(i)  
45 CFR 46.109 (b),(c)  
45 CFR 46.111  
45 CFR 46.116  
45 CFR 46.117  
Title 38 USC 1710(f) and 1710(g)  
Veterans Health Administration Handbook  
34 CFR 97 [Department of Education Subpart D]