

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: 03-15-19

## **OBJECTIVE**

To describe policies and procedures for obtaining and documenting informed consent/assent and for reviewing and requesting a waiver of informed consent or a 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 an 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 of the process.

The consent document is not a substitute for discussion between 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](#)). These regulations mandate the inclusion of a concise and focused presentation of the key information most likely to assist a prospective subject or Legally Authorized Representative (LAR) in understanding the reasons why one might or might not want to participate in the research. Additionally, the regulations mandate the inclusion of nine basic informed consent elements. Nine 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 outlines **basic elements and the additional elements** of informed consent. The investigator should only include the additional elements, as applicable. The basic elements of informed consent must be included unless the IRB has approved a waiver or

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alteration 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 the 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.

*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., U.S. Department of Health and Human Services (HHS), 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

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available for consultation; (e) the parents of the person; (f) the nearest living relative, or if more than one of the same relation, a majority of the nearest living relatives.

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

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

### *Waiver of Informed Consent Process*

The IRB has 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. A summary of applicable waivers of federal regulations and University requirements is as follows:

1. FDA-regulated or HHS-funded studies: to waive informed consent requirements, the IRB must find and document that the study meets the requirements in [45 CFR 46.116\(c\)\(d\)](#).
2. Non-FDA or HHS-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/HHS regulated research.
3. FDA regulated and/or HHS-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](#).
4. Single subject emergency use of an 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](#).
5. Waiver of parental or guardian permission in FDA-regulated and HHS-funded 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., 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](#).

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### *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\(c\)\(1\)](#).

### **RESPONSIBILITY**

Execution of SOP: Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff, IRB, UK Legal Counsel, Quality Improvement Program (QIP) Coordinator

### **PROCEDURES**

#### *Informed Consent Process and Documentation*

1. The PI submits a proposed informed consent procedure and written form in 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 informed consent template is available on the ORI website. Investigators use this template as a guide unless the IRB grants exceptions or a waiver. The consent template contains the nine (9) basic and nine (9) additional elements of informed consent as well as additional IRB requirements for UK research involving human subjects. See *Additional Elements Where Appropriate* below.
3. At a minimum, the proposed consent process and form must begin with key information and include the following nine (9) federally required elements and additional elements where appropriate:
  - Key Information: a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

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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 the 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, 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.
- 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.
- Collection of private information or identifiable biospecimens for future use: a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; OR a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- 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;
  - Biospecimens for commercial profit: a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

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- Return of individual research results: a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
  - Whole genome sequencing: for research involving biospecimens, a statement regarding whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
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 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 DNA banking, genetic research, or gene therapy;
  - Research activities directed toward fetuses and/or neonates;
  - Research involving economically or educationally disadvantaged persons;
  - Research involving prisoners;
  - Research involving individuals with impaired decision-making capacity.
5. The investigator also must address the following issues, if applicable to the proposed research:
- HHS/NIH-sponsored multicenter clinical trial: the investigator must include a copy of the HHS/NIH-approved sample informed consent document in the application. The investigator must justify 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 (NCI), investigators must provide copies of such IRB-approved changes, with their justifications to the appropriate Cooperative Group headquarters;
  - Investigational drugs, devices, or biologics: In the IRB approved consent form, 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;
  - Applicable FDA-regulated clinical trials: In the IRB approved consent form, the investigator must inform the subject that the clinical trial will be entered into a national clinical trial registry data bank; the consent form must also be posted on a publicly available federal website (clinicaltrials.gov or a docket folder on regulations.gov).

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- Early withdrawal from FDA-regulated clinical trials: In the IRB approved consent form, the investigator informs the subject that data collected to the point of withdrawal, remains part of the study database and may not be removed. The investigator informs the subject if the protocol includes continued follow-up activities such as accessing medical or confidential records to collect clinical outcome information after withdrawal from the interventional portion of a trial. In an IRB approved consent form, the investigator obtains the subject’s consent for this limited participation; otherwise, the researcher does not conduct follow-up activities to collect clinical outcome information.
  - 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 establishing a specimen/tissue repository or registry, the PI must address the applicable issues outlined in the “Sample Repository/Registry/Bank Consent” template.
  7. 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 the investigator, sponsor, or institution from liability for negligence). The IRB uses the Criteria for IRB Approval: Reviewer Checklist in conducting this assessment.
  8. The IRB determines whether disclosure of any investigator conflict of interest is warranted in the informed consent process and document.
  9. The IRB reviews the proposed informed consent document(s) to ensure that all applicable federal and UK requirements are met.
  10. When the IRB approves a study, the consent document is stamped with an approval date. 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.



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11. 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.
12. The subject or the subject's LAR sign and date the informed consent document at the time of consent. Only individuals authorized (in the IRB approved protocol) to obtain informed consent prints their name on the line entitled "Name of [authorized] person obtaining consent from the subject." The subject or LAR signing on the subject's behalf receives a copy of the signed form.

#### *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\(b\)](#).
3. When the IRB approves use of the short form written consent:
  - The PI ensures there is a witness to the oral presentation. For participants who do not speak English, the PI ensures the witness is conversant in both English and the language of the participant.
  - The IRB approves 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 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.

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

1. The PI completes the IRB application 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.

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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.)

#### *Assent*

1. The PI develops processes and forms consistent with guidance provided in a number of IRB policies including but not limited to: UK Impaired Consent Capacity Policy; UK IRB Policy on Children in Research; Assent Form Template; and requirements found in the IRB application related to assent.
2. The PI includes 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 18 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 18 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 18 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.
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.

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4. If a child or a class of subjects is deemed to be emancipated, [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, a LAR, or a guardian, the investigator follows the requirements of the state/country in which he/she conducts the research. The PI also determines 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 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 provides the IRB and prospective subjects a translated version of the consent/assent form(s).
2. ORI staff identifies a cultural consultant to review the study and informed consent/assent document(s) 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 the accuracy of the informed consent form(s) and evaluation of cultural appropriateness.
3. ORI staff ensure 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(s), and the cultural consultant attests to the accuracy of the translation.

#### *Competent English-Speaking Subjects with Reading or Visual Impairment*

1. Investigator, designated study personnel, or subject's family member reads the IRB approved consent document to the blind or illiterate potential subject or their LAR in the presence of an impartial third-party witness.

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2. The investigator allows ample time for the document to be read and the subject or LAR to consider participation.
3. The investigator may enroll a qualifying potential subject who 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.
4. The potential subject makes the decision and indicates approval or disapproval to study entry.
5. The subject makes his/her mark or the LAR signs to document consent.
6. The impartial third party witnesses the entire consent process and signs the consent document.

*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 occurs 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(s) (as determined by the IRB) monitors the informed consent/assent process. The monitoring involves direct observation, interviews of subjects, surveys of subjects, or other means as deemed appropriate by the IRB for the circumstances.

*Recordkeeping*

1. For studies conducted at a UK hospital or clinic, the PI scans a copy of the signed consent form or, if applicable, assent form into the electronic medical record unless the IRB waives the requirement. The PI must also keep the original signed consent/assent document(s), or an accurate reproduction(s), securely throughout the record retention period in accord with the IRB-approved protocol.
2. For studies conducted in other settings (i.e., not conducted in UK hospital/clinic), the PI keeps original signed informed consent/assent document(s), or an accurate reproduction(s), in accord with the ORI/IRB Recordkeeping SOP and study procedures as approved by the IRB.
3. For FDA-regulated research, the study personnel obtaining informed consent, document in the subject's case history, that the subject provided consent prior to participation.

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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*

1. The PI makes a preliminary decision to seek a 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; and
    - Whenever appropriate, study personnel provide subjects additional pertinent information after participation.
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 whether the study meets each of the criteria on the Expedited Reviewer Signature Page.

#### *Waiver of Informed Consent for FDA-regulated Planned Emergency 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 ask the PI to address any additional issues in accordance with [21 CFR 50.24](#) not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.
2. At the convened meeting, ORI staff provide the IRB Chair or designee with a copy of [21 CFR 50.24](#). The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable

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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.

*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*

1. The PI makes a preliminary decision to seek a 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 children who participate in the research.
2. The IRB approves the request provided the study meets the conditions outlined in [45 CFR Subpart D 46.408\(c\)](#) or [45 CFR 46.116\(f\)\(3\)](#).
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 whether the research meets the criteria on the Expedited Reviewer Signature Page.

*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 waives the documentation requirement to obtain a signed informed consent form 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 documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research and reviews a written description of the information that the PI will give to the subjects.
4. If the IRB reviews the request at a convened meeting, ORI staff include the discussion on each of the criteria in the IRB minutes.

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5. If the IRB reviews the study using expedited procedures, the expedited reviewer documents whether the research meets each of the criteria on the Expedited Reviewer Signature Page.

*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 informed consent form 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 confidentiality. Study personnel must ask each subject whether 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); or
  - If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
3. When 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 and reviews a written description of the information that subjects will receive.
4. When the IRB reviews the request at a convened meeting, ORI staff include the discussion on each of the criteria in the meeting minutes.
5. When the IRB reviews the protocol using expedited procedures, the expedited reviewer documents whether the research meets each of the criteria on the Expedited Reviewer Signature Page.

*Exception from Informed Consent Requirement for Screening, Recruiting, or Determining Eligibility of Potential Research Subjects*

1. The PI must obtain informed consent when screening, recruiting, or determining eligibility, unless the study meets certain conditions. An IRB approves a research proposal in which an investigator obtains information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without informed consent of the prospective

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subject or the subject's legally authorized representative, if either of the following conditions are met:

- The investigator obtains information through oral or written communication with the prospective subject or legally authorized representative, or
- The investigator obtains identifiable private information or identifiable biospecimens by accessing records previously collected or stored identifiable specimens.

*Studies approved prior to implementation of the Revised Common Rule (approved prior to January 21, 2019)*

For those studies receiving approval prior to the implementation of the Revised Common Rule, the previous regulations apply. No action is required on the part of the investigator as these studies are "grandfathered in" under the previous regulations and do not need to update consent forms to comply with the Revised Common Rule. For more information regarding the regulations applicable to these studies, please see archived Informed Consent SOP Revision #11.

## **REFERENCES**

[21 CFR 50.20](#)

[21 CFR 50.23](#)

[21 CFR 50.24](#)

[21 CFR 50.25](#)

[21 CFR 50.27](#)

[21 CFR 56.109 \(b\),\(c\)](#)

[45 CFR 46.111](#)

[45 CFR 46.116](#)

[45 CFR 46.117](#)

[34 CFR 97 \[Department of Education Subpart D\]](#)



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