


Approval Letter Determinations

As part of the overall protocol summary integration, other changes have been made to improve our processes and address the needs and requests of study teams. Over the years we have received a lot of feedback regarding the approval letters issued through ERICA, oftentimes referencing study team needs, sponsor requests, and record maintenance. In an attempt to expound on what is approved in the letter itself, the new approval letters for studies will include the determinations made for that study. While this most directly affects new studies, in the event that a new determination is made during a continuing review or amendment, that determination will be included in the letter.

Only determinations that apply to your study will appear in your letter. If something appears that shouldn't be there or if something is missing, please contact the IRB coordinator who was in charge of your application.

The table below includes all the possible determinations that may appear in your approval letters, an explanation of what that determination means, and other resources available to study teams.

Additional information and resources are available on our website at <http://www.research.utah.edu/irb/>. The A-Z Index and Investigator Guidance Series are excellent resources for additional information and links to relevant websites.

DETERMINATION LISTED IN YOUR APPROVAL LETTER	WHAT DOES THAT MEAN?
 WAIVERS/ALTERATIONS OF CONSENT	
<p>Waiver of Informed Consent <i>The IRB has determined that the request for the waiver of informed consent is approved for this research under 45 CFR 46.116(d).</i></p>	<p>What does this mean? Occasionally there are reasons to waive written consent. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. In order to qualify for a Waiver of Consent, the following conditions should be met: 1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver or alteration the research in question could not be carried out; and 4) information will be provided after participation is completed, if appropriate.</p> <p>If this determination appears in your approval letter, it means that you have been approved to pursue study procedures without gaining consent for participants (such as in the case of a chart review).</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/topic_pages/waiver_consent.html</p>

<p>Waiver of Authorization <i>The IRB has determined that the request for the waiver of authorization is approved for this research under 45 CFR 164.512(i).</i></p>	<p>What does this mean? In some situations, the IRB can waive the requirement to use a HIPAA Authorization Form. To qualify for a Waiver of Authorization, the research use of the health information should not represent more than a minimal risk to privacy, and the researcher should indicate that the research could not be done without the requested health information, that it would not be practical to obtain signed authorizations from the research subjects, and that the specific elements of health information that are requested are not more than the minimum necessary to accomplish the goals of the study.</p> <p>A Waiver of Authorization is most often approved for chart reviews. For studies which will use a chart review to establish eligibility of participants, only the Waiver of Authorization is required. For chart reviews whereby participant information will be pulled from charts for direct research purposes, however, both a Waiver of Authorization and a Waiver of Consent is required.</p>
<p>Waiver of Consent AND Authorization <i>The IRB has determined that the request for the waiver of consent and authorization is approved for this research under 45 CFR 46.116(c) and 56 CFR 164.512(i)(2)(ii).</i></p>	<p>What does this mean? The IRB may waive Consent and Authorization for a study if the board finds that the disclosure of health information involves no greater than minimal risk; the waiver will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver.</p> <p>For studies which include Protected Health Information (PHI), a waiver of Consent and Authorization is required for often requested for certain activities (usually chart reviews). For studies which do not include PHI, only a waiver of Consent would be necessary.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/topic_pages/waiver_consent.html</p>
<p>Waiver of Documentation of Consent <i>The IRB has determined that the request for waiver of documentation of informed consent is approved for this research under 45 CFR 46.117(c).</i></p>	<p>What does this mean? A Waiver of Documentation of Informed Consent is applied to situations in which normal consent processes are followed, but documentation of the participant’s agreement to participate using a signature is not required. Such a waiver may be granted to studies which employ a questionnaire cover letter, web-based consent, consent without signature, etc.</p>

	<p>In order for the IRB to approve such a waiver, one of the following justifications may apply:</p> <p>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. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participant’s wishes will govern.</p> <p>OR</p> <p>The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.</p>
<p>Alteration of Consent <i>The IRB has determined that the request for the alteration of informed consent is approved for this research under 45 CFR 46.116(d).</i></p>	<p>What does this mean?</p> <p>An Alteration of Consent applies on a case by case basis and is employed by studies in which circumstances prevent the investigator from presenting one or more of the elements of informed consent and for which a waiver is inappropriate.</p> <p>The most common use for an Alteration of Consent is for studies which employ deception as part of the design. In certain instances, the aim of the study depends on participants being misled or deceived in some way. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental.</p> <p>The IRB will determine if the use of deception is appropriate and necessary and will most often require that participants be debriefed following their participation in the study. While Alterations of Consent can be used under other circumstances as well, this is the primary application.</p> <p>If you have any questions about the use of an Alteration of Consent for your studies, please contact the IRB for more specific guidance.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/DeceptionDebriefing-G2709.pdf</p>



INVESTIGATIONAL DEVICE DETERMINATIONS

Non-Significant Risk - IRB Issued

The IRB has determined that this study involves the investigation of a non-significant risk (NSR) device; thus, the IRB issues an NSR determination for the purposes of this trial, according to 21 CFR 812.3(m) and 812.2(b).

This means that the study has been approved to use a device which the IRB has determined is non-significant risk to participants. An NSR device is an investigational device that does not meet the definition of a significant risk device. If an IRB finds that an investigational medical device study poses a NSR, the sponsor/investigator does not need to submit an IDE application to FDA before starting the study. Study teams using a NSR device are still required to follow the abbreviated IDE regulations set forth by the FDA [21 CFR 812.2(b)].

A device is considered NSR if all the following are true:
The medical device is not a significant risk device, because all of the following are true:

1. The medical device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
 1. The medical device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
 2. The medical device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
 3. The medical device is does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. The medical device is not banned.
3. The sponsor has provided the IRB with a brief explanation of why the medical device is not a significant risk device, and maintains such approval. Attach the explanation to the documents and attachments page.

Examples of NSR devices include:

Low-power lasers for pain treatment, contact lenses, conventional hospital catheters, dental filling materials, jaundice monitors for infants, etc.

More Info:

	<p>http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm</p> <p>http://www.research.utah.edu/irb/guidelines/ide.html</p> <p>http://www.research.utah.edu/irb/board/pdf/sr_nsr_device_guidance.pdf</p>
<p>Significant Risk - IRB Issued <i>The IRB has determined that this study involves the investigation of a significant risk (SR) device.</i></p>	<p>This means that the IRB (and FDA) have determined that the device being employed for the study poses a Significant Risk (SR) to participants.</p> <p>Because the IRB believes that a device study is SR, the investigation may not begin until both the IRB and FDA approve the investigation. To make the determination of the risk status of the device, the IRB has reviewed information such as reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria, and monitoring procedures.</p> <p>SR device studies are governed by the IDE regulations [21 CFR part 812].</p> <p>Examples of SR Devices include: Tissue adhesives for use in neurosurgery, rebreathers, tracheal tubes, joint prostheses, biliary stents, etc.</p> <p>More Info: http://www.research.utah.edu/irb/board/pdf/sr_nsr_device_guidance.pdf</p> <p>http://www.research.utah.edu/irb/guidelines/ide.html</p>
<p>Device Exemption - IRB Issued <i>The IRB has determined that this study involves the use of a device in an exempted investigation as defined in 21 CFR 812.2(c).</i></p>	<p>The IRB has determined that an IDE is not required for your study because it falls into a device exemption category described in 21 CFR 812.2c or because this is a post approval device study as designated by the FDA. However, you are still required to follow FDA regulations for IRB review and informed consent.</p> <p>More Info: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm</p> <p>http://www.research.utah.edu/irb/guidelines/ide.html</p>



INVESTIGATIONAL DRUG DETERMINATION

IND Exemption - IRB Issued

The IRB has determined that this study involves the use of an FDA approved drug for which an IND is not required; thus the IRB issues an IND exemption for the purposes of this trial, according to 21 CFR 312.2(b).

This means that the FDA has already approved the drug used for the study and the proposed use in the study does not require an Investigational New Drug application.

Such a drug qualifies for an IND exemption if:

It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.

It is not intended to support a significant change in the advertising for the product.

It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

It is conducted in compliance with the requirements for IRB review and informed consent.

The investigation is conducted in compliance with the requirements of 21 CFR 312.7, i.e., the drug may not be represented as safe or effective for any purposes for which it is under investigation, nor may it be commercially distributed or sold.

Exception from informed consent for emergency research will not be invoked.

More Info:

<http://www.fda.gov/Drugs/default.htm>

<http://www.research.utah.edu/irb/guidelines/pdf/IGS-InvestigatorResponsibilitiesForDrugStudies-J2709.pdf>




CHILDREN DETERMINATIONS

Category 1

- The IRB has determined that the inclusion of children is approved under 45 CFR 46.404 and 21 CFR 50.51. One parent/guardian may sign the parental permission*

Children's Category #1 applies to research involving children that the IRB has determined poses no more than Minimal Risk to participants. Your approval letter may indicate that either one or both parents are required to sign the parental permission form. In most cases, only one parent is required to sign, but the IRB can determine on a

<p><i>document, unless the IRB has approved a waiver of consent for this population.</i></p> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • <i>The IRB has determined that the inclusion of children is approved under 45 CFR 46.404 and 21 CFR 50.51. Both parents/guardians must sign the parental permission document, unless the IRB has approved a waiver of consent for this population.</i> 	<p>study by study basis whether or not this is appropriate.</p> <p>Studies are approved under this category are approvable regardless of whether there is a prospect of direct benefit to the child.</p> <p>Although this category allows for one or both parents to sign the permission form, if your form includes signature lines for both parents, then both signatures are required in order to be compliant, regardless of the determination.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Children-C1009.pdf</p>
<p>Category 2</p> <ul style="list-style-type: none"> • <i>The IRB has determined that the inclusion of children is approved under 45 CFR 46.405 and 21 CFR 50.52. One parent/guardian may sign the parental permission document, unless the IRB has approved a waiver of consent for this population.</i> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • <i>The IRB has determined that the inclusion of children is approved under 45 CFR 46.405 and 21 CFR 50.52. Both parents/guardians must sign the parental permission, unless the IRB has approved a waiver of consent for this population.</i> 	<p>Children’s Category #2 is applied to studies which pose Greater than Minimal Risk to participants, but that bear the prospect of direct benefit to the child. Like Category #1, your approval letter may indicate that either one or both parents are required to sign the parental permission form.</p> <p>Most therapeutic medical trials that hold out the prospect of direct benefit to the child may be approvable under this category. Phase I trials and placebo-controlled trials often do not hold out the prospect for direct benefit to participants and may not be approvable under this category. Any submissions that include children in such research practices should include a thorough justification for the involvement of children.</p> <p>Although this category allows for one or both parents to sign the permission form, if your form includes signature lines for both parents, then both signatures are required in order to be compliant, regardless of the determination.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Children-C1009.pdf</p>
<p>Category 3</p> <p><i>The IRB has determined that the inclusion of children is approved under 45 CFR 46.406 and 21 CFR 50.53. Both parents/guardians must sign the parental permission document, unless the IRB has approved a waiver of consent for this</i></p>	<p>Children’s Category #3 applies to research involving interventions or procedures that present a minor increase over minimal risk and no prospect of direct benefit to individual children, but that are likely to yield generalizable knowledge about the child's disorder or condition.</p> <p>The risk involved with each procedure must represent</p>

<p><i>population.</i></p>	<p>minimal risk or a minor increase over minimal risk. It is up to the board to determine the risk level presented by each procedure associated with the study to determine if the research can be approved under this category.</p> <p>For studies approved under category #3, permission from both parents is required.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Children-C1009.pdf</p>
<p>Category 4 <i>The IRB has determined that the inclusion of children is approved under 45 CFR 46.407 and 21 CFR 50.54. Both parents/guardians must sign the parental permission document.</i></p>	<p>Children’s Category #4 is only rarely permitted and requires approval from the Secretary of the Department of Health and Human Services (DHHS) prior to approval. These studies involve Greater than Minimal Risk to participants and is applied to studies that are not otherwise approvable under any other children’s category.</p> <p>For studies approved under this category, permission from both parents is required.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Children-C1009.pdf</p>
 COGNITIVELY IMPAIRED DETERMINATIONS	
<p>Non-VA Studies <i>The IRB has determined that the inclusion of cognitively impaired or mentally disabled adults is approved.</i></p> <ul style="list-style-type: none"> • <i>The PI has demonstrated that there is compelling reason to include incompetent individuals with impaired decision-making capacity as subjects.</i> • <i>The research entails no significant risk, OR if there is some probability of harm there is at least a greater probability of direct benefit to subjects.</i> • <i>Procedures have been devised to ensure that the subject’s representative is well informed about his/her role and obligation to protect the incompetent</i> 	<p>Studies that involve participants who have mental or cognitive impairment are required to take special precautions. These subjects generally have decisional impairment and cannot consent for themselves.</p> <p>Decisional Impairment: This term is used when an individual has a diminished capacity for understanding information and for making a reasoned decision due to a disorder that affects cognitive or emotional functions. Other individuals may be considered to have a decisional impairment because they have a degenerative disease affecting decision-making capacity or are comatose or otherwise incapacitated. The terms “decisional impairment” and “diminished decisional capacity” may be used interchangeably in this document.</p> <p>Studies which include this vulnerable population usually require the consent from a Legally Authorized Representative (LAR) for the subject to participate.</p>

<p><i>research subject with impaired decision-making capacity.</i></p>	<p>Because there are no specific guidelines required for this population in the federal regulations, the standards applied to research involving children have been adapted.</p> <p>Studies which include patients who cannot consent for themselves, for whatever reason, must take into account issues of eventual consent, re-consent, or the use of an assent for those with diminished capacity.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGSresearchInvolvingCognitively-ImpairedIndividualsNon-VA-D2209.pdf</p>
<p>VA Studies <i>The IRB has determined that the inclusion of cognitively impaired adults is approved.</i></p> <ul style="list-style-type: none"> • <i>Only incompetent persons or persons with impaired decision-making capacity are suitable as research subjects. (Competent persons are not suitable for the proposed research.)</i> • <i>The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant.</i> • <i>Health care agents (appointed under Durable Power of Attorney for Health Care (DPAHC) and next-of-kin, or guardians, must be given descriptions of both proposed research studies and the obligations of the person’s representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject’s wishes cannot be determined, what they think is in the incompetent person’s best interest.</i> 	<p>Studies that involve participants who have mental or cognitive impairment are required to take special precautions. These subjects generally have decisional impairment and cannot consent for themselves. If this research is conducted at the VA, additional steps are required.</p> <p>Decisional Impairment: This term is used when an individual has a diminished capacity for understanding information and for making a reasoned decision due to a disorder that affects cognitive or emotional functions. Other individuals may be considered to have a decisional impairment because they have a degenerative disease affecting decision-making capacity or are comatose or otherwise incapacitated. The terms “decisional impairment” and “diminished decisional capacity” may be used interchangeably in this document.</p> <p>Studies which include this vulnerable population usually require the consent from a Legally Authorized Representative (LAR) for the subject to participate.</p> <p>Because there are no specific guidelines required for this population in the federal regulations, the standards applied to research involving children have been adapted.</p> <p>Studies which include patients who cannot consent for themselves, for whatever reason, must take into account issues of eventual consent, re-consent, or the use of an assent for those with diminished capacity.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGSresearchInvolvingCognitively-ImpairedIndividualsNon-VA-D2209.pdf</p>

[archInvolvingCognitively-ImpairedIndividualsNon-VA-D2209.pdf](#)



PREGNANT WOMEN & FETUSES DETERMINATIONS

*The IRB has determined that the inclusion of pregnant women and fetuses is approved under 45 CFR 46.204, as research holds the **prospect of direct benefit for the pregnant woman and the fetus**. Consent from the pregnant woman is required, unless the IRB has approved a waiver of consent for this population.*

This determination is applied to research involving pregnant women and fetuses as subjects. Subpart B is found in 45 CFR 46 (DHHS). This designation in your approval letter means that the research being conducted benefits the pregnant woman or the fetus. For research approved under this category, only the pregnant woman is required to consent to participate. That said, the IRB has the ability to require both parent signatures if they deem it appropriate. Your approval letter will indicate as such.

More Info:

<http://www.research.utah.edu/irb/guidelines/pdf/IGS-PregnantWomenAndFetuses.pdf>

http://www.research.utah.edu/irb/guidelines/pdf/fetal_tissue_trans_research.pdf

*The IRB has determined that the inclusion of pregnant women and fetuses is approved under 45 CFR 46.204, as the research holds the **prospect of direct benefit for the pregnant woman**. Consent from the pregnant woman is required, unless the IRB has approved a waiver of consent for this population.*

This determination is applied to research involving pregnant women and fetuses as subjects. Subpart B is found in 45 CFR 46 (DHHS). This designation in your approval letter means that the research being conducted holds to potential to provide direct benefit to the woman only. In this instance, only the pregnant woman is required to consent to participate. That said, the IRB has the ability to require both parent signatures if they deem it appropriate. Your approval letter will indicate as such.

More Info:


<http://www.research.utah.edu/irb/guidelines/pdf/IGS-PregnantWomenAndFetuses.pdf>

http://www.research.utah.edu/irb/guidelines/pdf/fetal_tissue_trans_research.pdf

*The IRB has determined that the inclusion of pregnant women and fetuses is approved under 45 CFR 46.204, as the research holds the **prospect of direct benefit for the fetus**. Consent from the pregnant woman and the father of the fetus is required, unless the IRB has approved a waiver of consent for this*

This determination is applied to research involving pregnant women and fetuses as subjects. Subpart B is found in 45 CFR 46 (DHHS). This designation in your approval letter means that the research being conducted holds to potential to provide direct benefit to the fetus only. In this instance, consent must be obtained from the pregnant woman and the father of the fetus.

- The father’s consent does not need to be obtained

<p><i>population. The father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, temporary incapacity, or if the pregnancy resulted from rape or incest.</i></p>	<p>if he is unable to consent because of unavailability, incompetence, temporary incapacity, or if the pregnancy resulted from rape or incest.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-PregnantWomenAndFetuses.pdf http://www.research.utah.edu/irb/guidelines/pdf/fetal_tissue_trans_research.pdf</p>
<p><i>The IRB has determined that the inclusion of pregnant women and fetuses is approved under 45 CFR 46.204, as the research holds NO prospect of direct benefit to the woman or the fetus, the risk to the fetus is not greater than minimal, and the purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means. Only consent from the pregnant woman is required, unless the IRB has approved a waiver of consent for this population.</i></p>	<p>This determination is applied to research involving pregnant women and fetuses as subjects. Subpart B is found in 45 CFR 46 (DHHS). This designation in your approval letter means that the research being conducted holds NO potential to provide direct benefit to the pregnant woman OR the fetus. Such studies can only be approved if they pose no more than minimal risk and the purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means.</p> <p>Because these studies are minimal risk, only the consent of the pregnant woman is required. That said, the IRB has the ability to require both parent signatures if they deem it appropriate. Your approval letter will indicate as such.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-PregnantWomenAndFetuses.pdf http://www.research.utah.edu/irb/guidelines/pdf/fetal_tissue_trans_research.pdf</p>
 NEONATE DETERMINATIONS (UNCERTAIN VIABILITY AND NONVIABLE)	
<p><i>The IRB has determined that the inclusion of neonates of uncertain viability is approved under 45 CFR 46.205, as the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability. Any risk to the neonate is the least possible for achieving the objective of enhancing the probability of survival of the neonate to the point of viability. Consent from either parent of the neonate is required, unless</i></p>	<p>Federal regulations require additional safeguards when approving research involving neonates. These special protections are found in Subpart B. The IRB may approve research involving neonates only if the research meets the criteria outlined in Subpart B, provided that the research also meets the general criteria for approval. The term “neonates” refers to newborns from the time of delivery up until 28 days old. Research involving this population is approvable under Subpart B of the federal regulations 45 CFR 46 (DHHS).</p>

<p><i>the IRB has approved a waiver of consent for this population.</i></p>	<p>This designation in your approval letter means that the research being conducted involves neonates whose viability is uncertain. Although these infants are alive, it is uncertain whether or not they will survive.</p> <p>Studies approved under this category involve research which holds out the prospect of enhancing the probability of survival of the neonate to the point of viability. Any risk to the neonate is the least possible for achieving the objective of enhancing the probability of survival of the neonate to the point of viability.</p> <p>For these studies, the permission of only one parent is required for participation. That said, the IRB has the ability to require both parent signatures if they deem it appropriate. Your approval letter will indicate as such.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Neonates.pdf</p>
<p><i>The IRB has determined that the inclusion of neonates of uncertain viability is approved under 45 CFR 46.205, as the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. Consent from either parent of the neonate is required, unless the IRB has approved a waiver of consent for this population.</i></p>	<p>Federal regulations require additional safeguards when approving research involving neonates. These special protections are found in Subpart B. The IRB may approve research involving neonates only if the research meets the criteria outlined in Subpart B, provided that the research also meets the general criteria for approval. The term “neonates” refers to newborns from the time of delivery up until 28 days old. Research involving this population is approvable under Subpart B of the federal regulations 45 CFR 46 (DHHS).</p> <p>This designation in your approval letter means that the research being conducted involves neonates whose viability is uncertain. Although these infants are alive, it is uncertain whether or not they will survive.</p> <p>Studies approved under this category involve research which poses no additional risk to participants as a result of the research itself. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.</p> <p>For these studies, the permission of only one parent is required for participation. That said, the IRB has the ability to require both parent signatures if they deem it appropriate. Your approval letter will indicate as such.</p>

	<p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Neonates.pdf</p>
<p><i>The IRB has determined that the inclusion of nonviable neonates is approved under 45 CFR 46.205, as there is no additional risk to the neonate resulting from the research. Consent from both parents of the neonate is required, unless the IRB has approved a waiver of consent for this population. Consent from the father need not be obtained if the pregnancy resulted from rape or incest.</i></p>	<p>Federal regulations require additional safeguards when approving research involving neonates. These special protections are found in Subpart B. The IRB may approve research involving neonates only if the research meets the criteria outlined in Subpart B, provided that the research also meets the general criteria for approval. The term “neonates” refers to newborns from the time of delivery up until 28 days old. Research involving this population is approvable under Subpart B of the federal regulations 45 CFR 46 (DHHS).</p> <p>After delivery, nonviable neonates may be included in research if the following conditions are met:</p> <ol style="list-style-type: none"> 1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates; 2. Each individual providing consent is fully informed regarding the reasonable foreseeable impact of the research on the neonate; 3. Individuals engaged in the research will have no part in determining the viability of a neonate; 4. Vital functions of the neonate will not be artificially maintained; 5. The research will not terminate the heartbeat or respiration of the neonate; 6. There will be no added risk to the neonate resulting from the research; 7. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. <p>Consent from <u>both</u> parents of the neonate is required. If consent cannot be obtained from one parent because of unavailability, incompetence, or temporary incapacity, consent from one parent will suffice. If neither parent can give consent, the neonate may not be included in the research.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-Neonates.pdf</p>



PRISONER DETERMINATIONS

<p>Category 1 <i>The IRB has determined that the inclusion of prisoners is approved under 45 CFR 46.306, as the research proposes to study the possible causes, effects, and processes of incarceration, and of criminal behavior. The study presents no more than minimal risk and no more than inconvenience to the participants.</i></p>	<p>Studies involving prisoners as a vulnerable population are approved under Subpart C of the federal regulations. Subpart C is found in 45 CFR 46 (DHHS). Subpart C is applicable to research involving prisoners which is funded by DHHS or conducted within DHHS. The University of Utah commits to compliance with Subpart C. Therefore, research involving prisoners conducted by the University of Utah is subject to Subpart C.</p> <p>A prisoner means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations where a human participant becomes a prisoner after the research has commenced.</p> <p>Research including prisoners which is approved under category 1 looks at the causes, effects, and processes of incarceration, as well as criminal behavior as a study aim. Such studies are minimal risk and pose no more than inconvenience to participants (such as taking their time).</p> <p>Investigators including prisoners must provide additional protections and take into account additional considerations when conducting research on this population. Please see the references below for a more comprehensive discussion.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-ResearchInvolvingPrisoners-D2209%282%29.pdf http://www.research.utah.edu/irb/guidelines/pdf/ohrp_prisoner_guidance.pdf</p>
<p>Category 2 <i>The IRB has determined that the inclusion of prisoners is approved under 45 CFR 46.306, as the research proposes to study prisons as institutional structures or to study prisoners as incarcerated persons.</i></p>	<p>Studies involving prisoners as a vulnerable population are approved under Subpart C of the federal regulations. Subpart C is found in 45 CFR 46 (DHHS). Subpart C is applicable to research involving prisoners which is funded by DHHS or conducted within DHHS. The University of Utah commits to compliance with Subpart C. Therefore,</p>

<p><i>The study presents no more than minimal risk and no more than inconvenience to the subjects.</i></p>	<p>research involving prisoners conducted by the University of Utah is subject to Subpart C.</p> <p>A prisoner means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations where a human participant becomes a prisoner after the research has commenced.</p> <p>Research including prisoners which is approved under category 2 proposes to study prisons as institutional structures or to study prisoners as incarcerated persons. The study must be no more than minimal risk and no more than inconvenience to the participants.</p> <p>Investigators including prisoners must provide additional protections and take into account additional considerations when conducting research on this population. Please see the references below for a more comprehensive discussion.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-ResearchInvolvingPrisoners-D2209%282%29.pdf http://www.research.utah.edu/irb/guidelines/pdf/ohrp_prisoner_guidance.pdf</p>
<p>Category 3 <i>The IRB has determined that the inclusion of prisoners is approved under 45 CFR 46.306, as the research proposes to study the conditions particularly affecting prisoners as a class (e.g., research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).</i></p>	<p>Studies involving prisoners as a vulnerable population are approved under Subpart C of the federal regulations. Subpart C is found in 45 CFR 46 (DHHS). Subpart C is applicable to research involving prisoners which is funded by DHHS or conducted within DHHS. The University of Utah commits to compliance with Subpart C. Therefore, research involving prisoners conducted by the University of Utah is subject to Subpart C.</p> <p>A prisoner means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a</p>

	<p>penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations where a human participant becomes a prisoner after the research has commenced.</p> <p>Research including prisoners which is approved under category 3 proposes to study the conditions particularly affecting prisoners as a class. (For example: A vaccine trial and other research on hepatitis, which is much more prevalent in prisons than elsewhere or research on social and psychological problems such as alcoholism, drug addiction and sexual assaults.) Studies that fit into this category may only proceed after the Secretary of the Department of Health and Human Services has consulted with appropriate experts in penology medicine and ethics. The Secretary must also publish notice in the Federal Register of his/her intent to approve the research.</p> <p>Investigators including prisoners must provide additional protections and take into account additional considerations when conducting research on this population. Please see the references below for a more comprehensive discussion.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-ResearchInvolvingPrisoners-D2209%282%29.pdf http://www.research.utah.edu/irb/guidelines/pdf/ohrp_prisoner_guidance.pdf</p>
<p>Category 4 <i>The IRB has determined that the inclusion or prisoners is approved under 45 CFR 46.306, as the research proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants.</i></p>	<p>Studies involving prisoners as a vulnerable population are approved under Subpart C of the federal regulations. Subpart C is found in 45 CFR 46 (DHHS). Subpart C is applicable to research involving prisoners which is funded by DHHS or conducted within DHHS. The University of Utah commits to compliance with Subpart C. Therefore, research involving prisoners conducted by the University of Utah is subject to Subpart C.</p> <p>A prisoner means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations</p>

	<p>where a human participant becomes a prisoner after the research has commenced.</p> <p>Research including prisoners which is approved under category 4 proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants. The study may be designed for prisoners only or may have the option to include prisoners. In studies where prisoners may be assigned to a control group and may not benefit from the research, the study may not be approved for the inclusion of prisoners until the Secretary of the Department of Health and Human Services has consulted with appropriate experts in penology medicine and ethics. The Secretary must also publish notice in the Federal Register of his/her intent to approve the research.</p> <p>Investigators including prisoners must provide additional protections and take into account additional considerations when conducting research on this population. Please see the references below for a more comprehensive discussion.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-ResearchInvolvingPrisoners-D2209%282%29.pdf http://www.research.utah.edu/irb/guidelines/pdf/ohrp_prisoner_guidance.pdf</p>
<p>Category 5 <i>The IRB has determined that the inclusion of prisoners is approved under 45 CFR 46.306, as this is epidemiologic research that proposes to study the prevalence or incidence of a disease by identifying all cases or to study the potential risk factor associations for disease. The study presents no more than minimal risk, no more than an inconvenience to the participants and prisoners are not the particular focus of the study.</i></p>	<p>Studies involving prisoners as a vulnerable population are approved under Subpart C of the federal regulations. Subpart C is found in 45 CFR 46 (DHHS). Subpart C is applicable to research involving prisoners which is funded by DHHS or conducted within DHHS. The University of Utah commits to compliance with Subpart C. Therefore, research involving prisoners conducted by the University of Utah is subject to Subpart C.</p> <p>A prisoner means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations</p>

	<p>where a human participant becomes a prisoner after the research has commenced.</p> <p>Research including prisoners which is approved under category 5 involves epidemiologic studies when the research proposes to study the prevalence or incidence of a disease by identifying all cases or to study the potential risk factors associations for disease. The study must be no more than minimal risk, no more than an inconvenience to the participants, and prisoners cannot be the particular focus of the study.</p> <p>Investigators including prisoners must provide additional protections and take into account additional considerations when conducting research on this population. Please see the references below for a more comprehensive discussion.</p> <p>More Info: http://www.research.utah.edu/irb/guidelines/pdf/IGS-ResearchInvolvingPrisoners-D2209%282%29.pdf http://www.research.utah.edu/irb/guidelines/pdf/ohrp_prisoner_guidance.pdf</p>
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