

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.010
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In order to approve human subjects research, the IRB must determine that all of the following requirements are satisfied, as outlined in [45CFR 46.111\(a\)\(1-7\(b\)\)](#):

(a) 1. Risks to subjects are minimized

Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

1. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
2. Selection of subjects is equitable.
3. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.
4. Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.
5. When appropriate, the research plan makes adequate provision of monitoring the data collected to ensure the safety of subjects.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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**A. Assessing Sound Study Design**

*A human study should be well-designed according to sound scientific principles and be preceded by adequate laboratory and/or animal studies. A study which will not yield valuable data is unacceptable.*

*Excerpt from Responsible Conduct of Human Studies*

The SHIRB considers the following points when assessing sound study design:

1. Has the rationale and basis for the study hypothesis been provided in the background information?
2. Is the scientific design adequate to answer the research questions posed?
3. Is the sample size (number of subjects) adequate?
4. Is the method proposed for selecting and assigning subjects to treatment groups unbiased?
5. Are the study endpoints and methods of data analysis appropriate for the study?

**B. Assessing Risks and Anticipated Benefits, if any, to Subjects**

*The gain anticipated from a human experiment must be commensurate with the risk involved. Risks and hazards to be evaluated include the possibility of physical, psychological, sociological, or other harm that might be incurred as the consequence of a research activity. Sometimes large risks are taken for large gains in human knowledge, but in almost all cases such large risks should be taken only when an individual is likely to benefit directly in needed diagnosis or therapy. In all human research, concern for the individual takes precedence over the interests of science and society.*

*Excerpt from Responsible Conduct of Human Studies*

The SHIRB considers the following points when assessing risks and anticipated benefits, if any, to subjects:

- What are the anticipated risks to individual subjects?

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- What are the potential benefits, if any, to individual subjects?
- Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
- Are there adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design?

In evaluating the risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB does not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility [[45 CFR 46.111\(2\)](#)]

### **C. Assessing Equitable Selection of Subjects**

*While studies of a captive group of subjects, such as students, laboratory personnel, and hospitalized patients may be useful and desirable and can be conducted in an ethical fashion, a scrupulous effort must be made to preserve the individual's rights because of the possibility of coercion.*

*Studies of volunteers in the investigator's own department or who are the investigator's students should be avoided and will usually be disapproved by the IRB because of the subtle coercive factors that could be present in even the most harmonious situations.*

Excerpt from *Responsible Conduct of Human Studies*

The IRB considers the following points when assessing equitable selection of subjects:

- Does the nature of the research require or justify using the proposed study population?

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- Will the solicitation of subjects avoid placing a disproportionate share of the risks and discomfort as well as inconvenience of the research on any single group of individuals?
- Are women of childbearing potential eligible for participation or, if not eligible, has their exclusion been justified?
- Has the selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
- Are any payments to subjects reasonable based upon the complexities and inconveniences of the study and the particular subject population?

In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons [45 CFR 46.111(3)].

**D. Assessing Methods for Obtaining Informed Consent of Subjects or Representatives**

*Communication between subject and investigator should embody aspects similar to those in a good patient-doctor relationship. The discussion with the potential participant by the investigator or co-investigator should include the purpose of the research, the procedures to be followed, and the discomforts, risks and possible benefits, if any. The signing of the consent document should signify that a thorough discussion has taken place and will continue to take place during the conduct of the study.*

*Patients being asked to participate in diagnostic or therapeutic trials should be informed of any alternative choices for diagnosis or treatment. All subjects should know if their treatment is to be determined by random selection and if placebos are to be used. No information should be withheld that might influence the decision, nor should there be promises of beneficial results.*

Excerpt from *Responsible Conduct of Human Studies*

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The IRB considers the following points when assessing the methods for obtaining informed consent:

- Who will be explaining the research to potential subjects? Should the principal investigator or physician co-investigators be required to obtain consent? Should someone in addition to or other than the investigator be present? (e.g., subject advocate)?
- Does the investigator serve a dual role that may pose a conflict of interest?
- Will the consent process take place under conditions most likely to provide potential subjects an opportunity to make a decision about participation without undue pressure?
- Is the language and presentation of the information to be conveyed appropriate to the subject population, taking into consideration the reading level, use of complex sentence structure and use of technical terms as well as the need for translation into languages other than English?
- Do the consent documents describe the study design (including plans for randomization, use of placebos, and the probability that the subject will receive a given treatment) and conditions for breaking the code (if the study is blinded)?
- Do the consent documents describe the risks and benefits of each of the proposed interventions and alternative courses of action available to the participants?
- Do the consent documents clearly describe the extent to which participation in the study precludes other therapeutic interventions?

(a) General Requirements for Informed Consent

The following information shall be provided to each subject in accordance with [45 CFR 46.116\(a\)\(1-8\)\(b\)\(1-6\)](#), or [21 CFR 50.20, 23, 24, 25, 27](#), as quoted below:

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(b) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, who is responsible for the payment of the treatments, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

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- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
  
- (c) Additional elements of informed consent. When appropriate, the following information must be provided to each subject:
  - (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
  - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
  - (3) Any additional costs to the subject that may result from participation in the research;
  - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
  - (6) The approximate number of subjects involved in the study, locally and nationally/globally.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the

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investigator, the sponsor, the institution or its agents from liability for negligence.

While many of the additional elements of informed consent are included in the standard template for consent documents and are required for most studies, others are required for interventional studies depending upon the nature of the intervention. Where the risks of the intervention are not well known, there may be unknown risks to the subject or a developing fetus, and this should be stated. Where subjects are receiving a therapeutic intervention and their participation may be terminated or they may withdraw from participation, the consent form should include the procedure for stopping the study medication and disposition of the subject. This may include procedures such as a returning for a final study visit, returning unused study medications, and being referred back to their primary care physician for ongoing care for their medical condition.

(d) Alteration or Waiver of Informed Consent

Under the Common Rule ([45 CFR 46 116\(d\)\(1-4\)](#)) IRBs have the authority to alter or waive the requirement for informed consent of subjects; however the FDA ([21 CFR 50.24](#)) only provides an exception from informed consent requirements for emergency research.

For research not subject to FDA regulations, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that the regulatory requirements in 45 CFR 46.116(c)(d) quoted below are satisfied:

- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (1) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services

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under those programs; and (2) The research could not practicably be carried out without the waiver or alteration.

Or the IRB finds and documents that:

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

**E. Informed Consent Requirements in Emergency Research**

- (a) Research subject to FDA regulations (IND) or (IDE) research

When the research involves the planned enrollment of subjects who are in a life-threatening situation who are in need of emergency therapy and for whom legally effective informed consent cannot be obtained because of their medical condition and unavailability of legally authorized representative, the IRB may approve an exception from informed consent if the IRB finds and documents that the requirements detailed in 21 CFR 50.24 are met.

- (b) Research not subject to FDA regulations

When the research involves the planned enrollment of subjects who are in a life-threatening situation who are in need of emergency therapy and for whom legally effective informed consent cannot be obtained because of their medical condition and the unavailability of legally authorized representative, the IRB may approve a waiver of informed consent if the IRB finds and documents and reports to OHRP that the requirements detailed in the OPRR Report *Informed Consent Requirements in Emergency Research* dated October 31, 1996 are met.

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## **F. Assessing Documentation of Informed Consent**

An individual's willingness to join a study must be documented by a written consent form, or, in certain types of studies as determined by the IRB, by oral consent, noted in the subject's medical record (or research record, where no medical record exists). In rare cases, the IRB may waive documentation of informed consent when such documentation might constitute a potential risk to the subject's privacy or alter or waive the requirement as described below.

In certain circumstances, the regulations allow the IRB to waive written informed consent. For research subject to FDA regulations, the IRB may waive written informed consent only for research that meets (2) below.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

- (1) That 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 subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

The Sunrise Health IRB considers the following points when assessing documentation of informed consent:

- Does the consent form include the required elements of informed consent and additional elements, if applicable?

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- Does the consent form include the requirement for the signature of the subject or his/her legally authorized representative?
- Does the research involve minimal risk and would written consent be required for these procedures if they were not part of a research study?

In most cases a written consent form must be used to obtain informed consent of the subject or the subject's legally authorized representative. The consent form must include the elements of informed consent required by [45 CFR 46.116](#) or [21 CFR 50.25](#) and must be signed and dated by the subject or his/her legally authorized representative. The subject or his/her legally authorized representative must be given a copy of the consent. In-patient studies require a signed, SHIRB approved consent form on the Hospital medical record of each enrolled subject.

Unless consent has been waived, the investigator must conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. Authentication of this process must be demonstrated by affixing an original signature, date and time.

Examples of situations where the IRB may waive the requirement for written documentation of informed consent include studies limited to focus groups, or mail or telephone surveys or interviews. When the IRB waives the requirement for written documentation of informed consent, the findings will be documented in the Minutes or if through the expedited review procedure, in the review form completed by the IRB Chairperson.

Translations. Translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. There are two options available to obtain approval of translated consent forms.

- Option #1: The IRB-approved consent form is translated by the Sponsor or site and submitted to the IRB. A certification letter must be submitted stating that the translated consent matches the IRB approved English version of the consent.

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- Option #2: The Investigator (or Sponsor) may submit the IRB-approved English version of the consent to a certified translator. A certification letter must be submitted stating that the translated consent matches the IRB approved English version of the consent.

### G. Assessing Data and Safety Monitoring Plan

The Sunrise Health IRB requires investigators proposing interventional research with human subjects to address plans for monitoring the data to ensure the safety of subjects. The plan may be described by the sponsor in the corporate or cooperative group protocol or by the investigator in an investigator-initiated protocol. The Data and Safety Monitoring Plan (DSMP) must be presented in sufficient detail for the IRB to determine whether it is appropriate for the research.

***Data and safety monitoring*** is the process for reviewing accumulated outcome data for groups of subjects to determine if the research should be altered or stopped. Ongoing review of the aggregate data ensures that the study can continue without undue risk to participants. ***Safety monitoring*** also includes the continual assessment of risks and benefits through the review of individual adverse events and other safety parameters as they occur during the study to determine whether individual participants can safely continue to participate. ***Data monitoring*** is the process for ensuring the scientific integrity of the research data including its accuracy, completeness and its collection in compliance with the protocol.

A Data and Safety Monitoring Plan is unique to the trial and should be commensurate with the potential risk and with the size and complexity of the trial. Appropriate DSMPs may fall anywhere along a continuum from monitoring by the principal investigator or group of investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB). Regardless of the type of DSMP, the individuals participating in the monitoring plan must be objective.

In general, a DSMB is the most appropriate way to monitor data and safety for studies that involve:

- Large number of subjects;

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- Multiple sites;
- High risk therapies/procedures;
- High rates of morbidity or mortality related to the underlying disease process being studied; and/or
- Blinded studies.

The Sunrise Health IRB considers the following points when assessing the plan for monitoring the data:

- How will the trial be monitored? Will there be an independent data and safety monitoring board?
- How will decisions about stopping the trial be made? By whom? On what basis?

#### **H. Assessing Privacy and Confidentiality Protections**

During the course of a study, the highest standards should be maintained with regard to the privacy and confidentiality of information, including interviews, photographs, and other records concerning the subject. Although more investigators and staff may be involved in the conduct of a study than might occur in the usual course of treatment of a patient, confidentiality standards should not be relaxed.

The Sunrise Health IRB considers the following points when assessing privacy and confidentiality protections:

- If the investigator wants to review existing records to select subjects for further study, are subjects recruited through their physician or health care provider involved in their care?
- Will the investigator(s) be collecting sensitive information about individuals (e.g., related to sexual practices, substance abuse, or illegal behavior)? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study?

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- If the information obtained about subjects might interest law enforcement or other governmental agencies to the extent that they might demand personally identifiable information, should a certificate of confidentiality be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process?
- Are there adequate plans to protect participants from the risks of breach of confidentiality and invasion of privacy? If the protocol involves an epidemiologic study, will subjects or their relatives be protected from learning inappropriate information?

The Sunrise Health IRB does not serve as the Privacy Board for the institutions. The IRB's responsibilities as they pertain to HIPAA include:

- Development and implementation of research policies to comply with HIPAA and the Privacy Rule;
- Review of authorization language when merged with the research consent form; and
- Approval of waivers of authorization for research-related activities.

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## I. Vulnerable Populations

When the research involves the inclusion of vulnerable populations (e.g., pregnant women, human fetuses and neonates, prisoners, children, cognitively impaired persons), the IRB is responsible for considering additional protections [45 CFR 46 Subpart B, C, D].

The inclusion of a vulnerable population in the research must be justified and adequate safeguards must be in place to minimize risks unique to the particular vulnerable population.

### 1. Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research if all of the regulatory conditions in [45 CFR 46.204](#) are met, as quoted below:

- (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- (c) Any risk is the least possible for achieving the objectives of the research;
- (d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in

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accord with the informed consent provisions of subpart A of this part;

- (e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- (f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- (g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
- (h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- (i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- (j) Individuals engaged in the research will have no part in determining the viability of a neonate

## 2. Neonates

Neonates may be involved in research if all of the regulatory conditions in [45 CFR 46.205](#) are met, as quoted below:

- (a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
  - (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and

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provide data for assessing potential risks to neonates.

- (2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably 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) The requirements of paragraph (b) or (c) of this section have been met as applicable.
- (b) Neonates of uncertain viability may not be involved in research unless:
  - (1) The IRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or (ii) The purpose of 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; and
  - (2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part,

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except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

- (c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:
- (1) Vital functions of the neonate will not be artificially maintained;
  - (2) The research will not terminate the heartbeat or respiration of the neonate;
  - (3) There will be no added risk to the neonate resulting from the research;
  - (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
  - (5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or

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incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

- (d) Viable neonates may be included in research only to the extent permitted by [45 CFR 46 Subpart D](#) – Additional Protections for Children Involved as Subjects in Research.

3. Prisoners

Federal regulations ([45 CFR 46 Subpart C](#)) requires that an IRB must be constituted with at least one member who participates in reviews who is a prisoner or prisoner representative in order for the IRB to review research involving prisoners as subjects. The SHIRB does not currently have a member who is a prisoner or prisoner representative and therefore does not currently review research involving prisoners as subjects.

4. Children

According to Nevada State Law, minors are persons under the age of eighteen [NRS 159.023](#). The general rule is that a person may consent for his or her own medical care at the age of eighteen. Certain statutes and case law, however, provide minors with majority status in some circumstances, for example: emancipated minor. [NRS 129.030](#)

The Sunrise Health IRB may approve research that involves children as subjects of research if regulatory requirements at [45 CFR 46.404, 405, 406](#) are met, as quoted in part below:

- (a) The research does not involve greater than minimal risk;
- (b) The research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects; or
- (c) The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely

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to yield generalizable knowledge about the subject's disorder or condition.

If the IRB finds that the research is not approvable as indicated above, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, the research can be submitted for review by the Secretary of HHS in accordance with [45 CFR 46.407](#).

When children or minors (under the age of 18) are involved in research, the regulations require that assent (a child's affirmative agreement to participate in research) of the child or minor be obtained and the permission (the agreement of parent(s) or guardian(s) to the participation of their child or ward in research) of the parent(s) be obtained, in place of the consent of the subjects. Given that children have not reached their full intellectual and emotional capacities and are legally unable to give valid consent, involving children in research requires the permission of their parent(s) or legally authorized representatives.

The Sunrise Health Institutional Review Board requires that children greater than 7 must provide written assent.

While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research: (1) does not involve interventions likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

The IRB has developed a form for review of research involving children as subjects of research. When investigators plan to enroll minors in research, they must complete the form to address the level of risk to subjects and, if greater than minimal risk, the prospect for direct benefit to individual subjects, if any, and the importance of the information to be gained about the subject's condition in the protocol submission to the IRB.

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5. Cognitively-Impaired Persons

A person generally is legally competent to give informed consent to research when s/he understands the difference between treatment and research, understands the risks and benefits of a specific research protocol and its procedures, appreciates the consequences of acting (or not acting), and is able to make a choice.

In research involving a person with impaired decision-making capacity who cannot give informed consent, federal regulations require that consent be obtained from the person's legally authorized representative, as determined by state or local law. In such cases, the first step is for a qualified professional to assess the individual's competency. General competency measures – such as the Clinical Dementia Rating (CDR) or the Activities of Daily Living scale – may be helpful, but generally should not be the sole measure of competency. Similarly, the Mini Mental Status Exam (MMSE) may be a helpful starting point, but is not appropriate as a sole measure. A formal psychiatric and/or medical assessment typically is warranted, and importantly, should consider what level of understanding is needed for the specific research. The investigator should describe in detail how competency will be assessed, who will perform the assessments, and what that professional's relationship is to the individual and the research team in the protocol submission to the IRB. In order to strengthen the integrity of the enrollment process, in any research involving more than a questionnaire or cognitive test – such as a study of a new medication – consideration should be given to using an independent professional (who is not part of the research team) to assess a potential subject's competency.

The SHIRB considers the following points, where applicable, when assessing research involving vulnerable populations:

- Is the inclusion of the vulnerable populations necessary, e.g., the research pertains specifically to the vulnerable population;

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- Has the research been preceded by adequate preclinical and clinical studies;
- Is the risk to the subject and if applicable, the fetus, minimal or greater than minimal risk;
- Is there the potential for direct benefit to individual subjects;
- Is the information or knowledge to be gained important;
- Are the procedures for determining capacity to consent appropriate;
- Should decision-making capacity be assessed by an independent physician;
- Should the consent process be monitored;
- Is permission of both parents required;
- Is asset required; and
- Should a research subject advocate be involved in the consent process, initially and throughout the course of the study.

**J. Ancillary Committee / Department Review**

In addition to obtaining approval of the IRB, when applicable, the following ancillary review committees or departments must review and approve the research activity prior to initiation of the research and enrollment of subjects. The ancillary committees/departments are responsible for communicating issues and/or concerns to the investigators and IRB and when approved, for providing written notification of approval to the IRB.

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1. Pharmacy Review

The Pharmacy must review and approve human research that meets the following criteria:

- Research activities that direct drug administration, whether the drug is FDA-approved or not; or
- Research activities in which ancillary drugs are given for any procedure/test required by protocol and not for clinical care of the patient.

2. Biomedical Engineering Review

The Department of Biomedical Engineering must review and approved human research that meets the following criteria:

- Research activities involving electrically (line or battery) powered investigational devices;
- Research activities involving non-standard use of hospital electrically (line or battery) powered devices; or
- Research activities involving the use of non-hospital inventory electrically (line or battery) powered devices.

The use of any commercially available medical device in research must meet the same hospital safety standards as medical devices being used for patient care and as such is subject to the institution's medical equipment management program.

3. Radiation Safety Committee

The Radiation Safety Committee must review and approve human research that meets the following criteria:

- Research activities involving exposure to ionizing radiation for research purposes;

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- Research activities involving exposure to nonionizing radiation for research purposes; or
- Research activities that involve the use of radiopharmaceuticals.

4. Nursing Review

The Department of Nursing must review and approve research activities that involve facilitation by nurses or other members of Patient Care Services, such as:

- Administering and monitoring of investigational medications and devices;
- Procuring of any research-related specimens;
- Insertion of additional research-required intravenous catheters;
- Accompanying subjects to research-required tests;
- The use of research technology equipment; or
- Collection of data for research purposes.

**K. Notification to Principal Investigator of IRB Approval**

When the research protocol is approved, the PI is notified in writing of the date of IRB approval and expiration as well as the following responsibilities:

- Requirement to submit in writing any and all changes to the research project to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject. Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.

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- Requirement to submit in writing any and all adverse event(s) that occur during the course of this project that are both serious and unexpected within 10 working/14 calendar days of notification of event;
- Requirement to submit in writing any and all unanticipated problems involving risks to subjects or others;
- Requirement to use only IRB approved copies of the consent form(s), questionnaire(s), advertisement(s), etc; and
- Responsibility to inform all physicians listed on the project of changes and adverse events, and unanticipated problems.