### IU IRB Reviewer Checklist

Please complete all sections for all items reviewed. **Save every 3-4 minutes to avoid losing your work.**

#### Study Information

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<th>Study Number</th>
<th>Meeting Date</th>
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<th>Reviewer (last name only)</th>
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<th>Study Regulated By:</th>
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<td>FDA</td>
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### 1 - Criteria for Approval & Reviewer Comments

All IRB provisions should relate directly to the regulatory criteria for approval. Please categorize comments appropriately below.

Based on the information provided by the investigator, the study meets the criteria for approval under 45 CFR 46.111.

- [ ] Yes
- [ ] No
Please choose the appropriate level of risk for this submission. Level of risk is based on the procedures which will be conducted going forward. See Questionnaire A - Level of Review Assessment

**Minimal Risk:** the probability or magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

For minimal risk studies: the study meets the criteria for approval under Expedited Category:

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- One year
- Other:

Risks to subjects are minimized. All of the following criteria must be met. Please check those criteria that have been met.

- [ ] PI has the resources to conduct research in a way that will protect the rights and welfare of subjects.
- [ ] Procedures are consistent with sound research design.
- [ ] Research design is sound enough to yield the expected knowledge.
- [ ] Procedures do not unnecessarily expose subjects to risk.
- [ ] Whenever possible, procedures are already being performed for diagnostic or treatment purposes.

See:
- Protocol Summary: Subjects
- Questionnaire B - Lay Summary & Research Design
- Questionnaire D - Recruitment Methods
- Questionnaire E - Risks, Benefits, Protections

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. Consider only those risks and benefits that may result from the research and not possible long-range effects of the knowledge

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<th>Yes</th>
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Comments:
Selection of subjects is equitable. Consider the purposes and setting of the research, paying special attention to any vulnerable populations.

See:
- Protocol Summary: Organizations, Subjects
- Questionnaire C - Sites & Collaborations
- Questionnaire D - Recruitment Methods

Informed consent will be prospectively obtained and documented (unless the IRB approves a waiver of this requirement).

See:
- Questionnaire H - Informed Consent Process
- Questionnaire J - Child Assent & Parental Consent Process

Adequate provisions exist to monitor the data and ensure subject safety.

See:
- Questionnaire F - Data Safety Monitoring

Adequate provisions exist to protect privacy of subjects and maintain confidentiality of data.

See:
- Questionnaire E - Risks, Benefits, Protections

If some or all subjects are likely to be vulnerable to coercion or undue influence, additional safeguards exist to protect their rights and welfare.

See:
- Protocol Summary: Subjects
- Questionnaire G1 - Children
- Questionnaire G2 - Individuals Lacking Consent Capacity
### Questionnaire G3 - Pregnant Women, Fetuses, Neonates

If a conflict of interest management plan has been attached, the management plan is appropriate and additional information or action is required.

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<th>Yes</th>
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<th>Comments:</th>
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Additional Reviewer Comments:

### 2 - Research Design

**See Questionnaire B - Lay Summary & Research Design**

*For federally-funded research*, the IRB submission is consistent with the federal grant application and DHHS sample informed consent (if applicable).

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<th>Yes</th>
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The influence of payments on equitable selection and amount, method, and timing of compensation is not coercive or does not present undue influence to potential subjects. Consider if completion bonuses are reasonable and do not unduly influence subjects to remain in the study when they otherwise would withdraw.

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<th></th>
<th>Yes</th>
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*For studies involving investigational drugs or biological products:*

- N/A
- Agree with the IND exemption determination(s) as indicated on the Drug or Biological Product Form(s).
- Disagree with the IND exemption determination(s) as indicated on the Drug or Biological Product Form(s). An IND or confirmation of IND exemption from the FDA is required.

See Drug or Biological Product Form(s).

*For studies involving investigational devices:*

- N/A
Agree with the IDE exemption determination(s) as indicated on the Medical Device Form(s).

Disagree with the IDE exemption determination(s) as indicated on the Medical Device Form(s). An IDE or confirmation of IDE exemption from the FDA is required.

Device risk is:
- N/A
- Significant risk. An IDE from the FDA is required.
- Nonsignificant risk

For FDA guidance on significant risk/nonsignificant risk devices, please see http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf.

Consider whether the device is:
- Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant;
- Purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant;
- For use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant;
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

See Medical Device Form(s).

### 3 - Sites & Collaborations

See Questionnaire C - Sites & Collaborations

If this a multi-center study in which IU is the lead site, the PI has provided an adequate plan to manage communication of multi-site information relevant to protection of human subjects.

- Yes
- No
- N/A

### 4 - Recruitment Methods & Materials

See Questionnaire D - Recruitment Methods

The proposed subject recruitment methods, advertising materials, and participation payment arrangements are fair, honest, and appropriate.

- Yes
- No
- N/A
Recruitment materials include relevant study information, which may include as appropriate:
- Name and address of the investigator and/or research facility
- Location of the research and person or office to contact for further information
- Purpose of the study, including the condition under study, if applicable
- Criteria that will be used to determine eligibility for the study, in summary
- Participation benefits (brief list)
- Time or other commitments required of the subject (e.g. number of visits, total duration of participation)

Recruitment materials do NOT include any of the following:
- Payment information emphasized by larger or bold type
- Promises of “free medical treatment,” when the intent is only to say that participants will not be charged for taking part in the study
- Statements or implications of a certain favorable outcome or other benefits beyond what is outlined in the informed consent document and the protocol
- Exculpatory language
- Proprietary information or product name, unless approved by the sponsor

For FDA-regulated studies: recruitment materials do NOT include any of the following:
- Claims, either explicitly or implicitly, about the drug, biologic, or device that are inconsistent with FDA labeling
- Statements that compensation for participation will include a discount on the purchase price of the product after FDA approval
- Claims, either explicitly or implicitly, that the drug, biologic, device, or other type of intervention is safe or effective for the purposes under investigation
- Claims, either explicitly or implicitly, that the test article or intervention is known to be equivalent or superior to any other drug, biologic, device or intervention
- Terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article or treatment is investigational (e.g. not FDA-approved)

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5 - Informed Consent

See Questionnaire H - Informed Consent Process

- Informed consent will not be obtained for this study. Skip to the next sub-section.
- The proposed consent process is acceptable, including proposed consent tools and communication channels.
- Subjects will have sufficient time to carefully consider participation.
<table>
<thead>
<tr>
<th>Information provided to subjects (both written and oral) will be provided in language understandable to the subject (or representative).</th>
<th>Yes</th>
<th>No</th>
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<td>The information being communicated to subjects during the consent process will not include exculpatory language through which (1) the subject is made to waive or appear to waive any legal rights, or (2) the subject releases or appears to release the investigator, the sponsor, or the facility from liability from negligence.</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>The possibility of undue influence during the consent process has been minimized.</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>The investigator has appropriately considered the possibility that some insurance or other reimbursement mechanisms may not fund care delivered in a research context and will provide that information to subjects.</td>
<td>Yes</td>
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<td>The informed consent process will be documented by a written signature from all subjects.</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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- **This research does NOT involve a waiver of the informed consent process. Skip to the next section.**
- **A waiver of informed consent pursuant to § 46.116(d) has been requested:**

  Indicate the type of waiver requested:
  - ☐ Waiver of informed consent for all research procedures. *(See Question ID 901)*
  - ☐ Waiver of informed consent for a minimal risk research activity or procedure (other than recruitment) *(See Question ID 931)*
  - ☐ Modification or waiver of any of the elements of informed consent *(see Question ID 916)*

  All of the following criteria are met (check all that apply):
  - ☐ The research (or specific research activity or procedure) involves no more than minimal risk to the subjects.
  - ☐ The waiver will not adversely affect the rights and welfare of the subjects.
  - ☐ The research could not practicably be carried out without the waiver.
  - ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

### 6 - HIPAA & Authorization
See: Questionnaire K - HIPAA
Questionnaire L - VA Research (for VA studies only)

☐ This research is NOT subject to HIPAA. Skip to the next section.

HIPAA authorization is consistent with informed consent document, protocol, and other study documents.

☐ Yes  ☐ No  ☐ N/A

A waiver of authorization or waiver of the requirement for a written signature is being requested.

☐ No. Skip to the next section.
☐ Yes. (See Questionnaire K - HIPAA, Question IDs 23263, 23265, 23639, 23650, 23293 (VA studies only) and 23651. See also Questionnaire L - VA Research, Question ID 23385)

If yes, all of the following criteria are met (check all that apply)

☐ The PHI to be used or disclosed is determined to be the minimum necessary.
☐ The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient.
☐ There is an adequate plan to protect the identifiers from improper use and disclosure.
☐ There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research.
☐ There are adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
☐ The explanation of how this research could not be practicably conducted without waiver of authorization is adequate.
☐ The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate.

7 - Children

See: Questionnaire G1 - Children
Questionnaire J - Child Assent & Parental Consent Process

☐ This research does NOT involve children. Skip to the next section.

Indicate the appropriate category(ies) of research involving children.

☐ Category 1/45 CFR 46.404: Research not involving greater than minimal risk to children.
☐ Category 2/45 CFR 46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual
child. The anticipated benefit must justify the risk and the relation of the anticipated benefit to the risk must be at least as favorable as that of alternative approaches.

☐ Category 3/45 CFR 46.406: Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child’s disorder or condition. The risk must represent only a minor increase over minimal risk, the intervention or procedure must present experiences to the children that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations, and the intervention or procedure must be likely to yield generalizable knowledge about the children’s disorder or condition which is a vital importance for understanding or amelioration of the disorder or condition.

☐ Category 4/45 CFR 46.407: Research not otherwise approvable under one of the above categories, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The Secretary of HHS must approve, after consultation with a panel of experts following publication and public comment.

See Questionnaire G1 - Children

Adequate provisions are made for soliciting the assent of children, if capable of assenting, and I agree with the investigator’s justification for the proposed assent process.

☐ Yes

☐ No. Changes are necessary. Insert comments in Reviewer Comments above.

☐ No. A waiver of assent has been requested and the study meets the criteria for waiver of informed consent per 45 CFR 46.808(a).

☐ Research does not involve more than minimal risks to subjects.

☐ Waiver will not adversely affect the rights and welfare of the subjects.

☐ The research could not be practically carried out without the waiver.

☐ When appropriate, the subjects will be provided with additional pertinent information after participation.

See Questionnaire J - Child Assent & Parental Consent Process

Adequate provisions are made for soliciting the permission of each child’s parents or guardian.

☐ Yes

☐ No. Changes are necessary. Insert comments in Reviewer Comments above.

☐ No. A waiver of parental consent has been requested and one of the following criterion are satisfied. *Please choose one.*

☐ The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants, and the investigator has provided adequate justification and an appropriate mechanism for protecting children on the Request Form for the Inclusion of Children in Research per 45 CFR 46.408(c).

☐ The study meets the criteria for waiver of informed consent per 45 CFR 46.116(d).

☐ Research does not involve more than minimal risks to subjects.

☐ Waiver will not adversely affect the rights and welfare of the subjects.
The research could not be practicably carried out without the waiver.

When appropriate, the subjects will be provided with additional pertinent information after participation.

**8 - Individuals Lacking Consent Capacity**

*See Questionnaire G2 - Individuals Lacking Consent Capacity*

- **This research does NOT involve individuals lacking consent capacity. Skip to the next section.**

Investigator has outlined an appropriate plan for assessing potential subjects' capacity to consent to determine whether they are capable of consenting on their own behalf, including: which subjects will be assessed, timing of assessment, mechanism for assessment, any assessment tools to be used, and plans for reassessing subjects who may lose their capacity to consent during the course of the study.

*See Questionnaire H - Informed Consent Process, Question ID 910 & Question ID 912*

Investigator has outlined an adequate plan to identify persons authorized to give legally valid consent on behalf of individual(s) judged incapable of consenting and to adequately inform them of their roles and obligations for protecting the subject.

*See Questionnaire H - Informed Consent Process, Question ID 911*

If inpatient psychiatric subjects will be enrolled, adequate justification has been provided for the inclusion of that population and additional safeguards will be implemented to protect inpatient psychiatric subjects from potential coercion or undue influence.

*See Questionnaire G2 - Individuals Lacking Consent Capacity, Question ID 23137 and 205051.*

**9 - Pregnant Women, Fetuses, Neonates**

*See Questionnaire G3 - Pregnant Women, Fetuses, Neonates*

- **This research does NOT involve pregnant women, fetuses, or neonates. Skip to the next section.**

Research includes the following (choose all that apply)

- [ ] Pregnant Women
- [ ] Fetuses
- [ ] Neonates of Uncertain Viability
- [ ] Nonviable Neonates

Based on the information provided in *Questionnaire G3 - Pregnant Women, Fetuses, and Neonates*, adequate protections exist to protect the rights and welfare of the subject.

- [ ] Yes
- [ ] No
Investigator has outlined an adequate plan to obtain consent from the pregnant woman and/or permission from the father.

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<th>10 - Prisoners</th>
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<td>See Questionnaire G4 - Prisoners</td>
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- This research does NOT involve prisoners. Skip to the next section.

For federally-funded research, research represents one of the following categories of research permissible under 45 CFR 46.306(a)(2). Please choose one:

- [ ] A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
- [ ] A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
- [ ] Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research.
- [ ] Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research.

- Research is not federally-funded and the above criteria do not apply.

Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prisoner is impaired.

The risks involved in the research are equivalent with risks that would be accepted by non-prisoner volunteers.

Procedures for the selection of subjects within the prison are fair to all prisoners and not subject to arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the...
characteristics needed for that particular research project.

| Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. | ○ Yes ○ No |
| Where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing subjects of this fact. | ○ Yes ○ No ○ N/A |
| PI and the study team are appropriately qualified to work and interact with prisoners; based on previous research experience, academic preparation, and/or relevant training and oversight by the PI. | ○ Yes ○ No |
| The research is minimal risk for the prison population being studied or included. | ○ Yes ○ No |
| Consent document provides examples of when the research will be required by law to share information provided to subjects. | ○ Yes ○ No ○ N/A |

### 11 - Transnational Research

See Questionnaire G5 - Transnational Research

☐ This research is NOT transnational. Skip to the next section.

The PI has addressed all appropriate considerations and has provided an adequate plan for conducting transnational research.

| ○ Yes ○ No |

### 12 - VA Research

See Questionnaire L - VA Research

☐ This is NOT VA research. Skip this section.

The following additional consent elements must be included in the VA consent. Please check those criteria which have been included.

☐ Statement that the subject will not be required to pay for medical care or services received as a research subject except as follows: some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

☐ Statement that necessary care for research-related injuries will be provided by the VA
If the study plans to enroll non-veterans, sufficient justification has been provided.  

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The research is relevant to the mission of the VA and the veteran population.  

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Information describing photographs and video and/or audio recordings to be taken or obtained for research purposes is included in the document.  

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Privacy and confidentiality provisions have taken into consideration all applicable requirements per VHA Handbook 1605.1.  

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For studies involving subjects lacking decision-making capacity:  

*One of the following are true. Please check the applicable statement.*  

- Research presents no greater than minimal risk of harm to subjects.  
- Research presents greater than minimal risk and greater probability of direct benefit to the subjects than harm to the subjects.  
- Research presents greater than minimal risk and no prospect of direct benefit to individuals subjects, but is likely to yield generalizable knowledge about subjects’ disorder or condition that is of vital important for the understanding or amelioration of the disorder or condition.  

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*One of the following are true. Please check the applicable statement.*  

- The research cannot be performed solely with the persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects’ lack of decision-making capacity.  
- The subject of the research is not directly related to the subjects’ lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects.  

See Questionnaire L - VA Research

### 13 - Waiver of Informed Consent for Planned Emergency Research Under 21 CFR 50.23

(a)  

See Questionnaire H - Informed Consent Process

- This research does not involve a waiver of informed consent for planned emergency research. Skip this section.

**ALL of the following criteria must be met. Please check those criteria that have been met.**
The human subject is confronted by a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

Informed consent cannot be obtained from the subject because of the following:

- Subjects will not be able to give their informed consent as a result of their medical condition;
- The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and
- There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

Participation in the research holds out the prospect of direct benefit to the subjects because of all of the following:

- Subjects are facing a life-threatening situation that necessitates intervention;
- Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
- Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

The clinical investigation could not be practicably carried out without the waiver.

The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

There is an IRB-approved informed consent and approved informed consent procedure that will be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible.

IRB-approved procedures and information to be used when providing an opportunity for a family member to object to a subject’s participation in the clinical investigation are in place.

Additional protections of the rights and welfare of the subjects will be provided, including, at least:

- Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.
- Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.
- Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results
- Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation
- If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject’s family member who is not a legally authorized representative, and asking whether he/she objects to the subject’s participation in the clinical investigation
- The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review