WELCOME ALL BOARD MEMBERS:

10:30-12:00 (TRAINING)

ROXANNE JOHNSON: INTRODUCTION
CARLA ICHONEAUX: REGULATORY INFORMATION
MARVELLEN ROMERO: DISCUSSION OF AMENDMENT REVIEWS
JIM OUTLAND: DISCUSSION OF CONTINUING REVIEWS

12:00-1:00 (LUNCH)

WHAT IS AN INSTITUTIONAL REVIEW BOARD?

An IRB is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Tulane University has 2 IRBs: One Biomedical IRB (meets twice a month) and one Social/Behavioral IRB (meets once a month).

As a member of either IRB, each of you bring a unique professional and personal perspective.

The website for Tulane's Human Research Protection Office is:

http://tulane.edu/asvpr/irb/
THE MECHANICS OF AN IRB MEETING:

About 1-2 weeks prior to a meeting, an RSVP is sent via email. If you do not check your Tulane email, please provide us with an alternative email address. It is important for you to respond, as regulations require that we meet quorum.

You will receive another email if you have agreed to attend with the submissions for discussion and you will be notified if you have been assigned as a primary or secondary reviewer. You will find your review materials (including the reviewer sheet) within IRBNet along with all of the materials for the upcoming meeting.

www.irbnet.org

Biomedical submissions have a primary and secondary reviewer.
Social/Behavioral submissions have only a primary.
The Primary/Secondary reviewers should lead the discussion, but everyone contributes.

AAHRPP ACCREDITATION:

Both IRBs are part of Tulane University's Human Research Protection Program (HRPP), which was accredited by The Association for the Accreditation of Human Research Protection Programs in September of 2010.

As the “gold seal,” AAHRPP accreditation offers assurances to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence.

www.aahrpp.org
TIMELINE OF HUMAN SUBJECTS RESEARCH:
What follows is a brief history of the events that contributed to the federal rules and regulations governing human subjects in research:

1932-1972: Tuskegee Syphilis Study
1947: Nuremberg Code (Developed in response to unethical experimentation during WWII; the first major international document to provide guidelines on research ethics & informed consent)
1949's Milgram Studies of Obedience to Authority, Jewish Chronic Disease Hospital Study, Willowbrook Hepatitis Study
1964: Declaration of Helsinki signed by US (WMA adopted 12 principles to guide physicians on ethical considerations related to biomedical research)
1976: San Antonio Contraceptive Study, Tearoom Trade Study
1974: The National Research Act (The US Congress signs this act into law creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research partly in response to the Syphilis Study; implements provisions for IRBs)

*Throughout the 1970's, 1980's, 1990's additional revisions and guidelines have been adopted into law

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THE BELMONT REPORT OF 1979: A GUIDING ETHICAL PRINCIPLE

Prompted by ethical problems with human subjects research, The National Research Act of 1974 created The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was charged with identifying the basic ethical principles which should be followed when conducting human subjects research.

In 1979, The Belmont Report was published naming 3 fundamental ethical principles for using human subjects for research:

1. RESPECT FOR PERSONS: Protecting the autonomy of people and treating them with respect and allowing for informed consent
2. BENEFICENCE: Maximize the benefits of the research while minimizing the risk
3. JUSTICE: Ensure that reasonable procedures are administered fairly and equally to all research participants

Today, the Belmont Report serves as a historical document and provides the moral framework for understanding regulations in the United States on the use of humans in experimental research.
WHY DO WE REVIEW HUMAN SUBJECTS RESEARCH?

Historically, human subjects research has been problematic and therefore, federal regulations and guidelines have been adopted.

Guatemala Syphilis Experiment: Recently discovered (associated with the Tuskegee Syphilis Experiment) United States-sponsored human experiments conducted in Guatemala from 1946-1948. Doctors infected healthy soldiers, prisoners, and mental patients (approximately 1500 subjects) with syphilis and other STDs without informed consent of the subjects. The goal of the study seems to have been to determine the effect of penicillin in the treatment and prevention of STDs. The subjects were treated with antibiotics; however, it is unknown if all infected parties were cured.

Francis Collins, the current Director of the NIH called the experiments "a dark chapter in the history of medicine" and commented that modern rules absolutely prohibit conducting human subject research without informed consent.

In October of 2010, the US government formally apologized and The Presidential Commission for the Study of Bioethical Issues will ask a panel of international experts to review the current state of medical research on humans around the world and ensure that such incidents cannot be repeated.

Why Do We Review Human Subjects Research?

Ethics in Research continues to be important.

Death of a healthy volunteer: The Jesse Gelsinger Story: Jesse was the first person publicly identified as having died in a clinical trial for gene therapy. He suffered from a liver disease caused by a genetic mutation (Ornithine Transcarbamylase Deficiency, an inability to metabolize ammonia); however, this was controlled with diet and drugs. Jesse was enrolled in a clinical trial at the University of Pennsylvania. Study procedures included a high protein diet and injections that proved to be fatal. On September 17, 1999, he died suffering organ failure and brain death.

An FDA investigation concluded that the scientists involved in the trial broke several rules of conduct including:
- Wrongfully enrolling Jesse, as his high levels of ammonia should have excluded him from the trial.
- Failure of the University to report that two subjects had experienced serious side effects from the gene therapy.
- Failure to mention high risk of the treatment within the Informed Consent Documentation.

Also, both the PI and the University were reported to have financial stakes in the research.
REGULATIONS TO FOLLOW WHEN REVIEWING RESEARCH:

FOR ALL RESEARCH (THE COMMON RULE):
CHRP: CFR 45 PART 46: PROTECTION OF HUMAN SUBJECTS
SUBPART A: BASIC DHHS POLICY
SUBPART B: PREGNANT WOMEN, FETUS, AND NEONATES
SUBPART C: PRISONERS
SUBPART D: CHILDREN

FOR FDA REGULATED RESEARCH:
FDA: CFR 21 PART 50: PROTECTION OF HUMAN SUBJECTS
FDA: CFR 21 PART 56: INSTITUTIONAL REVIEW BOARDS
(http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm183775.htm)

FOR CLINICAL TRIALS:
ICH GOOD CLINICAL PRACTICE

IRB REVIEW OF RESEARCH: TYPES OF REVIEW
EXEMPT REVIEW, EXPEDITED REVIEW, FULL BOARD REVIEW

The Common Rule names 6 Categories of Exempt Research in which IRB approval is Exempt. These studies are Minimal Risk and the research is de-identified/anonymous. These reviews are conducted administratively by the HRPO Director or a Designee.

The Common Rule names 7 Categories of Expedited Research in which IRB approval may be Expedited. These studies are minimal risk and the review is conducted by the IRB Chair or a Designee.

Some common expedited review categories include:
- Blood Collection (within limits)
- Collection of other biological specimens
- Collection of data through non-invasive procedures
- Research on existing data (specimens or materials) collected for NON research purposes
- Surveys, Questionnaires, Focus Groups

Other research is reviewed by the Full Board at a Convened IRB Meeting as decided by the IRB Chair. IRB determines level of risk.
CRITERIA OF APPROVAL OF RESEARCH:

(45 CFR 46.111; 21 CFR 56.111)

Regardless of the Type of Research reviewed (Exempt, Expedited, Full Board), the Criteria of Approval must be met.

The following Criteria must be considered:

RISKS TO SUBJECTS ARE MINIMIZED
RISK/BENEFIT RATIO
EQUITABLE SELECTION OF SUBJECTS
INFORMED CONSENT PROCESS
DOCUMENTATION OF INFORMED CONSENT
DATA AND SAFETY MONITORING
PRIVACY AND CONFIDENTIALITY PROTECTIONS
INCLUSION OF VULNERABLE SUBJECTS

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CRITERIA OF APPROVAL OF RESEARCH:

RISKS TO SUBJECTS ARE MINIMIZED:

45 CFR 46.111(a)(1); 21 CFR 56.111(a)(1)

By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes, and

By addressing the likelihood of harm and magnitude of harm encompassing physical, psychological, social, economic, and/or legal risks to the subjects.

The level of risk to the subjects must be discussed by the IRB and a determination made whether the protocol represents a minimal risk or a greater than minimal risk to the subjects.

Definition of Minimal Risk: The probability and 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.
CRITERIA OF APPROVAL OF RESEARCH:

RISKS/BENEFIT RATIO:
45 CFR 46.111(a)(2); 21 CFR 56.111(a)(2)

Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects and the importance of the knowledge that may be expected to result.

In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research, as distinguished from risks and benefits of other activities or therapies that subjects would receive even if not participating in the research.

The IRB must also consider the professional qualifications and resources of the research team to ensure appropriate expertise is represented.

For clinical research using FDA products, (Investigational Drugs, Devices) Additional information is obtained including animal toxicity, side effects, short-term and long-term risks. Where appropriate, the IRB reviews provisions for monitoring the data collected to ensure the safety of subjects.

CRITERIA OF APPROVAL OF RESEARCH:

EQUITABLE SELECTION OF SUBJECTS:
45 CFR 46.111(a)(3); 21 CFR 56.111(a)(3)

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, fetuses, neonates, Non-English speakers, mentally disabled persons, or economically or educationally disadvantaged persons.
CRITERIA OF APPROVAL OF RESEARCH:

INFORMED CONSENT PROCESS:
45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4)

Informed Consent is a process. To minimize coercion, the IRB considers the circumstances under which consent is obtained including but not limited to: timing, relationship between prospective subject and individual obtaining consent, language used to recruit prospective subjects, and qualifications of individuals obtaining informed consent.

The use of exculpatory language through which the subject is made to waive or appear to waive any of the subject’s legal rights or releases the PI, the sponsor, or the institution from liability or negligence is prohibited.

The use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool and not as a legal instrument.

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IRB MEMBER TRAINING 3/21/2011

CRITERIA OF APPROVAL OF RESEARCH:

DOCUMENTATION OF INFORMED CONSENT:
45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5)

Informed Consent must be appropriately documented in accordance with all regulations unless the requirement is waived by the IRB.

Waiving the requirement for obtaining documentation of informed consent means the subject does not put in writing/document his/her agreement to participate in the study. The subject is still informed about the study and given the opportunity to decide whether to participate.

The IRB may waive the requirement for a signed consent if it finds:

a) 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 (the subjects would be placed at risk by documents linking them with an illegal or stigmatizing characteristic or behavior); or

b) The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

For example, research involving survey or retrospective chart reviews may meet the conditions for waiving the documentation of informed consent.

Tulane University Human Research Protection Program

IRB MEMBER TRAINING 3/21/2011
INFORMED CONSENT: (45 CFR 46.116)

The Tulane HRPO Biomedical and Social/Behavioral Consent Templates are designed to incorporate all Federally mandated basic and additional elements of informed consent:

The **REQUIRED ELEMENTS** of an Informed Consent Document are as follows:

- A statement that the protocol involves research
- Expected duration of the subject’s participation
- Description of the procedures to be followed and identification of those that are experimental
- Disclosure of the reasonably foreseeable invasive or non-invasive risks or discomforts
- Statement of any benefits to subjects or others that may be expected
- Appropriate alternative procedures, if any, that might be advantageous to subjects
- How confidentiality of records identifying the subject will be maintained and disclosure of all infringements upon privacy and confidentiality which may result from participation in the research
- Whether compensation is available for participation
- Contact information of the research team to obtain answers to questions about the research or to voice concern or complaints about the research
- Contact information for a person independent of the research team to obtain answers to questions about the research, to voice concerns, complaints or offer input about the research, in the case that the research staff could not be reached, or in the event the participant wanted to speak to someone other than the research staff
- A statement that participation is voluntary, that there are no penalties if the subject refuses to participate, and that the subject may withdraw at any time without penalty

INFORMED CONSENT: (45 CFR 46.116)

Also, the following **ADDITIONAL REQUIREMENTS** may be appropriate:

- If the subject is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable
- Outline the circumstances where a subject’s participation may be terminated by the PI without regard to the subject’s consent
- Whether there are costs for which subjects will be responsible
- The safety consequences of a subject’s decision to withdraw
- New and significant findings, which may affect the subject’s willingness to continue, will be disclosed to the subjects
- The appropriate number of subjects involved in the research at the institution and nationally
- The amount and schedule of payments to participants
### CRITERIA OF APPROVAL OF RESEARCH:

**DATA AND SAFETY MONITORING:**

45 CFR 46.111(a)(6); 21 CFR 56.111(a)(6)

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

The IRB reviews, if applicable:
- Procedures for promptly detecting harm and mitigating potential injuries
- Implementation of monitoring procedures and frequency
- Procedures to ensure accurate feedback of information to researchers and medical decision-makers
- Procedures for reporting temporary or permanent suspensions of a study to the appropriate entity and the criteria for suspension or termination of the study
- Any quality control measures to ensure protocol adherence
- Procedures and plans for communications such as protocol modifications, data safety monitoring reports and unanticipated problems between sites when research is part of a multicenter study.

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### DATA AND SAFETY MONITORING:

**DSMP VS. DSMB**

All research studies should provide a Data Safety Monitoring PLAN.

A Data Monitoring Plan should include:

- Specific elements of the data to be reviewed
- The frequency of the data monitoring
- A system for generating and resolving queries
- Who is responsible for the data review
- Methods for communicating findings to Research Team
- Methods for reporting Unanticipated Problems/Protocol Deviations to the IRB

Some studies require a Data Safety Monitoring Board.

FDA says, “All Clinical Trials require safety monitoring, but not all trials require monitoring by a formal committee that may be external to the trial organizers, sponsors, and investigators.”

NIH says, “All trials, even those that pose little likelihood of harm, should have an external monitoring body.”

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CRITERIA OF APPROVAL OF RESEARCH:

PRIVACY AND CONFIDENTIALITY PROTECTIONS:
45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The IRB reviews, if applicable:
- The methods used to identify and contact potential participants
- The settings in which an individual will interact with the investigator/research team
- The methods used to obtain information about participants
- How to access the minimum amount of information necessary to complete the study
- The long-range plan for protecting the confidentiality of the research data, including a scheduled destruction of the identifiers associated with the data
- The Consent Form adequately and clearly states the confidentiality risks and who will have access to the subject's information

CRITERIA OF APPROVAL OF RESEARCH:

INCLUSION OF VULNERABLE SUBJECTS:
45 CFR 46.111(b)

When some or all of the subjects, such as children, prisoners, adults with impaired decision capacity, persons who use English as a second language or are economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, the Tulane University IRB shall consider whether additional safeguards have been included in the study to protect the rights and welfare of these subjects.
VULNERABLE SUBJECTS:

45 CFR 46 SUBPART B: RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES:
If research is minimal risk, the research can be expedited.
There are specific regulations and guidance concerning the risks, benefits, and consent regarding this research.

45 CFR 46 SUBPART C: RESEARCH INVOLVING PRISONERS:
Any research involving prisoners must be reviewed by the Convened IRB with a prisoner representative present.
Specific regulations and guidance concerning the types of research allowed using prisoner populations and within prisons.

45 CFR 46 SUBPART D: RESEARCH INVOLVING CHILDREN:
If research is minimal risk, the research can be expedited.
There are 4 allowable categories of research involving children.
Specific regulations and guidance concerning Child Assent and Parental Permission.
The proposed involvement of these specific vulnerable populations must be approved specifically and protocol specific findings justifying the involvement of these subjects must be specifically stated.

SUGGESTED REVIEW STRATEGY:

Review Application Part 2
The Application is designed to give you a general idea of the research, the subjects, the recruitment, the consent process, the risks, how privacy & confidentiality will be maintained, how the data will be monitored, and if any vulnerable subjects will be involved.

Review the Study Protocol
If further detail is needed, these details should be presented within the Study Protocol.

Review the Consent Form/Documents
Is the Consent Process/Form appropriate? Is it readable? Is there too much information/not enough? Is the Template followed containing all required information?

Review Other Submitted Documents
Advertisements, Surveys/Questionnaires/Focus Group Guides, HIPAA Documents, Drug/Device Information, Investigator's Brochure, Wallet Cards, etc.

Complete Reviewer Sheet (within IRBNet)

Review for CONSISTENCY; This is a SUGGESTED strategy, of course, develop your own.
REVISED REVIEWER SHEETS:

If you are assigned a review, as a primary or secondary reviewer (only Biomedical IRB has secondary reviewers), a reviewer sheet must be completed to document your findings. The HRPO has revised the reviewer sheets. The regulations are more clear and cited on the reviewer sheets.

Reviewer Sheets included within this packet include:
- Full Board Reviewer Sheet (for either Biomedical or Social/Behavioral Research)
- Continuing Review Reviewer Sheet
- Amendment Reviewer Sheet

-REVIEW OF REVISED REVIEWER SHEET-

DETERMINATIONS OF THE IRB:

THERE ARE 4 POSSIBLE IRB ACTIONS:

APPROVAL

DEFERRAL FOR MINOR MODIFICATIONS:
- Approval cannot be granted, as the Protocol, the Recruitment Procedures, Research Tools, and/or Consent Form require minor revisions.
- Within HRPO Policy, under Deferral for Minor Modifications, it is stated, "None of the required modifications can be related to the regulatory criteria for approval."
- The response from the PI is reviewed by the IRB Chair or Designee.

DEFERRAL FOR MAJOR MODIFICATIONS:
- Approval cannot be granted, as study documents require major modification or clarification or insufficient information is provided.
- The response from the PI is brought back to the IRB for review and vote.

DISAPPROVAL
- Only the Convened IRB may disapprove research
IRBNET INSTRUCTIONS FOR BOARD MEMBERS:

- Log into http://www.irbnet.org using your username and password
- Access study documents on the SUBMISSION MANAGER
- To view submission details for a particular study, click on the study title
- If you are a reviewer, download the reviewer sheet, complete it, save to your computer, and upload to IRBNET
- You may add comments and recommendations in the reviewer comments text box.
- Once you have completed your review, you may SEND COMMITTEE MAIL to alert the HRPO that the review has been complete, or another reviewer

To review Meeting Agendas and Minutes:
Once logged into IRBNet, select the MEETING DATE AND TIME using the drop down menu, click SHOW SUBMISSIONS, and then, Agendas, Minutes and Other Administrative Documents for this Meeting.
As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in this study; or do you have any other conflict with this study?

☐ Yes  ☐ No

If Yes, do NOT complete this review and please contact the HRPO at 988-2665.

_________________________________________

SUMMARY: Please provide a short summary of the research protocol reviewed (a short paragraph):

_________________________________________

GENERAL:

In general, is the research practical? Is there a clearly formulated hypothesis? Is the research likely to answer the proposed question?

☐ Yes  ☐ No

COMMENTS:

_________________________________________

RESEARCH SETTING:

Is the PI/research staff qualified to conduct the research? Are the facilities to be used adequate?

☐ Yes  ☐ No

If needed, are there medical or psychological resources available for subjects?
Has the appropriate permission been given to conduct the research at any external sites?

☐ Yes  ☐ No

COMMENTS REGARDING RESEARCH SETTING:

I. RISK: 45 CFR 46.111(A)(1); 21 CFR 56.111(a)(1)

The research risks are:

☐ No more than Minimal  ☐ Greater than Minimal

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

☐ Yes  ☐ No

Consider the following: Are precautions developed to decrease the likelihood of harm? Contingencies are available to deal with harms if they occur?

COMMENTS REGARDING RISK:

II. RISK-BENEFIT ASSESSMENT: 45 CFR 46.111(A)(2); 21 CFR 56.111(a)(2)

Benefits to subjects are:

☐ Direct  ☐ Indirect  ☐ Both  ☐ None

*Risks to subjects are reasonable in relation to benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. (In evaluating risks and benefits, the IRB Committee will consider 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.)*

☐ Yes  ☐ No

COMMENTS REGARDING RISK-BENEFIT ASSESSMENT:

III. SUBJECT SELECTION: 45 CFR 46.111(A)(3); 21 CFR 56.111(a)(3)

*Selection of subjects is equitable. (In making this assessment, the IRB Committee will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special considerations of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons.)*
Consider the following: The Inclusion and Exclusion Criteria, whether prospective subjects will be vulnerable to coercion or undue influence, the recruitment methods, the influence of payments.

COMMENTS REGARDING SUBJECT SELECTION:

IV. INFORMED CONSENT PROCESS AND FORM: 45 CFR 46.111(A)(4); 21 CFR 50.111(A)(4)

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 the Federal regulations (45 CFR 46.116; 21 CFR 50 BELOW)

All of the following items must be true of the Consent Process (check all boxes):

☐ The investigator will obtain the legally effective informed consent of the subject or the subject’s legally authorized representative

☐ The circumstances of the consent process provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate

☐ The circumstances of the consent process minimize the possibility of coercion or undue influence

☐ The individuals communicating information to the subject or the legally authorized representative during the consent process will provide that information in language understandable to the subject or the representative

☐ The information being communicated to the subject or the subject representative during the consent process will not include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights or through which the subject or the legally authorized representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

☐ All required and appropriate additional disclosures will be provided to the subject or the subject’s representative

The required elements of an Informed Consent Document are as follows (check all boxes):

☐ A statement that the protocol involves research

☐ Expected duration of the subject’s participation

☐ Description of the procedures to be followed and identification of those that are experimental

☐ Disclosure of the reasonably foreseeable invasive or non-invasive risks or discomforts

☐ Statement of any benefits to subjects or others that may be expected
Appropriate alternative procedures, if any, that might be advantageous to subjects

How confidentiality of records identifying the subject will be maintained and disclosure of all infringements upon privacy and confidentiality which may result from participation in the research

Whether compensation is available for participation

Contact information of the research team to obtain answers to questions about the research or to voice concern or complaints about the research

Contact information for a person independent of the research team to obtain answers to questions about the research, to voice concerns, complaints or offer input about the research, in the case that the research staff could not be reached, or in the event the participant wanted to speak to someone other than the research staff

A statement that participation is voluntary, that there are no penalties if the subject refuses to participate, and that the subject may withdraw at any time without penalty

Also, the following additional requirements may be appropriate (check all applicable boxes):

If the subject is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable

Outline the circumstances where a subject’s participation may be terminated by the PI without regard to the subject’s consent

Whether there are costs for which subjects will be responsible

The safety consequences of a subject’s decision to withdraw

New and significant findings, which may affect the subject’s willingness to continue, will be disclosed to the subjects

The appropriate number of subjects involved in the research at the institution and nationally

The amount and schedule of payments to participants

**COMMENTS REGARDING THE CONSENT PROCESS AND FORM:**

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**V. DOCUMENTATION OF CONSENT: 45 CFR 46.111(A)(5); 21 CFR 56.111(A)(5)**

Informed Consent will be appropriately documented in accordance with, and to the extent required by the Federal Regulations (45 CFR 46.117; 21 CFR 50.26).

If a signed informed consent is to be obtained, a space must be provided for the subject or the subject’s legally authorized representative to sign and date the consent document and a copy must be given to the subject and/or legally authorized representative signing the form. Also, adequate time must be given for the subject to consider participation.
Comments Regarding the Documentation of Consent:

If a Waiver of Consent is requested, all of the following must apply in accordance with 45 CFR 46.116(d):

- The research must involve no more than minimal risk
- Granting the waiver will not adversely affect the rights and welfare of the subjects
- The research could not practicably be conducted without the waiver
- Whenever appropriate, subjects will be provided additional pertinent information after participation

☐ A Waiver of Consent is granted in accordance with 45 CFR 46.116(d).

If a Waiver of the Documentation of Consent is requested, either of the following must apply in accordance with 45 CFR 46.117(c):

- The only record linking the subject to the research would be the consent form, and the principal risk to the subject would be potential harm resulting from breach of confidentiality. 45 CFR 46.117(c)(1)

☐ A Waiver of the Documentation of Consent is granted in accordance with 45 CFR 46.117(c)(1).

- 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 research context. 45 CFR 46.117(c)(2)

☐ A Waiver of the Documentation of Consent is granted in accordance with 45 CFR 46.117(c)(2).

Note: These waivers may not be applied to FDA research. If the IRB grants this waiver, the investigator will still be required to provide information about the research to each potential subject, but the subject’s signature on the form will not be required. A written script of the information that will be read or given to potential subjects must be provided for IRB review. The scripts must contain the basic required elements of consent as referenced in 45 CFR 46.116(a).

Comments Regarding Granting a Waiver of Consent/Documentation of Consent:

VI. Data Safety Monitoring: 45 CFR 46.111(a)(6); 21 CFR 56.111(a)(6)

When appropriate, the research plan makes adequate provision for monitoring the data collected to assure safety of the subjects.

☐ Yes ☐ No

Consider the following: All greater than minimal risk research required a Data Safety Monitoring Plan. Is a DSMP necessary for this research? Was a DSMP submitted? Is the plan adequate? Who will monitor the data? Is the frequency adequate?

Comments Regarding Data Safety Monitoring:
VII. PRIVACY AND CONFIDENTIALITY: 45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)

When appropriate, there are adequate provisions to protect the privacy and confidentiality of subjects and to maintain the confidentiality of data.

☐ Yes ☐ No

Consider the following: The recoding of data, the identification of data, storage of data, sharing of data (including electronic transmission), the recruitment procedures, the privacy of the consent process.

COMMENTS REGARDING PRIVACY AND CONFIDENTIALITY:

VIII. VULNERABLE POPULATIONS: 45 CFR 46.111(b); 21 CFR 46.111(b)

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

☐ Yes ☐ No

COMMENTS REGARDING VULNERABLE POPULATIONS:

IF THE RESEARCH INVOLVES PREGNANT WOMEN, FETUSES, OR NEONATES, PRISONERS, OR CHILDREN, COMPLETE THE FOLLOWING:

RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES 45 CFR SUBPART B:

45 CFR 46.204: Pregnant Women/Fetuses may be involved in research if ALL of the following conditions are met; provide protocol specific findings justifying this determination.

☐ 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;

ONE of the following must be true:

☐ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or 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.

☐ Any risk is the least possible for achieving the objectives of the research;
☐ If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant women 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, consent of the mother is obtained in accord with the informed consent provisions of Subpart A of 45 CFR 46.116 and 117;

☐ 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 45 CFR 46.116 and 117, 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;

☐ Each individual providing consent as required above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

☐ For children who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D of 45 CFR 46;

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

☐ 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

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

45 CFR 46.205: Research Involving Neonates (Newborns):

NOTE: For Viable Neonates, they are considered Children and Subpart D applies.

For Neonates of Uncertain Viability, the following determinations must be made:

☐ The research hold out the prospect of enhancing the probability for survival of the PARTICULAR fetus to the point if viability;

☐ Any risk is the least possible; OR,

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate from the research;

☐ Either parent may consent or a legally authorized representative may provide consent.

For Nonviable Neonates, the following determinations must be made:

☐ Vital functions will not be artificially maintained;

☐ The research will not terminate the heartbeat or respiration of the fetus;

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate from the research;
☐ Both parents consent to the research; legally authorized representative consent is NOT permitted.

45 CFR 46.207: Research Involving Pregnant Women that is NOT Otherwise Approvable

The IRB must determine the following:

☐ The research does meet the requirements of 45 CFR 46.204 or 205 above.

☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviations of a serious problem affecting the health and welfare of pregnant women, fetuses, or neonates.

NOTE: This determination must be forwarded to the Secretary of DHHS who will consult with experts and determine whether the research should go forward.

The proposed involvement of pregnant women, fetuses, or neonates is:

☐ Approvable

☐ Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES AS SUBJECTS IN RESEARCH:

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RESEARCH INVOLVING PRISONERS 45 CFR SUBPART C:

45 CFR 46.305(a): Prisoners may be involved in research if ALL of the seven findings below are met and provide protocol specific findings justifying this determination.

☐ (1) The research under review represents ONE of the categories of research permissible under 45 CFR 46.306(a)(2): MARK THE ONE CATEGORY:

☐ Research on 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;

☐ Research on 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, provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts (in penology, medicine, and ethics) and published notice in the Federal Register of the intent to approve such research;

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☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects. If the research includes the assignment of prisoners to control groups that might not benefit from the research, it may proceed only after the Secretary of DHHS has consulted with appropriate experts and published a note in the Federal Register of the intent to approve the research;

☐ Epidemiologic studies whose sole purpose is one of the following:

- To describe the prevalence or incidence of a disease by identifying all cases.
- To study potential risk factor associations for a disease.

The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research.

☐ (2) Advantages to participation are not coercive; AND
☐ (3) Risks are commensurate with what would be acceptable to nonprisoners; AND
☐ (4) The selection procedures are fair; AND
☐ (5) The information is presented in an understandable language; AND
☐ (6) There is no effect on decisions related to parole; AND
☐ (7) Provisions for follow-up are adequate.

The proposed involvement of prisoners is:

☐ Approvable
☐ Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING PRISONERS AS SUBJECTS IN RESEARCH:

RESEARCH INVOLVING CHILDREN 45 CFR 46 SUBPART D:

The regulations specify the following FOUR CATEGORIES of permissible child research. Check the ONE appropriate category for the reviewed research and provide protocol specific findings justifying this determination.

☐ CATEGORY 1: 45 CFR 46.404/21 CFR 50.51: Research not involving greater than minimal risk.
  ☐ The permission of one parent is sufficient
☐ CATEGORY 2: 45 CFR 46.405/21 CFR 50.52: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

NOTE: The IRB must find that (a) the risk is justified by the anticipated benefits to the subjects; (b) the relation of the anticipated benefit to the risk is at least favorable to the subjects as that presented by the available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents and guardians.

☐ The permission of one parent is sufficient

☐ CATEGORY 3: 45 CFR 46.406/21 CFR 50.53: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

NOTE: The IRB must find that (a) the risk represents a minor increase over minimal; (b) the intervention or procedure represents experiences to subjects that are reasonable commensurable with those inherent their actual or expected medical, dental, psychological, social, or educational situations; (c) the research is likely to yield knowledge of vital importance; and (d) adequate provisions are made for soliciting the assent of the children and permission of both parents or guardians is needed.

☐ CATEGORY 4: 45 CFR 46.407/21 CFR 50.54: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children.

NOTE: The IRB must submit this category of research to HHS for approval. Approval cannot be granted until HHS approves and publishes the proposal in the Federal Register.

☐ Parental permission is waived under 45 CFR 46.116(c), 45 CFR 46.116(d), or 45 CFR 46.408(c).

Provisions to solicit the Assent of Children:

Assent will be obtained from:

☐ All Children ☐ None of the Children* ☐ Some Children*

*If None of the Children or Some Children was selected, the protocol must provide reasoning; complete the following:

Reason Why Assent is Not Necessary: One or more of the following must be true

☐ The capability of these children is so limited that they cannot reasonably be consulted

☐ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

☐ Assent is waived under 45 CFR 46.116(d)/21 CFR 50.55: ALL must apply

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

☐ Assent is waived under 45 CFR 46.408(a)/45 CFR 46.116(c): ALL must apply

☐ The research is NOT FDA regulated
☐ The research is to be conducted by or subject to the approval of state or local government officials
☐ The research is designed to study, evaluate, or otherwise examine one or more of the following:
- Public benefit or service programs
- Procedures for obtaining benefits or services under those programs
- Possible changes in or alternatives to those programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs

☐ The research could not be practicably carried out without the waiver or alteration

COMMENTS REGARDING ASSENT:

Wards (45 CFR 46.405, 406, 409 and 21 CFR 50.53): If the research involves children who are wards of the state or any other agency, institution or entity, indicate whether:

☐ The research is related to their status as wards
☐ The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards

The proposed involvement of children is:

☐ Approvable
☐ Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING CHILDREN AS SUBJECTS IN RESEARCH:

IF THE RESEARCH INVOLVES USE OF A PLACEBO, COMPLETE THE FOLLOWING:

USE OF PLACEBOS:

The use of a placebo in lieu of an approved, FDA-indicated drug must be justified; **ONE of the following must apply:**

☐ Standard therapy is unavailable or is efficacy unproven; OR
☐ Standard therapy possesses unacceptable side effects; OR
Minimal harm may result from the use of the placebo (e.g. ongoing disease has little adverse effect on the subject during the course of the trial and is reversible); OR

Placebo itself may be appropriate approach; OR

The disease process is characterized by exacerbation and remission OR

The placebo is being used for a control in a non-treatment research protocol.

Consider the following: If the subjects are being washed out from an approved FDA-indicated drug, are procedures described? Is rescue therapy information provided? Are appropriate alternative treatments allowed with placebo use?

COMMENTS REGARDING THE USE OF A PLACEBO:

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IF THE RESEARCH INVOLVES THE USE OF INDS/IDEs, COMPLETE THE FOLLOWING:

USE OF INVESTIGATIONAL DRUGS (INDs) OR DEVICES (IDEs):

When a clinical investigation involves the use of a drug, biologic, or device other than the use of an FDA approved, marketed drug/biologic/device in the course of medical practice, ONE of the following must be true:

☐ The drug, biologic, or device has an IND/IDE issued by the FDA or an Exemption.

Is the IND/IDE valid? The Investigators Brochure may NOT be used to verify. One of the following must be true:

- The number is imprinted on the sponsor’s protocol
- The number is noted in written correspondence from the sponsor

NOTE: Written Correspondence is required when the PI holds the IND/IDE

☐ An IND/IDE is required.

NOTE: If the IRB determines that an IND/IDE is required for a specific research study, that determination may be satisfied by a letter from the FDA stating that an IND/IDE for that study is not required.

COMMENTS REGARDING THE USE OF DRUGS/DEVICES:

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ICH-GCP REQUIREMENTS FOR CLINICAL TRIALS ONLY:

Are the following ICH-GCP requirements satisfied?

- The current Curriculum Vitae or other documentation evidencing qualifications must be submitted for the Principal Investigator.
- The Consent Form must comply with the following ICH-GCP requirements (1) For alternative procedures or treatment that may be available to the subject, include their important potential risks and benefits (2) The monitor, the auditor, the IRB, and the regulatory authority will be granted direct access to the
subject’s medical records for verification of clinical trial procedures or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations that, by signing a written consent form, the subject or the subject’s legally acceptable representative is authorizing such access.

COMMENTS REGARDING THE ICH-GCP REQUIREMENT:

HIPAA AUTHORIZATION:
Is a HIPAA Authorization form required?

☐ Yes  ☐ No

Does this study qualify for a Waiver of HIPAA Authorization? (45 CFR 164.512(i)(2)(ii))

☐ Yes  ☐ No

COMMENTS REGARDING HIPAA:

REVIEWER RECOMMENDATION:

MOTION:

☐ APPROVE

Research is acceptable as is. NO changes are required. Criteria for IRB Approval have been met (45 CFR 46.111 and 21 CFR 56.111).

DURATION OF APPROVAL:

☐ 1 YEAR ☐ OTHER:  (Please specify; must be less than 1 year)

☐ DEFER FOR MINOR MODIFICATIONS

Criteria for IRB Approval met (45 CFR 46.111 and 21 CFR 56.111) except specific, non-substantial revisions are required. Member comments must be directive requesting simple, specific revisions. Upon the receipt of these revisions, the IRB Chair or another member designated by the Chair will verify that the appropriate revisions were made and grant a decision including approval.

List ALL Required Modifications:

☐ DEFER FOR MAJOR MODIFICATIONS

Substantial modifications and/or additional information are required that are directly relevant to the Criteria for Approval. This action requires that the study revisions or additional study materials be reviewed by the IRB at a convened meeting.
List ALL Required Modifications:

☐ DISAPPROVAL

The Criteria for Approval are not met. Only the convened IRB may disapprove a study. Justification of this action must be provided to the PI.

Reviewer Confirmation - please check the box and input your name below to verify your review:

☐ I verify that review was completed by (Name) on (Date).
Tulane University Human Research Protection Program
IRB Initial Submission Reviewer Sheet for Social/Behavioral Research

IRB Study Number:

Protocol Title:

Principal Investigator:

Sponsor:

Meeting Date:

Primary Reviewer:

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in this study; or do you have any other conflict with this study?

☐ Yes ☐ No

If Yes, do NOT complete this review and please contact the HRPO at 988-2665.

SUMMARY: Please provide a short summary of the research protocol reviewed (a short paragraph):

GENERAL:

In general, is the research practical? Is there a clearly formulated hypothesis? Is the research likely to answer the proposed question?

☐ Yes ☐ No

COMMENTS:

RESEARCH SETTING:

Is the PI/research staff qualified to conduct the research? Are the facilities to be used adequate?

☐ Yes ☐ No

If needed, are there medical or psychological resources available for subjects?

☐ Yes ☐ No
Has the appropriate permission been given to conduct the research at any external sites?

☐ Yes  ☐ No

COMMENTS REGARDING RESEARCH SETTING:

I. RISK: 45 CFR 46.111(A)(1):

The research risks are:

☐ No more than Minimal  ☐ Greater than Minimal

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

☐ Yes  ☐ No

Consider the following: Are precautions developed to decrease the likelihood of harm? Contingencies are available to deal with harms if they occur?

COMMENTS REGARDING RISK:

II. RISK-BENEFIT ASSESSMENT: 45 CFR 46.111(A)(2):

Benefits to subjects are:

☐ Direct  ☐ Indirect  ☐ Both  ☐ None

*Risks to subjects are reasonable in relation to benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. (In evaluating risks and benefits, the IRB Committee will consider 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.)*

☐ Yes  ☐ No

COMMENTS REGARDING RISK-BENEFIT ASSESSMENT:

III. SUBJECT SELECTION: 45 CFR 46.111(A)(3):

*Selection of subjects is equitable. (In making this assessment, the IRB Committee will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special considerations of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons.)*

☐ Yes  ☐ No
Consider the following: The Inclusion and Exclusion Criteria, whether prospective subjects will be vulnerable to coercion or undue influence, the recruitment methods, the influence of payments.

COMMENTS REGARDING SUBJECT SELECTION:

IV. INFORMED CONSENT PROCESS AND FORM: 45 CFR 46.111(A)(4):

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 the Federal regulations (45 CFR 46.116 BELOW)

☐ Yes  ☐ No

All of the following items must be true of the Consent Process (check all boxes):

☐ The investigator will obtain the legally effective informed consent of the subject or the subject’s legally authorized representative

☐ The circumstances of the consent process provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate

☐ The circumstances of the consent process minimize the possibility of coercion or undue influence

☐ The individuals communicating information to the subject or the legally authorized representative during the consent process will provide that information in language understandable to the subject or the representative

☐ The information being communicated to the subject or the subject representative during the consent process will not include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights or through which the subject or the legally authorized representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

☐ All required and appropriate additional disclosures will be provided to the subject or the subject’s representative

The required elements of an Informed Consent Document are as follows (check all boxes):

☐ A statement that the protocol involves research

☐ Expected duration of the subject’s participation

☐ Description of the procedures to be followed and identification of those that are experimental

☐ Disclosure of the reasonably foreseeable invasive or non-invasive risks or discomforts

☐ Statement of any benefits to subjects or others that may be expected

☐ Appropriate alternative procedures, if any, that might be advantageous to subjects
☐ How confidentiality of records identifying the subject will be maintained and disclosure of all infringements upon privacy and confidentiality which may result from participation in the research

☐ Whether compensation is available for participation

☐ Contact information of the research team to obtain answers to questions about the research or to voice concern or complaints about the research

☐ Contact information for a person independent of the research team to obtain answers to questions about the research, to voice concerns, complaints or offer input about the research, in the case that the research staff could not be reached, or in the event the participant wanted to speak to someone other than the research staff

☐ A statement that participation is voluntary, that there are no penalties if the subject refuses to participate, and that the subject may withdraw at any time without penalty

Also, the following additional requirements may be appropriate (check all applicable boxes):

☐ If the subject is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable

☐ Outline the circumstances where a subject’s participation may be terminated by the PI without regard to the subject’s consent

☐ Whether there are costs for which subjects will be responsible

☐ The safety consequences of a subject’s decision to withdraw

☐ New and significant findings, which may affect the subject’s willingness to continue, will be disclosed to the subjects

☐ The appropriate number of subjects involved in the research at the institution and nationally

☐ The amount and schedule of payments to participants

COMMENTS REGARDING THE CONSENT PROCESS AND FORM:

V. DOCUMENTATION OF CONSENT: 45 CFR 46.111(A)(5):

Informed Consent will be appropriately documented in accordance with, and to the extent required by the Federal Regulations (45 CFR 46.117).

☐ Yes  ☐ No

If a signed informed consent is to be obtained, a space must be provided for the subject or the subject’s legally authorized representative to sign and date the consent document and a copy must be given to the subject and/or legally authorized representative signing the form. Also, adequate time must be given for the subject to consider participation.
COMMENTS REGARDING THE DOCUMENTATION OF CONSENT:

If a Waiver of Consent is requested, ALL OF THE FOLLOWING MUST APPLY in accordance with 45 CFR 46.116(d):

- The research must involve no more than minimal risk
- Granting the waiver will not adversely affect the rights and welfare of the subjects
- The research could not practicably be conducted without the waiver
- Whenever appropriate, subjects will be provided additional pertinent information after participation

☐ A Waiver of Consent is granted in accordance with 45 CFR 46.116(d).

If a Waiver of the Documentation of Consent is requested, EITHER OF THE FOLLOWING MUST APPLY in accordance with 45 CFR 46.117(c):

- The only record linking the subject to the research would be the consent form, and the principal risk to the subject would be potential harm resulting from breach of confidentiality. 45 CFR 46.117(c)(1)

☐ A Waiver of the Documentation of Consent is granted in accordance with 45 CFR 46.117(c)(1).

- 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 research context. 45 CFR 46.117(c)(2)

☐ A Waiver of the Documentation of Consent is granted in accordance with 45 CFR 46.117(c)(2).

Note: If the IRB grants this waiver, the investigator will still be required to provide information about the research to each potential subject, but the subject's signature on the form will not be required. A written script of the information that will be read or given to potential subjects must be provided for IRB review. The scripts must contain the basic required elements of consent as referenced in 45 CFR 46.116(a).

COMMENTS REGARDING GRANTING A WAIVER OF CONSENT/DOCUMENTATION OF CONSENT:

VI. DATA SAFETY MONITORING: 45 CFR 46.111(A)(6):

When appropriate, the research plan makes adequate provision for monitoring the data collected to assure safety of the subjects.

☐ Yes ☐ No

Consider the following: All greater than minimal risk research required a Data Safety Monitoring Plan. Is a DSMP necessary for this research? Was a DSMP submitted? Is the plan adequate? Who will monitor the data? Is the frequency adequate?

COMMENTS REGARDING DATA SAFETY MONITORING:

VII. PRIVACY AND CONFIDENTIALITY: 45 CFR 46.111(A)(7):

Issued: 11/4/09
Effective: 03/11/11
Form #: 514
When appropriate, there are adequate provisions to protect the privacy and confidentiality of subjects and to maintain the confidentiality of data.

☐ Yes  ☐ No

Consider the following: The recoding of data, the identification of data, storage of data, sharing of data (including electronic transmission), the recruitment procedures, the privacy of the consent process.

COMMENTS REGARDING PRIVACY AND CONFIDENTIALITY:

VIII. VULNERABLE POPULATIONS: 45 CFR 46.111(b):

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

☐ Yes  ☐ No

COMMENTS REGARDING VULNERABLE POPULATIONS:

IF THE RESEARCH INVOLVES PREGNANT WOMEN, FETUSES, OR NEONATES, PRISONERS, OR CHILDREN, COMPLETE THE FOLLOWING:

RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES 45 CFR SUBPART B:

45 CFR 46.204: Pregnant Women/Fetuses may be involved in research if ALL of the following conditions are met; provide protocol specific findings justifying this determination.

☐ 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;

ONE of the following must be true:

☐ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or 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.

☐ Any risk is the least possible for achieving the objectives of the research;

☐ If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant women 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, consent of the mother is obtained in accord with the informed consent provisions of Subpart A of 45 CFR 46.116 and 117;

☐ 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 45 CFR 46.116 and 117, 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;

☐ Each individual providing consent as required above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

☐ For children who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D of 45 CFR 46;

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

☐ 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

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

45 CFR 46.205: Research Involving Neonates (Newborns):

NOTE: For Viable Neonates, they are considered Children and Subpart D applies.

For Neonates of Uncertain Viability, the following determinations must be made:

☐ The research hold out the prospect of enhancing the probability for survival of the PARTICULAR fetus to the point if viability;

☐ Any risk is the least possible; OR,

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate from the research;

☐ Either parent may consent or a legally authorized representative may provide consent.

For Nonviable Neonates, the following determinations must be made:

☐ Vital functions will not be artificially maintained;

☐ The research will not terminate the heartbeat or respiration of the fetus;

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate from the research;

☐ Both parents consent to the research; legally authorized representative consent is NOT permitted.
45 CFR 46.207: Research Involving Pregnant Women that is NOT Otherwise Approvable

The IRB must determine the following:

☐ The research does meet the requirements of 45 CFR 46.204 or 205 above.

☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviations of a serious problem affecting the health and welfare of pregnant women, fetuses, or neonates.

*NOTE: This determination must be forwarded to the Secretary of DHHS who will consult with experts and determine whether the research should go forward.*

The proposed involvement of pregnant women, fetuses, or neonates is:

☐ Approvable

☐ Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES AS SUBJECTS IN RESEARCH:

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RESEARCH INVOLVING PRISONERS 45 CFR SUBPART C:

45 CFR 46.305(a): Prisoners may be involved in research if ALL of the seven findings below are met and provide protocol specific findings justifying this determination.

☐ (1) The research under review represents ONE of the categories of research permissible under 45 CFR 46.306(a)(2): MARK THE CATEGORY:

☐ Research on 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;

☐ Research on 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, provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts (in penology, medicine, and ethics) and published notice in the Federal Register of the 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 subjects. If the research includes the
assignment of prisoners to control groups that might not benefit from the research, it may proceed only after the Secretary of DHHS has consulted with appropriate experts and published a note in the Federal Register of the intent to approve the research;

☐ Epidemiologic studies whose sole purpose is one of the following:

• To describe the prevalence or incidence of a disease by identifying all cases.
• To study potential risk factor associations for a disease.

The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research.

☐ (2) Advantages to participation are not coercive; AND
☐ (3) Risks are commensurate with what would be acceptable to nonprisoners; AND
☐ (4) The selection procedures are fair; AND
☐ (5) The information is presented in an understandable language; AND
☐ (6) There is no effect on decisions related to parole; AND
☐ (7) Provisions for follow-up are adequate.

The proposed involvement of prisoners is:

☐ Approvable
☐ Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING PRISONERS AS SUBJECTS IN RESEARCH:

RESEARCH INVOLVING CHILDREN 45 CFR 46 SUBPART D:

The regulations specify the following FOUR CATEGORIES of permissible child research. Check the ONE appropriate category for the reviewed research and provide protocol specific findings justifying this determination.

☐ CATEGORY 1: 45 CFR 46.404: Research not involving greater than minimal risk.

☐ The permission of one parent is sufficient

☐ CATEGORY 2: 45 CFR 46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
NOTE: The IRB must find that (a) the risk is justified by the anticipated benefits to the subjects; (b) the relation of the anticipated benefit to the risk is at least favorable to the subjects as that presented by the available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents and guardians.

☐ The permission of one parent is sufficient

☐ CATEGORY 3: 45 CFR 46.406: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

NOTE: The IRB must find that (a) the risk represents a minor increase over minimal; (b) the intervention or procedure represents experiences to subjects that are reasonable commensurable with those inherent their actual or expected medical, dental, psychological, social, or educational situations; (c) the research is likely to yield knowledge of vital importance; and (d) adequate provisions are made for soliciting the assent of the children and permission of both parents or guardians is needed.

☐ CATEGORY 4: 45 CFR 46.407: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children.

NOTE: The IRB must submit this category of research to HHS for approval. Approval cannot be granted until HHS approves and publishes the proposal in the Federal Register.

☐ Parental permission is waived under 45 CFR 46.116(c), 45 CFR 46.116(d), or 45 CFR 46.408(c).

Provisions to solicit the Assent of Children:

Assent will be obtained from:

☐ All Children ☐ None of the Children* ☐ Some Children*

*If None of the Children or Some Children was selected, the protocol must provide reasoning; complete the following:

Reason Why Assent is Not Necessary: One or more of the following must be true

☐ The capability of these children is so limited that they cannot reasonably be consulted

☐ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

☐ Assent is waived under 45 CFR 46.116(d): ALL must apply

- The research involves no more than minimal risk to the subjects
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
\[\square\] Assent is waived under 45 CFR 46.408(a)/45 CFR 46.116(c): ALL must apply

- The research is NOT FDA regulated
- The research is to be conducted by or subject to the approval of state or local government officials
- The research is designed to study, evaluate, or otherwise examine one or more of the following:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services under those programs
- The research could not be practically carried out without the waiver or alteration

COMMENTS REGARDING ASSENT:

Wards (45 CFR 46.405, 406, 409): If the research involves children who are wards of the state or any other agency, institution or entity, indicate whether:

\[\square\] The research is related to their status as wards
\[\square\] The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards

The proposed involvement of children is:

\[\square\] Approvable
\[\square\] Not Approvable

Protocol specific findings justifying this determination:

COMMENTS REGARDING INVOLVING CHILDREN AS SUBJECTS IN RESEARCH:

REVIEWER RECOMMENDATION:

MOTION:

\[\square\] APPROVE

Research is acceptable as is. NO changes are required. Criteria for IRB Approval have been met (45 CFR 46.111).

DURATION OF APPROVAL:

\[\square\] 1 YEAR \[\square\] OTHER: (Please specify; must be less than 1 year)

\[\square\] DEFER FOR MINOR MODIFICATIONS

Criteria for IRB Approval met (45 CFR 46.111) except specific, non-substantial revisions are required. Member comments must be directive requesting simple, specific revisions. Upon the receipt of these revisions, the IRB
Chair or another member designated by the Chair will verify that the appropriate revisions were made and grant a decision including approval.

List ALL Required Modifications:

☐ DEFER FOR MAJOR MODIFICATIONS

Substantial modifications and/or additional information are required that are directly relevant to the Criteria for Approval. This action requires that the study revisions or additional study materials be reviewed by the IRB at a convened meeting.

List ALL Required Modifications:

☐ DISAPPROVAL

The Criteria for Approval are not met. Only the convened IRB may disapprove a study. Justification of this action must be provided to the PI.

Reviewer Confirmation - please check the box and input your name below to verify your review:

☐ I verify that review was completed by (Name) on (Date).
IRB Study Number:

Protocol Title:

Principal Investigator:

Sponsor:

Reviewer:

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in this study; or do you have any other conflict with this study?

☐ Yes  ☐ No

If Yes, do NOT complete this review and please contact the HRPO at 504-988-2665.

In accordance with 45 CFR 46.110 and 21 CFR 56.110, an IRB may use the expedited review procedure to review minor changes to a previously approved study (for an amendment). Changes are minor if they do not represent a material change in the research (i.e., (a) changes do not adversely alter the overall risk-benefit ratio; (b) changes will not potentially affect the willingness of current participants to remain in the study or the willingness of potential participants to enroll in the study; (c) changes will not diminish the scientific validity of the study; (d) any added procedures involve no more than minimal risk to subjects, and (e) any added procedures fall into categories (1)-(7) of research that can be reviewed using the expedited procedure.

I. AMENDMENT REVIEW:

Describe the purpose of the amendment requested and any new or revised study documents submitted:

Did the PI provide adequate rationale for the amendment?

☐ Yes  ☐ No

As a result of this amendment:

Risks to subjects have:  ☐ Increased  ☐ Decreased  ☐ Remained unchanged

Benefits to subjects have:  ☐ Increased  ☐ Decreased  ☐ Remained unchanged

Describe how risks/benefits to subjects have increased/decreased:
II. REVIEW OF CRITERIA OF APPROVAL FOR RESEARCH (45 CFR 46.111; 21 CFR 56.111):

45 CFR 46.111(a)(1); 21 CFR 56.111(a)(1): Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

☐ Yes ☐ No

45 CFR 46.111(a)(2); 21 CFR 56.111(a)(2): 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.

☐ Yes ☐ No

45 CFR 46.111(a)(3); 21 CFR 56.111(a)(3): Selection of subjects is equitable taking into account the purposes of the research and the setting in which the research will be conducted and being particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively impaired persons, economically or educationally disadvantaged persons, and any other vulnerable populations.

☐ Yes ☐ No

45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4): 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 45 CFR 46.116, 21 CFR 50.

☐ Yes ☐ No

45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5): Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117, 21 CFR 50.27.

☐ Yes ☐ No

A waiver or alteration of consent was previously granted in accordance with 45 CFR 46.116(d) and continues to be relevant.

☐ Yes ☐ No

Written documentation of consent was previously waived in accordance with 45 CFR 46.117(c) and continues to be relevant.

☐ Yes ☐ No

45 CFR 46.111(a)(6); 21 CFR 56.111(a)(6): Whenever appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

☐ Yes ☐ No ☐ N/A

45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7): There are adequate provisions to protect the privacy interests of subjects and to maintain the confidentiality of data.
☐ Yes ☐ No

45 CFR 46.111(b); 21 CFR 56.111(b): When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, cognitively impaired persons, economically or educationally disadvantaged persons, or any other vulnerable population, additional safeguards had been included in the study to protect the rights and welfare of these subjects.

☐ Yes ☐ No ☐ N/A

The Criteria for Approval of Research (45 CFR 46.111; 21 CFR 56.111) continue to be met:

☐ Yes ☐ No

COMMENTS RELATED TO THE CRITERIA FOR APPROVAL:

III. REVIEWER ACTION:

Provide any modifications/clarifications needed for approval:

☐ Approve via Expedited Review in accordance with 45 CFR 46.110 and 45 CFR 46.111, as the Criteria for Approval of research continue to be met.

☐ Requires a Full Board review, decision, and vote

Recommended Action:

☐ Approve as submitted (The Criteria for Approval set forth in Section 46.111 of the Federal Regulations continue to be met)

☐ Defer for MINOR revision

☐ Defer for MAJOR revision

☐ Disapprove

If the recommendation is for deferral or disapproval, provide an explanation.

Reviewer Comments/Recommendations/Regulatory Information:

Reviewer Confirmation - please check the box and input your name below to verify your review:

☐ I verify that review was completed by (Name) on (Date).
*Forms are subject to change. Check for the latest forms on IRBNet.

Amendment Reviewer Sheet

Issued: 11/4/09
Effective: 11/4/09
Form #: 514

Last Reviewed: 11/4/09
Last Revised: 11/4/09
*Forms are subject to change. Check for the latest forms on IRBNet.

Tulane University
Human Research Protection Program
Continuing Review Reviewer Sheet

IRB Study Number:

Protocol Title:

Principal Investigator:

Sponsor:

Reviewer(s):

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in this study; or do you have any other conflict with this study?

☐ Yes  ☐ No

If Yes, do NOT complete this review and please contact the HRPO at 504-988-2665.

In accordance with 45 CFR 46.110 and 21 CFR 56.110, an IRB may use the expedited review procedure to review certain kinds of research involving no more than minimal risk to human subjects. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. A research activity may be disapproved only after review by a convened IRB in accordance with 45 CFR 46.108(b) and 21 CFR 56.108(c).

1. STUDY SPECIFIC INFORMATION:

The Continuing Review/Progress Report submission should provide sufficient information concerning the following: (1) number of subjects IRB approved, (2) number of subjects enrolled in the past approval period, (3) cumulative number of subjects enrolled, (4) number of subjects withdrawn from the study with an adequate explanation, (5) any vulnerable subjects enrolled, (6) any problems with the conduct of the research study, (7) copies of any sponsor correspondence (monitoring/audit reports, etc).

Provide a short description of the study reviewed for Continuing Review and the research activities within the past year:

Explain any significant changes to the Consent Form/Consent Process/Protocol/Other Revisions:

II. REVIEW OF CRITERIA OF APPROVAL FOR RESEARCH (45 CFR 46.111; 21 CFR 56.111):

Issued: 11/4/09
Effective: 03/11/11
Form #: 514

Last Reviewed: 03/11/11
Last Revised: 03/11/11
45 CFR 46.111(a)(1); 21 CFR 56.111(a)(1): Risks to subjects are **minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

☐ Yes  ☐ No

45 CFR 46.111(a)(2); 21 CFR 56.111(a)(2): **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.

☐ Yes  ☐ No

45 CFR 46.111(a)(3); 21 CFR 56.111(a)(3): **Selection of subjects** is **equitable** taking into account the purposes of the research and the setting in which the research will be conducted and being particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively impaired persons, economically or educationally disadvantaged persons, and any other vulnerable populations.

☐ Yes  ☐ No

45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4): **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 45 CFR 46.116, 21 CFR 50.

☐ Yes  ☐ No  ☐ N/A

45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5): **Informed consent** will be **appropriately documented**, in accordance with, and to the extent required by 45 CFR 46.117, 21 CFR 50.27.

☐ Yes  ☐ No  ☐ N/A

A waiver or alteration of consent was previously granted in accordance with 45 CFR 46.116(d) and continues to be relevant.

☐ Yes  ☐ No

Written documentation of consent was previously waived in accordance with 45 CFR 46.117(c) and continues to be relevant.

☐ Yes  ☐ No

45 CFR 46.111(a)(6); 21 CFR 56.111(a)(6): Whenever appropriate, the research plan makes adequate provision for **monitoring the data** collected to ensure the safety of subjects.

☐ Yes  ☐ No  ☐ N/A

45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7): There are adequate provisions to **protect the privacy** interests of subjects and to **maintain the confidentiality** of data.

☐ Yes  ☐ No
45 CFR 46.111(b); 21 CFR 56.111(b): When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, cognitively impaired persons, economically or educationally disadvantaged persons, or any other vulnerable population, additional safeguards had been included in the study to protect the rights and welfare of these subjects.

☐ Yes  ☐ No  ☐ N/A

The Criteria for Approval of Research (45 CFR 46.111; 21 CFR 56.111) continue to be met:

☐ Yes  ☐ No

Comments related to the Criteria for Approval:

For Drug Studies Only:

RESEARCH PHARMACY (HRPP SOPs, SECTION 7.4.2.1):

Has the investigator utilized the TMC Research Pharmacist involving investigational medications?

☐ Yes  ☐ No  ☐ N/A

Has the investigator contracted with an outside pharmacy/pharmacist to provide oversight of investigational medications used in this research study?

☐ Yes  ☐ No  ☐ N/A

If Yes, has this information been provided to the IRB for review and approval?

☐ Yes  ☐ No

If the above Research Pharmacy questions are No, did the investigator provide an appropriate explanation, and/or research pharmacy plan?

☐ Yes  ☐ No  ☐ N/A

III. REVIEWER ACTION:

Provide any modifications/clarifications needed for approval:

☐ Approve via Expedited Review in accordance with 45 CFR 46.110 and 45 CFR 46.111, as the Criteria for Approval of research continue to be met.

The Continuing Review may be expedited if the research falls into one of the following:

☐ The research was originally reviewed as Expedited and deemed no more than minimal risk in accordance with 45 CFR 46.110.
☐ 45 CFR 46.110: CATEGORY 8: Continuing Review of research previously approved by the convened IRB as follows:

The research at this site is permanently closed to the enrollment of new subjects; and
All subjects at this site have completed all research-related interventions; and
The research at this site remains active for long-term follow-up of subjects; or

☐ No subjects have been enrolled at this site and no additional risks have been identified anywhere;
☐ The remaining research activities at this site are limited to data analysis.

☐ 45 CFR 46.110: CATEGORY 9: Continuing Review of research previously approved research not conducted under an IND or IDE as follows:

The research is not conducted under an IND or IDE; and
The IRB has determined and documented at a convened IRB meeting that the research involved no more than minimal risk; and
No additional risks have been identified since IRB review at a convened meeting.

☐ Requires a Full Board review, decision, and vote

Recommended Action:

☐ Approve as submitted (The Criteria for Approval set forth in Section 46.111 of the Federal Regulations continue to be met)

☐ Defer for MINOR revision

☐ Defer for MAJOR revision

☐ Disapprove

If the recommendation is for Deferral or Disapproval, provide an explanation:

The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

☐ For this study, annual continuing review is adequate.

☐ A more frequent continuing review is recommended, as follows:

Reviewer Comments/Recommendations/Regulatory Information:
If a Lapse of Approval has occurred, provide comments:

Reviewer Confirmation - please check the box and input your name below to verify your review:

☐ I verify that review was completed by (Name) on (Date).