Social/Behavioral IRB Member Informational Session
January 18, 2013

AGENDA:

- Preparing for IRB Meetings
- Conducting Expedited Reviews
- Navigating IRBNet
IRB MEETINGS:

All Board Members will be provided with a list of studies/submissions to be discussed during upcoming IRB Meetings for which they are scheduled to attend. Such submissions will be shared on IRBNet. This list will be generated and emailed to members approximately one week prior to the meeting.

It is suggested that all Board Members who are scheduled to attend a given meeting familiarize themselves with the studies/submissions to be discussed by viewing all study documents.

The primary objectives of the IRB are to identify issues, make decisions, and develop communications to PIs regarding subject safety, i.e. risk/benefit ratio.

The discussion should be focused on the **CRITERIA FOR APPROVAL** and the following Criteria should be addressed for EACH protocol reviewed:

- **RISK**: A determination of risk should be identified (Minimal or Greater than Minimal) and how the PI has minimized risks for subjects.
- **SUBJECT SELECTION**: Who are the potential subjects? What are the inclusion/exclusion criteria? Is the selection process equitable/reasonable?
- **CONSENT PROCESS**: Who will be performing the Consent Process? Is this appropriate?
- **DOCUMENTATION OF CONSENT**: Will subjects be documenting their Consent appropriately? If a waiver of documentation is requested, is this appropriate?
- **DATA SAFETY MONITORING**: Is there a Data and Safety Monitoring Plan and is it adequate?
- **PRIVACY & CONFIDENTIALITY**: Are provisions for Privacy & Confidentiality needed, and if so, are these appropriate for the subjects and data to be collected?
- **VULNERABLE POPULATIONS**: Are vulnerable populations anticipated (pregnant women, children, prisoners, persons with limited cognitive ability, non-English speakers, vulnerable international subjects, etc.) and are the protections afforded such subjects appropriate?

The IRB Committee will vote on the actions and recommendations to the investigator that will be included in the determination letters. All items must be clearly stated and revisions should be sufficiently detailed to enable investigators to make the necessary changes in response to the IRB recommendations.
Recommendations for Reviewing an Initial Submission:
Using a Systematic Approach

- Establishing a routine for reviewing the application package within IRBNet.
  
  o **Read the consent document (form or statement):** The consent document should explain the purpose and important aspects of the study in lay terminology. As such, it should provide an overview of the study. *Take notes and identify items to be clarified or corrected.*

  o **Read the protocol:** The protocol provides more detail on important aspects of the study that facilitates IRB review relative to the criteria for the approval of research. Importantly, in addition to study design/procedures, the protocol will include descriptions of risks and benefits, remuneration (if any), costs, alternatives, consent process and documentation, and qualifications of the investigator. *Take notes and identify items to be clarified or corrected.*

  o **Read Application Part 2 and supporting materials:** The Application Part 2 expands upon the protocol and provides specific information on a number of issues such as the adequacy of resources to protect subjects, location information, recruitment information, privacy and confidentiality, data storage, and so on. Information in Part 2 should be consistent with information contained in the protocol. In addition, supplemental materials (e.g., letters of approval to recruit subjects at particular sites) should be aligned with information in Application Part 2 (e.g., the study locations). *Take notes and identify items to be clarified or corrected.*

  o **Reread the consent document:** After reviewing submission materials reconsider whether the consent document presents the main implications of research participation and whether it needs to be revised to improve the protection of subjects. *If necessary, record suggested corrections or questions for principal investigator.*

- Using a reviewer template.
  
  o The Tulane Expedited Initial Submission Reviewer Sheet has prompts for making specification determinations about all aspects of a submission. In particular, attend to providing comments to support assessments of the criteria for the approval of research. For a recommendation of deferral, provide detail on requested revisions or questions to be addressed. For a recommendation of approval, it is helpful to summarize recommendations along with the number of subjects approved for enrollment.
Questions that Frequently Arise with respect to Particular Aspects of a Review

- Specific aims, study design, and research procedures:
  - Are the scientific aims clear? Is there appropriate justification for this research?
  - Are the scientific design and research procedures described and adequate to answer the research question(s)?
  - Are the objectives achievable within a given time period?
  - Are the investigators qualified and is the location for conducting the research acceptable?

- Privacy, confidentiality, and informed consent:
  - Are there adequate provisions to protect the privacy and ensure the confidentiality of subjects?
  - Are the plans for storing data adequate?
  - Is the use of identifiers or links to identifiers necessary, and how is this information protected?
  - Does the consent document contain the basic elements of informed consent?
  - If a waiver of consent is requested is it justified and does the investigator provide subjects with additional pertinent information after participation?
  - If children are to be enrolled, are provisions for obtaining the assent of the children and permission of the parent or guardian included and adequate?

- Potential risks and benefits for subjects:
  - Are the risks and benefits adequately identified, evaluated, and described?
  - Are the potential risks minimized and is the risk/benefit ratio acceptable?

- Recruitment and inclusion/exclusion criteria for subjects:
  - Is the choice of subjects appropriate for the research question?
  - Is subject selection equitable and, in particular, are reasons for excluding some individuals acceptable (if requested)?
  - Are the recruitment methods well-defined and is the person performing the recruitment appropriate for this process?
  - Are the location and timing of the recruitment process acceptable?

- Data analysis:
  - Is the rationale for the proposed number of subjects reasonable?
  - Are the plans for data analysis defined and justified?

- Compensation and costs for subjects:
  - Is the amount or type of compensation or reimbursement reasonable?
CONDUCTING EXPEDITED REVIEWS

The IRB uses an expedited review process to review studies that meet the expedited categories adopted by the DHHS that involve no greater than minimal risk.

The expedited review process can be carried out by the Chair of the IRB or one or more experienced reviewers designated by the Chair among voting members of the IRB.

CONDUCTING EXPEDITED REVIEWS

The expedited reviewer makes the determination as to whether research activities are MINIMAL RISK and meet the EXPEDITED REVIEW CRITERIA.

The expedited reviewer makes the determination whether the research meets the CRITERIA FOR APPROVAL.
CONDUCTING EXPEDITED REVIEWS

Minimal Risk:

To be eligible for expedited review, research must involve "minimal risk" to participants. Federal Regulations define "minimal risk" as follows: "the probability and magnitude of harm or discomfort anticipated in the research are not greater than in an of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"

(45 CFR 46.102)

CONDUCTING EXPEDITED REVIEWS

Expedited Review Criteria:

For minimal risk research, Federal Regulations designate certain categories of research procedures as being eligible for expedited review. According to Federal Regulations, the seven "Expedited Review Categories" represent research procedures which may be reviewed through the expedited process.

In order for research to be approved via Expedited Review, all research procedures must fall into one or more of the following seven categories:
CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   
a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples:
   • hair and nail clippings in a nondisfiguring manner;
   • deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   • permanent teeth if routine patient care indicates a need for extraction;
   • excreta and external secretions (including sweat);
   • unstimulated saliva collected either in an unstimulated fashion or stimulated by chewing gum/base or wax or by applying a dilute citric solution to the tongue;
   • placenta removed at delivery;
   • amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   • supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   • mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   • sputum collected after saline mist nebulization.

CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
   Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples:
   • physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   • weighing or testing sensory acuity;
   • magnetic resonance imaging;
   • electrocorticography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   • moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
CONDUCTING EXPEDITED REVIEWS

Expedited Review Categories: (45 CFR 46.110)

7. **Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

CONDUCTING EXPEDITED REVIEWS

The Tulane University IRB must apply the following criteria, taken from 45 CFR 46.111 before approving research protocols involving human subjects.

**8 Criteria Required to Approve Research:**

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative unless waived
- Informed consent will be appropriately documented as required by regulations unless waived
CONDUCTING EXPEDITED REVIEWS

8 Criteria Required to Approve Research (continued):

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When appropriate, additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.

THESE CRITERIA ARE ALL ADDRESSED WITHIN THE EXPEDITED/FULL BOARD APPLICATION PART 2.

THE FINDINGS OF THE REVIEWER(S) MUST BE CLEARLY DOCUMENTED.

CONDUCTING EXPEDITED REVIEWS

Basic Elements of a Consent Form:

- Statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
CONDUCTING EXPEDITED REVIEWS

Basic Elements of a Consent Form (continued):

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

 THESE ELEMENTS ARE BUILT INTO THE CONSENT FORM TEMPLATE.

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CONDUCTING EXPEDITED REVIEWS

The Consent Process:

- Obtaining informed consent is a critical component of ethical research with human subjects. Normally, investigators are required to provide sufficient information about the study such that subjects can decide for themselves whether or not they wish to participate. A subject’s decision to participate should be documented through a signed consent form. However, there are instances where obtaining signed consent is not feasible or even not in the best interests of the subject. Further, there are limited times when obtaining consent can be waived altogether. The IRB (or expedited reviewer) will determine whether or not a waiver can be granted based on the regulations in cases where the investigator has requested a waiver and provided sufficient and specific reasons for doing so.

 THE PI WILL REQUEST THE WAIVER WITHIN THE APPLICATION AND COMPLETE SUPPLEMENT H.
CONDUCTING EXPEDITED REVIEWS

Waivers of Consent:

- Waiving Some or All of the Elements of Consent:
  45 CFR 46.116(d) states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent if it finds and documents that:
  - the research involves no more than minimal risk to the subjects; and
  - the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
  - the research could not practically be carried out without the waiver or alteration; and
  - whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Examples include Deception studies in which subjects are not informed of the purpose of the study up front, but a de-briefing process is in place. Also, research studies evaluating test scores or medical records may be approved without obtaining subjects' consent.

- Waiving Documentation of Consent:
  According to 45 CFR 46.117(c), an IRB may waive the requirement for the investigator to obtain a signed consent form from some or all subjects if it finds either:
  - that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a break of confidentiality, or
  - that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

A waiver of documentation only means that subjects will not need to sign a document prior to participation in the study. Subjects should still take part in a consent process, and, in some cases, receive a written document.

Minimal risk research studies involving an online, mail-in or telephone survey may qualify for a waiver of documentation or consent. Also, studies requesting sensitive information such as criminal activity may qualify for a waiver.
CONDUCTING EXPEDITED REVIEWS

Continuing Reviews:

- In accordance with 45 CFR 46.110, continuing reviews of minimal risk research previously expedited may be expedited.

- Continuing review of research previously approved by the convened IRB as follows: where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

- Continuing review of research where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Amendments:

- In accordance with 45 CFR 46.110, minor changes in previously approved research during the period (of one year or less) for which approval is authorized may be expedited.

CONDUCTING EXPEDITED REVIEWS

Tulane University HRPO Reviewer Sheets:

- Included within this packet are the following:
  - Expedited Initial Submission Reviewer Sheet
  - Continuing Review Reviewer Sheet
  - Amendment Reviewer Sheet
CONDUCTING EXPEDITED REVIEWS

Tulane University HRPO Review Timeline:

- Full Board
  - If the Board requires Revisions
  - Greater than Minimal Risk
    - 6-8 Weeks
  - Greater than Minimal Risk
    - 4-5 Weeks
  - Minimal Risk
    - AND falls into one of the OHRP Categories
      - 2-3 Weeks
  - Exempt
    - Designated by the Regulations as being Exempt
      - 1-2 Weeks

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CONDUCTING EXPEDITED REVIEWS

Completing an Expedited Review:

PI submits a submission/package for Expedited Review. → The submission is pre-reviewed by HRPO staff for completeness, communicates with PI (if necessary), places the submission on an Agenda and assigns a reviewer.

The reviewer will review the submission, complete and upload the reviewer sheet within IRBNet and notify the HRPO staff coordinator that the review has been completed. ← The reviewer will receive an email via IRBNet that they have been assigned to review the submission.

REVIEWER OPTIONS:

APPROVAL:
If reviewer approves the research, the HRPO staff coordinator will process the approval and publish a determination letter addressed to the PI within IRBNet.

DEFERRAL:
The reviewer may defer the submission if revisions/clarifications are needed. Notify the HRPO staff coordinator of the deferral/review conducted within IRBNet. The PI will respond to the deferral in a new package within IRBNet for review.

REFERRAL TO THE FULL BOARD:
Any submission may be referred to the convened IRB for review/discussion and decision. HRPO staff coordinator is to be notified to place submission on the Agenda.
CONDUCTING EXPEDITED REVIEWS
IRBNet Instructions for Board Members:

- Conducting Reviews via IRBNet
- Communicating with the HRPO via IRBNet
- Finding Meeting Agendas/Minutes via IRBNet
Social Behavioral Board Member Instructions

Log in to IRBNET:

Go to http://www.irbnet.org and log in using your username and password.

Access Study Documents:

Step 1: Make sure Tulane University Social-Behavioral is selected next to “Submissions for” at the top.

Click SUBMISSION MANAGER to view a list of studies awaiting your review.

Step 2: Select the correct MEETING DATE AND TIME using the drop down menu next to view by agenda. Make sure the box below next to “only show submissions awaiting review” is checked.

Click SEARCH.

Step 3: To view submission details for a study, click on the study title that appears in blue font.

Execute Review Process:

Step 1: Click the paper icon near the HRPO Coordinator’s name/comments at the bottom of the Submission Details page to access your reviewer sheet. Download your reviewer sheet and save it to your computer for editing.

Step 2: Click SUBMISSION DETAIL to return to the study, then click each document type in blue to view study documents.

Step 3 (optional): Click SEND COMMITTEE MAIL to send email to other reviewer(s) to discuss the study. Make sure the box under send mail is checked for only the reviewer you would like to email and then type your message and send.

Step 4: Fill out the reviewer sheet and save once completed.

Click ADD next to comment and reviewer documents to this submission.

Add reviewer comments in the text box, give a recommendation for approval, CHECK the box next to mark my personal review as complete. Click SAVE.

Step 5: Click ADD NEW DOCUMENT in the Reviewer Documents section to upload your completed reviewer sheet.
Select the DOCUMENT TYPE, then click BROWSE to find the completed viewer sheet on your computer then click ATTACH.

Step 6: Click SAVE & EXIT and you are finished.

Step 7: Click SEND COMMITTEE MAIL and select the person's name who sent you the review. Send a message letting them know you have completed your review.

Step 8: Log out of IRBNET.

Review Agenda and Minutes:

Step 1: Click SUBMISSION MANAGER to get to the main page.

Step 2: Select the correct MEETING DATE AND TIME using the drop down menu next to view by agenda. Make sure the box below next to "only show submissions awaiting review" is checked.

Click SEARCH.

Step 3: Scroll down and go to Agenda, Minutes and other Administrative Documents for this Meeting. Click on either Agenda or Minutes. To view individual documents click on the document title in blue.
Tulane University Human Research Protection Program
Expedited Initial Submission Reviewer Sheet

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 certain kinds of research involving no more than minimal risk to human subjects and one or more of the following procedures listed in categories 1-7 below.

Under an expedited review procedure, the review may be carried out by the IRB chairperson 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 reviewers may not disapprove the research, a research activity may be disapproved only after review by a convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b) and 21 CFR 56.108(c).

Note: If the research is classified, it is not eligible for expedited review. If the protocol involves prisoners in any way, or where the identification of the participants or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standings, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal the protocol does not fall under the Expedited Review Procedure and must be reviewed by the Full Board.

1. RISK EVALUATION:

In order to qualify for expedited review, the research must pose no greater than minimal risk to research participants.

*Minimal Risk means that 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. (45 CFR 46.102(i))

Issued: 11/4/09
Effective: 03/22/11
Form #: 509

Last Reviewed: 11/01/12
Last Revised: 03/22/11
Is the research no greater than minimal risk?

☐ Yes; Expedited review may continue
☐ No; Research must be reviewed by Full Board

II. EXPEDITED CATEGORIES:

*Select one or more of the following Expedited Categories under 45 CFR 46.110 that the research reviewed falls under.

☐ CATEGORY 1: Drugs or devices which do not require an IND or IDE

Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

(a) Research on drugs for which an investigational new drug application (IND) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is NOT eligible for Expedited Review.)

(b) Research on medical devices for which (i) an investigational device exemption application (IDE) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ CATEGORY 2: Blood Samples

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ CATEGORY 3: Specimens

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples include: (a) Hair and nail clippings in a non-disfiguring manner; (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) Permanent teeth if routine patient care indicates a need for extraction; (d) Excreta and external secretions (including sweat); (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) Placenta removed at delivery; (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) Supra-and
subgingival dental plaque and calculus, provided the collection procedure is not more invasive that routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) Sputum collected after saline mist nebulization.

☐ CATEGORY 4: Data (collected through non-invasive, routine clinical procedures)

Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for Expedited Review, including studies of cleared medical devices for new indications.)

Examples include: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) Weighing or testing sensory acuity; (c) Magnetic resonance imaging; (d) Electrocardiography; (e) Electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (f) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ CATEGORY 5: Materials (collected retrospectively or prospectively, depending on circumstance)*

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment diagnosis).

NOTE: It is the interpretation of the HHS Office of Human Research Protections (OHRP) that this category includes research involving materials (data, documents, records, or specimens) that (a) will be prospectively collected solely for non-research purposes such as medical treatment or diagnosis, or (b) have already been collected for either non-research or research purposes, provided the materials were not collected for the currently proposed research.

☐ CATEGORY 6: Voices, video, digital or image recordings

Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ CATEGORY 7: Individual or group characteristics or behavior; surveys, interviews, etc.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

III: STUDY SPECIFIC INFORMATION:

Provide a short description of the study reviewed:
Study Design: Is the PI qualified to carry out the responsibilities of this protocol? Is the research setting and are the resources adequate? Consider access to the desired study population and recruitment procedures, sufficient time to conduct the research, adequate trained staff, and the availability of medical or psychological resources that participants might require as a consequence to the research.

Comments regarding study design:

IV. REVIEW OF INFORMED CONSENT PROCESS AND FORM:

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, and Informed Consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117. (45 CFR 46.111 (a)(4) and (5).

☐ Yes  ☐ No; if a Waiver is requested, continue to next section.

If a Consent Document is to be used, consider the following required basic elements of consent (45 CFR 46.116(a)(1-8)):?

- A statement that the study involves research;
- An explanation of the purposes of the research;
- Expected duration of the subject’s participation;
- Description of the procedures to be followed and identification of those which 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:

- 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

Consider the language used within the Consent Form and the participants and minimizing the possibility of coercion/undue influence.

Comments regarding consent form/process:

A WAIVER OR ALTERATION OF CONSENT:

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent (above), or waive the requirements to obtain informed consent, provided the IRB finds and documents that 45 CFR 46.116(d)(1-4) applies.

45 CFR 46.116(d)(1-4): ALL of the following 4 findings must apply:

- 45 CFR 46.116(d)(1): The research involves no more than minimal risk to the subjects;
- 45 CFR 46.116(d)(2): The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 45 CFR 46.116(d)(3): The research could not practicably be carried out without the waiver or alteration;
☐ 45 CFR 46.116(d)(4): Whenever appropriate, subjects will be provided with additional pertinent information after participation.

A WAIVER OF DOCUMENTATION OF CONSENT:

The IRB may approve a waiver of the documentation if consent in accordance with 45 CFR 46.117(c)(1) or 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).

☐ 45 CFR 46.117(c)(1): A waiver of signed consent may be granted if the consent document is the only record linking the subject to the research and the principal risk is potential harm resulting from breach of confidentiality, the participants will be asked whether they want documentation linking them to the research, the researcher provides an adequate explanation in the research plan to justify the waiver, the investigator will provide the subjects a written statement regarding the research, and the study is NOT FDA regulated.

☐ 45 CFR 46.117(c)(2): A waiver of signed consent may be granted if the research involves no more than minimal risk to subjects, and involves no procedures for which written consent is normally required outside of the research context, the researcher provides an adequate explanation in the research plan to justify the waiver, and the investigator provides the participants with a written statement regarding the research.

Comments regarding granting a waiver of consent/documentation of consent:

V. REVIEW OF CRITERIA FOR APPROVAL OF RESEARCH (45 CFR 46.111):

Are risks to subjects minimized? 45 CFR 46.111(a)(1)

☐ Yes ☐ No

Are risks to subjects reasonable in relation to anticipated benefits? 45 CFR 46.111(a)(2)

☐ Yes ☐ No

Is the selection of subjects equitable? 45 CFR 46.111(a)(3)

☐ Yes ☐ No

Where appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects? 45 CFR 46.111(a)(6)

☐ Yes ☐ No ☐ N/A

Where appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data? 45 CFR 46(a)(7)

☐ Yes ☐ No ☐ N/A
Have appropriate safeguards been included to protect vulnerable subjects? 45 CFR 46.111(a)(8)

☐ Yes ☐ No ☐ N/A

Comments regarding these criteria for approval:

VI. VULNERABLE SUBJECTS/SPECIAL CIRCUMSTANCES:

Consider the enrollment of vulnerable subjects such as Non-English speakers, Children, Pregnant Women, etc. or other situations such as the use of medical records, sensitive questionnaires, etc.

☐ Children may be enrolled in this no greater than minimal risk study in accordance with 45 CFR 46.404 and adequate provisions are made for soliciting the assent of the minors as well as permission from the parent or guardian in accordance with 45 CFR 46.408.

☐ Pregnant women may be enrolled in this no greater than minimal risk study in accordance with 45 CFR 46.204.

☐ For studies involving PHI and requesting a HIPAA Waiver: A waiver of authorization to use and disclose protected heath information is granted in accordance with 45 CFR 164.512(i)(1)(i).

☐ For retrospective chart reviews, the requirement for informed consent is waived in accordance with 45 CFR 46.116(d) and waiver of authorization to use and disclose protected health information is granted in accordance with 45 CFR 164.512(i)(1)(i).

Comments regarding vulnerable populations/research with special circumstances:

VII. 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 research poses no greater than minimal risk.

☐ Upgrade to Full Board Review

Continuing Review is standard at least annually. Is a more frequent review schedule necessary for this study?

☐ No, annual continuing review is adequate.

☐ Yes, a more frequent continuing review is recommended, as follows:

Recommended Action:

☐ Approve as submitted (The Criteria for Approval set forth in Section 46.111 of the Federal Regulations continue to be met)
Minutes are not generated from Reviewer Sheets.
Reviewer Sheets only serve as guidance documents.

☐ 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).
Minutes are not generated from Reviewer Sheets.
Reviewer Sheets only serve as guidance documents.

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):

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:
Minutes are not generated from Reviewer Sheets.

Reviewer Sheets only serve as guidance documents.

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).
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Tulane University Human Research Protection Program
Amendment Reviewer Sheet

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:

Issued: 11/4/09
Effective: 03/22/11
Form #: 503

Last Reviewed: 11/01/12
Last Revised: 03/22/11
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:
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☐ I verify that review was completed by (Name) on (Date).