### Standard Operating Procedures

<table>
<thead>
<tr>
<th>SOP #304.2 Revision 2</th>
<th>TITLE: Initial Expedited Review</th>
<th>Effective Date: 8/3/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 9/6/2016</td>
</tr>
<tr>
<td>Approved By: IRB Chair</td>
<td>Signature</td>
<td>Date 9/6/11</td>
</tr>
</tbody>
</table>

**PURPOSE**
To define policies and procedures for conducting expedited initial review.

**REVISIONS FROM PREVIOUS VERSION**
Addition of minimal risk prisoner research; designation of expedited reviewers; clarification of administrative review of minor changes

**POLICY**
The IRB uses an expedited review process to review studies that meet the categories adopted by the Department of Health and Human Services (DHHS) that involve no greater than “minimal risk.” The expedited applicability criteria, including the definition of “minimal risk” and federally mandated categories are attached. Expedited review procedures allow the IRB to review and approve studies that meet the criteria in the attached document without the fully convened IRB. The IRB Chair and designated reviewers from among the IRB membership (regular and alternate members) conduct expedited initial review.

The expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR56.111. Also, expedited reviewers ensure that the study’s informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 21 CFR 56.116 unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOP.) For studies that have vulnerable populations, the reviewer will follow the procedures described in Protection of Vulnerable Populations SOP.

Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity in accord with non-expedited procedures set forth in the DHHS regulations.

The IRB minutes for convened meetings advises the IRB of research studies approved using expedited review procedures. Any member can request to review the entire IRB file for an expedited study.

**RESPONSIBILITIES**
Execution of SOP: IRB Chairs, IRB Members, Researchers, OIRB Staff.
PROCEDURE

Submission and Screening
1. The PI submits a completed submission package to the OIRB through IRBNet. Instructions for preparing the application are available on the OIRB website. The researcher may call the OIRB with questions.
2. Upon receipt of the submission, OIRB staff conduct intake and pre-review activities as described in the Staff Intake and Pre-Review SOP. OIRB staff make a preliminary determination that the study meets the criteria for expedited review, including minimal risk, and identifies the research categories. If the application does not meet the criteria for expedited or exempt review, OIRB staff schedule the study for full board review according to the Initial Full Review SOP.
3. OIRB staff note during the pre-review process that the proposal involves areas of research requiring federally mandated specific findings. OIRB staff provide the appropriate Reviewer Checklists to alert the expedited reviewer(s) of the areas requiring determinations.
4. OIRB staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights and Privacy Act (FERPA) concerns. If the PI includes a HIPAA form or otherwise indicates that Protected Health Information (PHI) is being collected or if there are any HIPAA or FERPA concerns, OIRB staff forward the submission to the OIRB Director for review, who reviews the application and submits suggestions in writing. OIRB staff forward these suggestions to the expedited reviewer for a final determination.
5. After completing screening, OIRB staff assign the study to an expedited reviewer(s), who conducts the expedited initial review.

Assigning Reviewers
1. Each year, after finalizing the list of IRB members, OIRB staff and IRB Chair query the board members to determine interest in serving as an expedited reviewer. Members are selected based on expertise and availability and serve on rotating terms. All expedited reviewers undergo initial training with OIRB prior to conducting expedited reviews. Members who have served on the IRB for at least three months may qualify as an experienced member. Once this additional training has been completed, the member receives a letter outlining associated responsibilities and officially designating them as an expedited reviewer.
2. OIRB staff make initial reviewer assignments based on the member’s familiarity with IRB issues, experience, and expertise. OIRB staff keep the approved list of expedited reviewers on file.
3. The expedited reviewer notifies OIRB staff if he/she is not available to conduct expedited review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. OIRB staff document who served as expedited reviewer on the applicable reviewer form.

IRB Expedited Review Process
1. Expedited reviewers are provided all documents submitted by the researcher.
2. The expedited reviewer documents federally mandated specific findings (e.g. Subpart B, C, D, or waiver of informed consent or documentation), if applicable, by completing the Reviewer Checklists.
3. Expedited reviewers review all information in the expedited review packet in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval.
4. Research not involving interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
   a. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
   b. The prisoner representative must review the research as a reviewer. This may be as the sole reviewer or in addition to another reviewer, as appropriate.

Review Outcomes
1. Expedited reviewers make the final determination as to whether research activities meet the expedited review criteria outlined in the attached document.
2. The reviewers can recommend that the activities do not fall under IRB purview. In these cases the IRB handles the review using procedures outlined in the Determination of Activities That Need IRB Review SOP.
3. The reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111 or 21 CFR 56.111.
4. Expedited reviewers ensure that the researcher will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117 and 21 CFR 56.116 and 117 unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOP.)
5. The expedited reviewers only raise those controverted issues or request changes that they have determined do not meet the federal criteria for approval or OIRB policies.
6. The expedited reviewers document on the Reviewer Checklist their determinations regarding expedited eligibility, applicable expedited category, and whether the research meets the federal criteria for approval.
7. The expedited reviewer makes one of the following three determinations:
   - APPROVED: IRB approval indicates that the IRB reviewer(s) has concluded that the research and consent forms meet the federal criteria for approval. An IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. OIRB staff send the researcher an approval letter, accompanied by an informed consent/assent document with the affixed "IRB Approval" validation stamp which includes valid dates of IRB approval.
   - MODIFICATIONS and/or ADDITIONAL INFORMATION REQUIRED: The IRB reviewer(s) withhold approval pending submission of revisions/additional information. OIRB staff send the researcher a letter describing the modifications requested by the IRB expedited reviewer(s). The PI responds to modifications requested by the IRB in writing and sends the response to the OIRB. If the expedited reviewer was unable to determine that all approval criteria were met, OIRB staff forward the responses to the expedited reviewer for further review. If the modifications were minor, modifications can be verified administratively.
   - FULL REVIEW REQUIRED: The IRB expedited reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting.
8. The expedited reviewer(s) can determine that the research is eligible for a less stringent mechanism of review (i.e. the project is exempt from requirements for review or the activities do not fall under the purview of the IRB). In these cases, the expedited reviewer, with assistance from OIRB staff if
necessary, documents the exempt categories or the rationale for determining that the activities do not meet the federal definitions of research or human subject.

9. The OIRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters outlined in the Initial Full Review SOP apply for expedited review as well. See Initial Full Review SOP for details.

10. Once the IRB reviewer(s) approves the study, he/she assigns the approval period at intervals appropriate to the degree of risk. For federally funded research, approval periods will not be less than once per year. Non-federally funded minimal risk faculty research may qualify for continuing review every two years (see SOP 205). The date the expedited reviewer completes the review in IRBNet for final approval on the study is the date the approval period starts. OIRB staff document the approval period dates in the approval letter to the PI.

11. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns to the IRB reviewer via a written document that includes justification for changing the IRB decision. The PI sends the request to the expedited reviewer and/or to the IRB Chair or Vice Chair for final resolution. If the researcher is still dissatisfied with the IRB decision, OIRB staff send the study to the convened IRB for review.

REFERENCES

45 CFR 46.102(i)
45 CFR 46.110
21 CFR 56.102(i)
21 CFR 56.110
63 FR 60364-60367; 63 FR 60353 – 60356 DHHS-FDA list published in Federal Register November 9, 1998
Federally Mandated Expedited Review Criteria – Effective November 9, 1998 – Definition of Minimal Risk Guidance to PI and Reviewers

Expeditied procedures can only be used to review a study if the only involvement of human subjects fits one or more of the categories specified in the federal regulations and if all of the procedures present no greater than “minimal risk.”

The IRB reviewer confirms that all of the research activities fit in one or more of the expedited categories. If the research includes activities that do not fit in the categories, the study is not eligible for expedited review even if the research involves “minimal risk.”

The Department of Health and Human Services defines minimal risk to mean “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(2)(i)].

It is the IRB reviewer's responsibility to determine whether the research meets the federal definition. The IRB reviewer must consider two questions:

- Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests? OR
- Is the magnitude of the harm or discomfort greater than that encountered ordinarily in the daily life or during the performance of routine physical or psychological examinations or tests?

If the answer is “yes” to either of these questions, then the research does not meet the definition of minimal risk.

Federal Expedited Review Applicability and Categories

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, 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.

(D) The expedited review procedure may not be used for classified research involving human subjects.
(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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.

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 (persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) 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.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring 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) uncanullated 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) supragingival 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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: (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, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) 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 or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

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. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:
   (a) 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
   (b) Where no subjects have been enrolled and no additional risks have been identified; or
   (c) Where the remaining research activities are limited to data analysis.

9) Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but 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.

Page 7 of 7