REVIEW OF NEW HUMAN SUBJECTS RESEARCH SUBMISSIONS
BY THE INSTITUTIONAL REVIEW BOARD

POLICY

All research protocols involving human subjects, all modifications to approved research, and all continuing reviews must be submitted to the IRB for review. The IRB will determine whether the research qualifies for exempt status, expedited review, or whether the research will be reviewed by the IRB at a convened meeting.

CATEGORIES OF PROPOSALS TO BE SUBMITTED TO THE IRB
Not Human Subjects Research determinations
Exempt Human Subjects Research
Expedited Human Subjects Research
Convened Human Subjects Research

TYPES OF REVIEW CONDUCTED BY THE IRB
Expedited Review
Not Human Subjects Research determinations
Exempt Human Subjects Research
Expedited Human Subjects Research
Review by the Convened IRB
Convened Human Subjects Research
Review Referred by an Expedited Reviewer

PROCEDURES USED DURING IRB REVIEW OF NEW RESEARCH PROPOSALS
- Administrative Pre-Review and assignment of reviewers (Procedure 301)
- Additional reviews (e.g. hazardous materials etc.; see listing of relevant policies at end of this document)
- Protection of Vulnerable Participants
  Policy V.01 Protecting Vulnerable Populations in Human Subjects Research
  Procedure 303 IRB Review of New Human Subjects Research Studies
  Procedure 305 Inviting Consultants to Review IRB Protocol Documents
  Procedure 308 IRB Review of Research Involving Pregnant Women, Fetuses, and Nonviable Neonates
  Procedure 331 IRB Review of Prisoner Research
  Procedure 332 IRB Review of Minor research
  Procedure 333 IRB Review of Research Involving Cognitively Impaired Individuals
  Procedure 334 IRB Review of Research Involving Other Vulnerable Populations
All research under this policy must be reviewed at a convened meeting of the IRB unless the IRB determines the research qualifies for expedited review or exempt status.

The IRB will conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year for research for research classified as requiring expedited or full board review (i.e. excluding research classified as exempt from review). The IRB may require more frequent reviews based on: the degree of risk, the inclusion of any vulnerable populations, occurrence of problems with the research, and determination of noncompliance will all be taken into consideration when determining the length of the interval for continuing review. Individuals as specified for vulnerable populations will be in attendance at any meeting where research involves vulnerable participants.

CONSULTANTS

When the IRB or the IRB Chair determines that there is not at least one member with sufficient expertise among the membership to review a human subjects research protocol, the IRB Chair must obtain an individual or individuals with appropriate expertise review and comment on the human subjects’ research as described in Procedure 305 Inviting Consultants to Review Institutional Review Board Protocol Documents

CONTINGENT APPROVALS

When the convened IRB is able to stipulate specific revisions that require simple concurrence or changes to the study by the investigator, the IRB may determine that the IRB Chair or designee may administratively review the revised research protocol on behalf of the IRB.

When the convened IRB requests non-directive or substantive modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material.

These approval processes are described in Procedure 307 IRB Review of New Research Proposals at a Convened Meeting
FURTHER APPROVALS

Human subjects research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials may not approve the human subjects research if it has not been approved by an IRB.

DOCUMENTATION

The minutes of the IRB meetings document separate deliberations, actions, and votes for each protocol under regular review. Within ten days of the IRB meeting, the IRB staff will distribute the minutes to the IRB members for review. Minutes will be approved at a convened IRB meeting. The approved minutes are available to the Institutional Official and the Director of the Office of Research Integrity.

RESEARCH WHICH IS EXEMPT FROM CONTINUING REVIEW

Only the IRB may make the determination that the research is exempt from continuing review. In addition, if a researcher wishes to modify research previously determined by the IRB to be exempt, the amendment must be submitted to the IRB for review.

PROCEDURE FOR DETERMINATION OF EXEMPTION

In order to request a determination from the IRB as to whether a particular activity qualifies for exempt status, the Investigator must submit for review:

- Protocol Submission Form,
- List of all key personnel on the study and completed/signed conflict of interest forms for each of those researchers, and
- Any data collection tools or other study related materials.

The IRB Chair, Vice-Chair, or designee reviews the research and determines whether it is exempt based on the criteria for exemption as stated in this policy. The exemption under Category 2 does not apply to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

The reviewer shall take into consideration the level of risk involved as well as ethical concerns that may potential harm to the participant. If the reviewer finds that the ethical issues pose more than a minimal risk to the participant, but the type of review falls within the exempt criteria, the
reviewer shall determine whether the project will be reviewed either as expedited or by the convened IRB. The reviewer may require additional information to determine exemption eligibility or may deny the exemption request. The reviewer shall document the appropriate exemption criteria in the reviewer sheet or database.

If the reviewer decides that the research is exempt from continuing review the members are given a written summary of the research and the criteria upon which the determination of exemption was made at the next convened meeting of that IRB. Members are given the opportunity to ask questions about the research or challenge the determination of exemption. If the IRB decides that the research is not exempt, it is then reviewed in the same manner as research which is not exempt. The determination and the criteria for exemption become part of the minutes of the IRB meeting at which the determination was presented to the IRB. The results of exemption determinations will be promptly provided in writing to the Investigator requesting the determination.

CHILDREN AS SUBJECTS

Projects involving research in educational settings must be designed to comply with the federal Family Educational Right to Privacy Act:

CRITERIA FOR EXEMPTION

The IRB Chair must document that the research is exempt under one of the following criteria, as taken directly from the Common Rule:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   a. Research on regular and special education instructional strategies; or
   b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: Classroom evaluation activities do not require submission of an application to the IRB when assessment involves regular classroom activities and results of the evaluation are intended to be used for the sole purpose of informing teaching practices of the instructor.

Additionally, the following criteria apply:
• The research does not involve prisoners as participants;
• The research is not FDA-regulated;
• The research must comply with the Federal Educational Rights and Privacy Act; and
• The research meets all institutional ethical standards.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

   b. Any disclosure of the human participants' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. NOTE: The Veterans Affairs Medical Center (VAMC) also includes loss of insurability in this category.

      Additionally, the research must meet the following:

      • The research does not involve prisoners as participants;
      • The research is not FDA-regulated;
      • If the research involves children as participants, the procedures are limited to educational tests or observations of public behavior where the investigators do not participate in the activities being observed;
      • The research meets all institutional ethical standards.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if:

   a. The human participants are elected or appointed public officials or candidates for public office; or

   b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

      Additionally, the research must meet the following:
• The research does not involve prisoners as participants;
• The research is not FDA-regulated; and
• The research meets all institutional ethical standards.

Research activities that are requirements of a course, are being conducted for the purpose of learning research skills only, and do not meet the federal definition of human subjects research are not required to be submitted to the IRB for review.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants, and:

• The data must exist at the time the research is proposed;
• The investigator must provide a complete description of the data to be recorded;
• The research does not involve prisoners as participants;
• The Research is not FDA-regulated;
• The research meets all institutional ethical standards.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

• Public benefit or service programs;
• Procedures for obtaining benefits or services under those programs;
• Possible changes in or alternatives to those programs or procedures; and
• Possible changes in methods or levels of payment for benefits or services under those programs.

Additionally, the research must:

• Be conducted pursuant to specific federal statutory authority;
• Have no statutory requirements for IRB review;
• Not involve significant physical invasions or intrusions upon the privacy interests of participants;
• Have authorization by, or concurrence of, the funding agency;
• Not involve prisoners as participants;
• Not be FDA-regulated; and
• Meet all institutional ethical standards.

6. Taste and food quality evaluation and consumer acceptance studies may be exempt if:

   a. Wholesome foods without additives are consumed; or

   b. Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

   • The research must not involve prisoners as participants; and
   • The research meets all institutional ethical standards.

EXPEDITED RESEARCH

The categories of research that may be reviewed by the IRB Chair or designee through an expedited review procedure include research activities that (1) present no more than minimal risk to the human participants, and (2) involve only procedures in one or more of the specified categories listed in the regulations at 45 CFR 46.110 and 21 CFR 56.110.

The IRB member designee, with the approval of the Chair, may seek assistance by another IRB member or consultant who has scientific or scholarly expertise in the research being reviewed.

The IRB Chair or designee cannot disapprove an item submitted for expedited review, the item must be presented to the convened IRB for determination.

Research reviewed by the expedited process must be reviewed using the same criteria as the IRB uses to review research at a convened meeting. 45 CFR 46.111.

RESEARCH CATEGORIES ELIGIBLE FOR EXPEDITED REVIEW:

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:
   - From healthy, non pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two times per week; or,
   - From other adults and children, considering 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. From such 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 two 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) uncannulated 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; (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 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 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 subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroneuroretinography, 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).

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.

8. Continuing review of research previously approved by the convened IRB where:

   a. The research is permanently closed to enrollment of new participants, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or

   b. No subjects have been enrolled and no additional risks have been identified; or

   c. The only 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.

AMENDMENTS

Modifications to approved research that are minor and present no additional risk to participants may be made by the expedited review procedure so long as the applicability criteria are met and the research falls into one of the categories for expedited approval set forth in this policy.
Examples of additional items appropriate for expedited review:

- Board requested changes that require minor concurrence;
- Modifications or amendments as described in IRB Procedure 314 *Submission and Review of Amendments by the IRB*;
- Reported events that the Chair or designee determines are not unanticipated problems involving risks to participants or others;
- Protocol deviations;
- Miscellaneous items such as correspondence from the sponsor or investigator;
- IRB minutes contingently approved by the convened IRB.

**DEFINITION OF MINIMAL RISK**

Minimal risk is defined as “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) and 21 CFR 56.102 (i)

**APPLICABILITY**

Research may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110 only if:

1. That research a) presents no more than minimal risk to participants; and b) involves only procedures listed in one or more of the categories listed below. 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 participants.

   The categories in the list apply regardless of age of subjects, except as noted;

2. 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, 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 greater than minimal;

3. Expedited review procedure cannot be used for classified research;
4. The standard requirements for informed consent (or its waiver, alteration, or exception) apply, regardless of the type of review.

**AUTHORITY OF THE IRB CHAIR OR DESIGNEE**

Expedited initial or continuing review and amendments to approved research shall be carried out by the IRB Chair or designee provided that all of the following apply:

1. The reviewer(s) selected for the delegated review are qualified, in the opinion of the Chair, to review the submission by virtue of appropriate expertise, experience or other qualification;

2. A written record of the referral is made and retained in the IRB study file or database.

The IRB Chair or designee may exercise the authority of the IRB except that the reviewers may not disapprove the research. A research project may be disapproved only after review of the convened IRB.

The protocol submission will be reviewed and approved, when appropriate by the Chair or designee. The delegated IRB member will make the determination that the research does or does not qualify for expedited review, guided by established criteria applicable to review and approval of research as used for initial review, continuing review, or review of modifications to previously approved research.

The Chair or designated reviewer will review the research evaluating whether the research fits the applicability, and if so, will determine whether the research fits into one more of the categories for expedited review. The reviewer(s) may approve the research, require modification, defer consideration with a request for additional information, or refer the research for review at a convened meeting of the IRB. If the review approves the research, the reviewer will document the applicability and the category.

Notification to the Investigator of approvals with conditions, requests for additional information, and similar communications shall include a notification of the manner and time period during which the PI may respond.
NOTIFICATION OF THE IRB

When the expedited review process is used, Human Research Protection Program (HRPP) staff shall inform the Principle Investigator (PI) of the reviewer(s) expedited review decision, including the qualifying category for expedited review.

The results of the reviewer(s)’ action will be promptly communicated in writing to the PI. The documentation will be included in the approval letter to the researcher, in the notification to IRB members of the approval, and in the minutes of the IRB meeting. Notification to the PI of approvals with conditions, requests for additional information, and similar communications shall include a notification of the manner and time period during which the PI may respond.

All IRB members are informed of the actions taken by the Chair or designee at the next convened meeting. The meeting agenda reflects a written summary of the research and the determination of the criterion (category) for expedited approval.

DOCUMENTATION

Documentation for initial and continuing reviews as well as amendments to approved research conducted under an expedited review procedure includes:

1. Notation of applicability (including determination of risk);
2. The category justifying the expedited review with protocol specific findings;
3. Documentation of the review and action taken by the IRB Chair or designated reviewer and any finding required under Department of Health and Human Services (DHHS) regulations.

Determinations or review status must be documented by the reviewer in a verifiable manner. The IRB minutes shall include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members raised concerning the research reviewed.

REVIEW AT A CONVENED MEETING

If a research protocol is not exempt from continuing review or cannot be reviewed under the expedited review process, it must be reviewed and approved at a convened meeting of the IRB before the research or data collection can begin.
RESPONSIBILITY

The Human Protections Administrator (HPA) is responsible for the initial identification of submissions that qualify for expedited review and for forwarding all such submissions to the IRB Chair or designee. The IRB Chair or designee is responsible for making the final determination of eligibility for expedited review and for marking the expedited category on the application form.

IRB Chair or designee is responsible for conducting the expedited review.

The HPA is responsible for posting the expedited reviews to the agenda/minutes for presentation and review by the IRB.

Applicable Regulations, Document(s):
45 CFR 46.110
45 CFR 46.116
45 CFR 46.117
21 CFR 56.110
Procedure 301 Administrative Pre-Review of Research Submissions, Initial Determination of Review Type, and Assignment of Reviewers
Policy III.04 Safety Monitoring in Human Subjects Research
Policy III.08 Review of INDs and IDEs in Human Subjects Research
Policy III.10 International
Policy V.01 Protecting Vulnerable Populations in Human Subjects Research
Procedure 303 IRB Review of New Human Subjects Research Studies
Procedure 305 Inviting Consultants to Review IRB Protocol Documents
Procedure 308 IRB Review of Research Involving Pregnant Women, Fetuses, and Nonviable Neonates
Procedure 314 Submission and Review of Amendments by the IRB
Procedure 316 Review of Continuing Review Submissions by the Institutional Review Board
Procedure 331 IRB Review of Prisoner Research
Procedure 332 IRB Review of Minor Research
Procedure 333 IRB Review of Research Involving Cognitively Impaired Individuals
Procedure 334 IRB Review of Research Involving Other Vulnerable Populations
### Review of New Human Research Subject Research Submissions by the Institutional Review Board

**Adopted:** 11/2005

**Revised:** 03/2015

<table>
<thead>
<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/2005</td>
<td>IRB Director</td>
<td>07/2007</td>
<td>J. Lindwall</td>
<td>Revision has been made to remove text regarding the IRB accepting a letter explaining the protocol if a protocol is not available.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>03/2007</td>
<td>J. Gerlach</td>
<td>Revision made to remove text indicating department chair signature on research review submission form.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>05/2014</td>
<td>A.Braggs-Brown</td>
<td>Revised to reflect organizational changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>09/2014</td>
<td>A.Braggs-Brown</td>
<td>Revised to reflect AAHRPP recommendations</td>
</tr>
<tr>
<td>3/2015</td>
<td></td>
<td>3/2015</td>
<td>J. Strasser</td>
<td>Revisions for clarification</td>
</tr>
</tbody>
</table>

**Date Adopted** March 2015  
**Signature** signed copy on file