OBJECTIVE

To describe the policy and procedures for initial and continuing review by the Institutional Review Board (IRB).

GENERAL DESCRIPTION

If the IRB Chair or their designee determines that a research activity constitutes human participant research and requires IRB review and approval, the Principal Investigator (PI) must complete and submit the research protocol and all supporting documents required for IRB initial review and approval (research protocol application) under one of two processes: Expedited Review or Full Board Review. Once approved and initiated, the research protocol may be subject to Continuing Review. This means that the protocol must be submitted for review and continuation of IRB approval under the Expedited or Convened Committee process at an interval appropriate to the protocol's degree of risk, but not less than once per year [45 CFR 46.108(b); 45 CFR 46.109; 45 CFR 46.110; JMU Policy # 1104]. This Standard Operating Procedure (SOP) sets forth the research protocol application submission requirements, criteria for IRB approval, and procedures for each review process.

RESPONSIBILITY

Execution of SOP: IRB Chairs, IRB Members, Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff

PROCEDURES

Submission and Screening
If the IRB Chair or their designee determines that a research activity (a) constitutes human participant research, and (b) is not eligible for exemption from IRB review, the PI must submit the research protocol for IRB review and approval under the Expedited Review or Full Board Review process, in accordance with the following procedures:

Training
Before the IRB can approve the research protocol, the PI, all co-investigators, and all personnel named on the protocol who will have human subjects interaction or access to identifiable data must successfully complete the IRB online training addressing the appropriate conduct of human participant research through the Collaborative Institutional Training Initiative (CITI) Program. Proof of completion through CITI Program of this requirement by all investigators and key personnel is maintained in the protocol through the online electronic Research Administration (eRA) software system. Proof of completion through another institution must be provided to ORI for verification. All researchers named on a protocol are required to renew their training every (3) years.

Forms to be Completed and Submitted by PI
To submit a protocol, the PI will need to go to: https://era.jmu.edu to access the eRA software system. They will need a JMU eID and be connected to the JMU Official wireless network in order to access the system.

Processing of Research Protocol Application by ORI
Upon receipt of the research protocol and supporting documents, ORI will:

1. Verify that the research activity constitutes human participant research;
2. Verify the completeness of the materials or coordinate with the PI to achieve completion; and
3. Review the protocol and attached materials to determine whether Exempt, Expedited, or Full Board process is appropriate.

After it has been determined that the research protocol application is complete, ORI will submit the materials for IRB review and approval via the Expedited Review process or the Full Board Review process. Exemptions are determined by the IRB chair or their designee using procedures outline in SOP # 3: Exempt Review.

Possible Decisions Made Upon IRB Review
No research activity shall be initiated until the PI has received written notification from ORI that the protocol has been "approved" by the IRB.

The PI shall be notified by ORI via the eRA system that the IRB has made one of the following decisions after reviewing the research protocol application: (1) Approved, (2) Modifications Required to Secure Approval, (3) Tabled, or (4) Disapproved. Within the IRB, only the Convened IRB can disapprove a protocol. While sponsors and/or other administrative review may override a decision by the IRB to approve the implementation of a research protocol, they may not override an IRB decision to disapprove a research protocol. All other decisions may be made under both the Expedited and Full Board Review processes and will be communicated by ORI in the eRA system.

Approved: If the protocol is approved, ORI will provide email notice of approval to the PI and advisor, if student, through eRA. Only after receiving the email notice of approval may the PI initiate the research activity

Modifications Required to Secure Approval: The Expedited Reviewer(s) or the Convened IRB may stipulate that approval of the research protocol will be granted only after the PI makes specific minor revisions to the protocol, informed consent documents and/or process, recruitment materials, etc. ORI will send the PI a notification of the required changes through eRA. If the PI makes the revisions, they shall then submit them for review via the Expedited Review process. After all specific minor revisions have been approved, ORI will send an email notice of approval to the PI and advisor, if student, through eRA. Upon receipt of the notice, the PI may initiate the research activity. If, however, the PI suggests or makes revisions that the Expedited Reviewer

believes affect the risk-benefit ratio of the project, such revisions will be designated as major and referred for review by the Convened IRB. The PI may request the IRB to review at a Convened meeting any specific minor revisions that were required during the Expedited Review process with which they disagrees. However, that research protocol cannot begin until all specific minor revisions have been satisfactorily addressed or the Convened IRB has reviewed and approved the research protocol.

Tabled: A protocol is tabled when the Expedited Reviewer(s) or the Convened IRB request additional information, substantive clarifications or modifications regarding the protocol, informed consent documents, etc. that are relevant to the evaluation of the risk/benefit ratio required for approval. The IRB may also table a protocol where it does not have a member with expertise adequate to the scope and complexity of the proposed research and thus seeks review by an expert in the appropriate field. The PI may suggest an expert to the IRB for this purpose. A protocol requiring Convened Committee Review may be tabled for lack of appropriate expertise in attendance, lack of time, loss of quorum, etc. In the event a research protocol application is tabled for such administrative reasons, ORI will assign it for review at a future meeting of the Convened IRB. When a protocol is tabled, ORI shall draft and transmit to the PI an email setting forth the reasons for this action. The PI shall then have the opportunity to respond to the concerns outlined in the email and to make appropriate revisions to the documents in question. The PI will submit any revisions and responses to the concerns or questions outlined in the email to ORI, which will assign them for IRB review.

The IRB may make one of the following decisions with respect to a revised research protocol application: (1) Approved, (2) Modifications Required to Secure Approval, (3) Tabled, or (4) Disapproved. This cycle will continue until the IRB issues a final decision—either approved or disapproved.

Disapproved: The IRB at a Convened meeting may elect to disapprove a research protocol when it identifies significant concerns about potential risk to participants or a lack of scientific validity to support the proposed research activities. ORI will draft and transmit to the PI and advisor, if student, a written statement of the reasons for the IRB's decision. The PI will have the opportunity to respond in person or in writing. The IRB at a convened meeting will review any written responses and make a decision about the appeal of the initial decision to disapprove the research protocol. As with all protocols, the PI may not initiate the corresponding research activity until the protocol has been approved by the IRB. The PI always has the right to submit a new protocol that addresses the concerns outlined during the initial review.

Criteria for IRB Approval upon Initial or Continuing Review

Role of IRB

The IRB evaluates each protocol application to assess the risk/benefit ratio and the methods used by the principal investigator and the research staff for protecting the rights of the research participants while allowing the research data to be collected for the benefit of society. In making

this assessment, the IRB will examine the initial protocol application, which consists of the protocol itself, outside approval letters, letters of support, recruitment materials, consent documents, any funding or thesis documents, and other supporting documents. The IRB will also consult the PI, as necessary, to gather additional information. The goal of IRB review is to ensure approval only of research projects that meet the minimum criteria for approval of research, delineating the parameters for adequate protection of the rights and welfare of human participants, as derived from (1) federal and state laws, (2) federal and state regulations, and (3) the principles of justice, beneficence, and autonomy articulated in applicable ethical codes like the Belmont Report and the Declaration of Helsinki.

Minimal Criteria for Approval of Research
The IRB Expedited Reviewer(s) or the Convened IRB may approve a research project only when they find that the project fulfills all of the following conditions, their consideration of which shall be documented on the IRB Reviewer's Checklist.
Risks to participants are minimized: The protocol uses procedures that (1) are consistent with sound research design and (2) do not unnecessarily expose participants to risks without the informed consent of the participants.

Risks to participants are reasonable in relation to any anticipated benefits to participants and to the importance of any knowledge that is expected to result: When social or behavioral therapy or services are being provided to participants independent of their participation in the proposed research protocol, the Expedited Reviewer or the Convened IRB will consider those additional risks and benefits.

Selection of participants is equitable: The IRB should consider the purposes of the research, the setting in which it will be conducted, and its inclusion/exclusion criteria, so as to maximize the equitable distribution of burdens and benefits. Moreover, the IRB should evaluate the recruitment practices and materials, as well as payments to participants. The IRB should consider particularly the special problems and additional safeguards posed by research involving vulnerable population participants such as children, prisoners, pregnant women, physically or mentally compromised individuals, or economically or educationally disadvantaged persons who may be vulnerable to coercion or undue influence in the context of the research.

Informed consent/assent: Informed consent or assent will be sought from each participant or their legally authorized representative and appropriately documented, in accordance with and to the extent required by local, state, and federal regulations.

Privacy and confidentiality: The protocol, if appropriate, will provide adequately for the protection of participants' privacy and the confidentiality of identifiable data. The Expedited Reviewer(s) or the Convened IRB may request that ORI obtain verification from sources other than the PI under the following circumstances:

1. The IRB has concerns about information provided by the PI.

2. The IRB has received information from the PI that is not consistent with other information known to the IRB and communication with the PI has not resolved the inconsistency.
3. The IRB is aware of previous or continuing non-compliance with Continuing Review requirements.
4. The IRB and/or ORI have been made aware of concerns expressed by research participants, university employees, sponsors, regulatory agencies, and/or a member of the general public.

Procedures for EXPEDITED REVIEW

Expedited Reviewer Process

Only the Chair of the IRB or their designee may make the determination that a research protocol is eligible for Expedited Review and approval.

An IRB member with relevant expertise will be selected by ORI as the Expedited Reviewer for the protocol. The Expedited Reviewer will review the protocol and provide comments to ORI. ORI will submit the Expedited Reviewer's comments, questions, and/or suggestions for revisions to the PI through eRA. The PI's response will be reviewed by the Expedited Reviewer or ORI, if designated by the reviewer. These communications may continue until the Expedited Reviewer approves the protocol or refers the protocol for review by the Convened IRB.

The Expedited Reviewer(s) may exercise all of the decisional authorities of the IRB, except that Expedited Reviewer(s) *may not disapprove the research protocol*. The Expedited Reviewer(s) may approve, require modifications to secure approval, or refer the research to the Convened IRB for review and approval. If there are concerns about whether or not an individual research project meets the definition of minimal risk or if the project may involve procedures that cannot be reasonably reviewed via the Expedited Review process, the protocol will be submitted for consideration at a Convened IRB meeting.

Conditions of Eligibility for Expedited Review

The Expedited Review process may be employed for new protocols, continuations of previously approved protocols, previously Full Board protocols, or amendments to approved protocols.

To be eligible for approval via the Expedited Review process, a research activity must **always** meet both of the following conditions:

(1) It must present no more than minimal risk to human participants; and
(2) It must involve only procedures listed in one or more of the categories of research activities listed below in Categories of Research Activities Eligible for Expedited Review

In sum, inclusion on the list means only that the activity is eligible for review through the Expedited Review process **when** the specific circumstances of the proposed research involve no more than minimal risk to human participants. If the protocol is eligible for review through the

Expedited Review process but the Expedited Reviewer has additional concerns, the protocol will be submitted to the Convened IRB for review.

The following types of protocols **will not** receive Expedited Review:

(1) Those posing more than minimal risk to the participants;
(2) Classified research involving human participants;
(3) Those involving prisoners;
(4) Those involving mentally compromised individuals, when they are the focus of the research;
(5) Minors (under 18 years of age);
(6) Pregnant women, fetuses, or neonates;
(7) Other protected or potentially vulnerable population; and
(8) Those where the activities of the participants fall outside the categories below.

Categories of Research Activities 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:
    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.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    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 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, electroretinography, 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 paragraph may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104(d)(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.

Procedures for CONVENED COMMITTEE REVIEW

Categories of Research Activities that Require Review by the Convened IRB

1. Protocols that appear to involve more than minimal risk or that otherwise do not meet the criteria for Exemption from IRB review or Expedited Review;
2. All other protocols that are determined by the IRB Chair or an Expedited Reviewer to require Convened Committee Review; and
3. Revisions to initial Full Board protocols that contain non-minor changes.

Review Process

1. ORI will assign a protocol through eRA in advance of an IRB meeting to allow for sufficient time to review. All members are expected to review and familiarize themselves with all protocols before the meeting.
2. The full committee shall review the protocol and submit their comments in eRA the Friday before the convened meeting. ORI will distribute these comments to the PI and advisor, if student, and the IRB Chair via email the Friday before the meeting. The PI will have the opportunity to respond to these comments before the meeting and their comments will be included in the discussion of the research protocol by the Convened IRB. These communications may continue until the time of the IRB meeting.
3. At the start of the IRB meeting, materials relevant to the meeting, including protocol documentation for those protocols that are under review and the minutes from the previous meeting will be made available to each committee member. An agenda, a report on all protocols that were processed since the last IRB meeting, and any other materials for voting and/or discussion will be made available to each committee member prior to the start of the meeting.
4. At the IRB meeting, the PI will respond to the reviewers' comments that were sent to them prior to the meeting and address any concerns raised during the discussion. If the PI is not in attendance, the committee will review the PI's responses, if provided, to the reviewers' comments. All members are expected to discuss the significant concerns outlined by the reviewers, identify additional concerns, provide necessary clarifications,

and/or propose solutions or modifications. The ORI representative will keep minutes of the meeting, including key discussion points and IRB decisions.

Quorum Requirements for Votes on Convened IRB Decisions

A Convened IRB meeting is one at which a quorum is present (or participating via teleconference), which means that a majority (more than half) of the members of the IRB are present, including at least one member whose primary concern is in a non-scientific area. Members attending by telephone- or video-conference count towards the quorum and may vote providing they have received all pertinent material prior to the meeting and they can participate actively and equally in the discussion of the protocols. The minutes should make clear which members, if any, participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.

Approval of research is by a majority vote of the full IRB, minus the ex-officio, who does not vote except to break a tie.

A quorum can fail during a Convened meeting through recusal of members with conflicts of interest, early departures, or the absence of a non-scientist member. In the case of quorum failure, the remaining group may continue discussion of protocols, but may not take further actions unless and until the quorum can be restored.

Procedures for CONTINUING REVIEW

The IRB will conduct Continuing Review of all ongoing research protocols in order to ensure that the protection of human participants is consistent throughout the execution of the research project and that the research protocol is revised, as appropriate, to include new knowledge generated since the last Continuing Review. Continuing Review shall not occur less frequently than once per year, but may occur more frequently depending upon the perceived risk of the research activity and the uniqueness of the specific research protocol.

Neither the collection of prospective research data nor the performance of research-related procedures can occur after the approval date until a Continuing Review form has been reviewed and approved under the Expedited or Convened Committee Review process, as appropriate. Data collected after the previous approval date and before the approval of the continuation shall not be eligible for use in the research protocol.

Continuing Review is required as long as the research project remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing Review is required even when the remaining research activities are limited to analysis of private identifiable information.

Intervals for Continuing Review

Research activities are approved for a finite time period and use of any data after the approval period is considered unapproved research. The IRB will conduct Continuing Review of all ongoing research protocols at intervals relevant to the degree of risk involved, but not less than once per year. The purpose of the Continuing Review is to ensure the continuing protection of human participants in the research and the modification of the research, as appropriate, to reduce risk and incorporate any new knowledge that has been identified since the last Continuing Review. Not less than once per year means that the research must be reviewed and approved on or before the one-year anniversary of the previous IRB review date (i.e. the date of expiration of the approval period), even though the research activity may not have been initiated until sometime after the IRB granted approval. Under most conditions, it is assumed that the approval period will be 364 days from the date of initial IRB approval, unless the IRB determines at the time of initial review and approval that the degree of risk attendant to the protocol requires a shorter approval period. The approval period will be specified in the approval notice given to all PIs and no research can be conducted outside of the time period identified in the approval notice. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may choose to retain the anniversary date as the date by which the continuing review must occur.

Procedure for Submitting a Research Protocol for Continuing Review

Receipt of Reminder Notice
Investigators are responsible for maintaining their IRB approval and for submitting a Continuing Review Form to the IRB, as appropriate. eRA sends automatic renewal notices 60, 30, and 15 days before the protocol expiration date, requesting that they complete and submit a Continuing Review form for IRB review or a Final Report if no research with human participants is expected to continue past the expiration date.

Documents Constituting Protocol Continuation Application
PIs must submit the completed Continuing Review Form to the IRB in sufficient time to allow review and approval of the application before the expiration date. The PI is required to also to submit to the IRB any changes being made to the previously approved protocol and any amended material, if applicable.

Continuation Review Process
Upon receipt of the Continuing Review Form, ORI will verify the completeness of the materials or coordinate with the PI to achieve completion; review the application to determine whether the Expedited or Convened Committee Review process is appropriate; and Initiate the review process for the application.

Consequences of Failure to Submit Research Protocol for Continuing Review
There is no grace period extending the conduct of the research beyond the expiration date of the approval period. Extensions beyond the expiration date are not granted. If the Continuing Review Form is not received as required, and continuation of the research has not been

approved, the PI must terminate the research on the date of expiration unless the safety of the research participants would be compromised. Principal Investigators should consult with the IRB on the process for withdrawing human participants from the research protocol when there is concern about their safety.

No research activity shall continue past the expiration date until the PI has received written notification from ORI that the protocol has been "approved for continuation" by the IRB. Such notification will sent through eRA.

Approved: If the Expedited Reviewer or the Convened IRB approves the continuation application without revisions, ORI will send to the PI a written notification of approval through eRA. If the date of expiration has passed before the date of approval of the continuation application, the PI may re-initiate the research project on the approval date for the continuation of the research protocol.

Specific minor revisions required for approval: The Expedited Reviewer or the Convened IRB may stipulate that approval of the continuation will be granted only after the PI implements specific minor revisions. The required revisions will be communicated to the PI by ORI through eRA and must be completed or otherwise resolved before the revised protocol can be approved. Upon approval of the Continuing Review Form, ORI will send a written notification of approval to the PI and advisor, if student, through eRA. If the date of expiration has passed before the date of approval of the continuation application, the PI may re-initiate the research project on the approval date for the continuation of the research protocol. An Expedited Reviewer may decide that the Convened IRB should review a continuation application. In this event, ORI will assign the Continuing Review to a future IRB meeting agenda.

Tabled: The Expedited Reviewer or the Convened IRB may decide to require substantive clarifications or modifications to the protocol or informed consent documents. In this event, ORI shall draft an email outlining the required changes and send it to the PI, who must respond to the concerns outlined in this email, make appropriate revisions and send them to ORI. ORI will assign the revisions for Expedited Review or, if the revisions relate to the risk/benefit ratio of the research, for discussion by the Convened IRB at a future meeting.

Where Convened Committee Review is required, a protocol may be tabled for lack of appropriate expertise in attendance, lack of time, or loss of quorum.

The IRB may make one of the following decisions for the revised protocol: (1) Approved, (2) Modifications required to secure approval, (3) Tabled, or (4) Disapproved. This cycle continues until the IRB issues a final decision—either approved or disapproved.

Disapproved: The Convened IRB may elect to disapprove a continuation application when it identifies significant concerns about potential risk to participants or a lack of scientific validity to support proposed research activities. On behalf of the IRB, ORI will provide the PI a written

statement of the reasons for the IRB's decision. The PI will have the opportunity to respond in person or in writing. The Convened IRB will review any written responses. If the PI chooses to alter or to replace the research activity in accordance with any IRB recommendations for major revisions to the protocol, the PI may submit an entirely new research protocol application for that revised/replacement research activity.

Procedures for REVIEW of AMENDMENTS

A PI may not implement an amendment to a previously approved research project during the approval period, even if requested by a sponsor, unless and until the IRB reviews and approves it under the Expedited or Full Board review process, except where necessary to eliminate apparent immediate hazards to human participants. An amendment is necessary for all modifications or changes to the research protocol. The IRB will review the amendment in the context of the entire research protocol and will approve the amendment before it is incorporated into the approved research protocol.

Definition of Modifications and Corresponding IRB Review Requirements

There are two types of modifications: minor modifications and non-minor modifications. Minor modifications to previously approved research protocols are those that meet all of the following criteria:

(1) Involve the addition of no more than minimal risk or reduce a risk that was reviewed and approved previously by the Convened IRB; and
(2) Involve the addition of procedures or activities that would be exempt from IRB review or eligible for initial review under the Expedited Review process if they were considered independently of the previously approved research protocol.

Examples of minor modifications include, but are not limited to:

(3) minor increases or decreases in the number of participants;
(4) changes in remuneration;
(5) changes to improve the clarity of statements or to correct typographical errors in informed consent documents or debriefing texts, provided that the changes do not alter the content or intent of the statements; and
(6) additions or deletions of co-investigators or key personnel.

However, if a PI has any question as to whether a change or modification to a previously approved protocol requires IRB review and approval, they should contact ORI for further information.

Minor modifications may be eligible for Expedited Review.

Modifications that do not meet both of these criteria are non-minor modifications, which require IRB review and approval under the Convened Committee process.

Procedure for Submitting an Amendment for IRB Review

Documents to Submit: The PI must submit an amendment request to the IRB in writing by completing the Amendment Request form and submitting it through eRA. The PI should include all amended instruments and consent/assent form/information sheets, etc. These documents will comprise the amendment.

Selection of Expedited or Convened Committee Review
Upon receipt of the amendment request form, ORI will evaluate the amendment and its risk level to determine whether it is appropriate for review under the Expedited or Convened Committee Review process. If there is doubt as to whether an amendment qualifies for Expedited Review, it should be reviewed by the Convened IRB.

Possible IRB Decisions Regarding IRB Amendment

No amendment shall be implemented until the PI has received written notification that the amendment has been approved.

Approved: If the amendment is approved, ORI will provide email notice to the PI and advisor, if student through eRA. Only after receiving the email notice of approval may the PI implement the amendment.

Specific minor revisions required for approval: The Expedited Reviewer(s) or the Convened IRB may stipulate that approval of the amendment will be granted only after the PI makes specific minor revisions to it. ORI will send the PI a notification of the required changes through eRA. If the PI makes the revisions, they shall then re-submit the amendment for review via the Expedited Review process. After all specific minor revisions have been approved, ORI will send an email notice of approval to the PI through eRA. Upon receipt of this notice, the PI may implement the amendment. If, however, the PI suggests or makes revisions that the Expedited Reviewer believes affect the risk-benefit ratio of the amendment or the project as a whole, such revisions will be designated as major and referred for review by the Convened IRB. The PI may request the IRB to review the required specific minor revisions at a Convened meeting. However, the amendment cannot be implemented until all specific minor revisions have been satisfactorily addressed or the Convened IRB has reviewed and approved the amendment.

Tabled: An amendment is tabled when the Expedited Reviewer(s) or the Convened IRB request additional information, substantive clarifications or modifications regarding some aspect of its substance or implementation that is relevant to the evaluation of the risk/benefit ratio required for approval. The IRB may also table an amendment where it does not have a member with expertise adequate to its scope and complexity and thus seeks review by an expert in the appropriate field. The PI may suggest an expert to the IRB for this purpose.

An amendment requiring Convened Committee Review may be tabled for lack of appropriate expertise in attendance, lack of time, loss of quorum, etc. In the event an amendment is tabled for

such administrative reasons, ORI will assign it for review at a future meeting of the Convened IRB.

When an amendment is tabled, ORI shall draft and transmit to the PI an email setting forth the reasons for this action. The PI will to respond to the concerns outlined in the email and make appropriate revisions to the amendment in question and submit the revised amendment through eRA. ORI will assign it for Expedited Review or, if the revisions relate to the risk/benefit ratio of the research, for discussion by the Convened IRB. The IRB may make one of the following decisions with respect to a revised amendment application: (1) Approved, (2) Modifications required to secure approval, (3) Tabled, or (4) Disapproved. This cycle will continue until the IRB issues a final decision—either approved or disapproved.

Disapproved: The Convened IRB may elect to disapprove an amendment when it identifies significant concerns about potential risk to participants or a lack of scientific validity to support the amendment. ORI will draft and transmit to the PI a written statement of the reasons for the IRB's decision. The PI will have the opportunity to respond in person or in writing. The IRB, at a Convened meeting, will review any written responses and make a decision about the appeal of the initial decision to disapprove the amendment. As with all protocols, continuations, and amendments, the PI may not initiate the corresponding amendment until it has been approved by the IRB. The PI always has the right to submit a new amendment that addresses the concerns outlined during the review of the previous version of the amendment.

Revision History

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	11/16/2015
01	Updated criterion for full board review	06/27/2017
02	Revision of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.104(d)(4)
45 CFR 46.108(b)
45 CFR 46.109
45 CFR 46.110
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
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