1. POLICY

All research with human subjects that poses greater than minimal risk to subjects, or poses minimal risk to subjects but does not qualify for expedited review as defined in RR 403 Initial Expedited Review, will be reviewed by the IRB at a convened meeting (i.e. full board review) with a quorum present. Additionally, the following items may lead to a research application being scheduled for full board review:

- Significant changes in the risk/benefit ratio, changes to inclusion/exclusion criteria, or application changes that specifically note full board review;
- Submissions involving protected populations; i.e., prisoners, pregnant women and/or fetuses; and
- Submissions forwarded from expedited review.

Specific Procedures

1.1 Submission

1.1.1 The investigator makes a preliminary decision that her or his application requires full board review. The IRB Chair (or the designee) makes the final decision regarding whether full board review is required.

1.1.2 The investigator submits one (1) completed IRB application form requesting full board review to the IRB Office, which is housed in the Office of University Research Compliance (URC).

1.1.3 Upon receipt of the application form, it is entered into the IRB electronic tracking system and assigned an IRB number by the IRB Coordinator. It is then assigned to the agenda for the next available meeting. The IRB Coordinator notifies the investigator that the application was received and invites the investigator, or her or his designee, to attend the upcoming meeting.

1.2 Pre-Review

1.2.1 The application will be screened for completeness and the protocol review category will be confirmed by the IRB Coordinator or IRB Manager to confirm that it contains all necessary attachments and signatures). If it is incomplete, the application will be returned to the investigator. If omissions are minor, the investigator will be asked to provide the missing information or items.

1.2.2 The application will be screened by the IRB Coordinator or IRB Manager to ensure coordination with other university committee reviews, including the Institutional Biosafety Committee (IBC), the Radiation Safety Committee (RSC), the Institutional Animal Care and Use Committee (IACUC), and the Laser Safety Committee (LSC).
1.2.3 Once the application is complete, the entire document will be scanned into an electronic file by the IRB Coordinator.

1.2.4 The application will be screened by the IRB Manager or the IRB Chair to determine whether additional expertise outside that of the IRB is necessary for the review. If so, the IRB Manager will seek assistance from the investigator, IRB members, OSU faculty (including research deans and department heads) or others to identify consultants who can provide the needed expertise.

1.2.5 The IRB Manager will ensure that a consultant to the IRB does not have a financial conflict of interest, as defined by the University’s Conflict of Interest Policy (4-0130), or secondary interests that could unduly influence the deliberative process.

1.2.6 The IRB Manager or IRB Chair, or his/her designee, will assign a primary reviewer to review the application based on the experience and expertise of the respective IRB members. If no Board member possesses the required expertise, the IRB Manager or IRB Chair will ask a consultant to serve as the primary reviewer.

1.2.7 Approximately 10-14 days prior to each convened meeting, the IRB Coordinator will prepare the electronic file of the application to be sent to the primary reviewer, and consultant(s) when appropriate, while all IRB members will be provided access to the application and other meeting materials via the IRB members’ secure website. The electronic file will include a transmittal email message along with the date of the scheduled meeting, a link to the complete application, and the appropriate IRB Review Sheet(s) to document the reviewers’ approval decision and comments.

1.2.8 The primary reviewer is responsible for performing a complete review of the application in accordance with IRB SOP OR 203. At the convened meeting, the primary reviewer will present his/her findings resulting from review of the application materials and provide an assessment of the soundness and safety of the research application. The primary reviewer recommends specific actions to the IRB and initiates IRB discussion of the proposed research study.

1.2.9 All IRB members review all applications scheduled for full board review in advance of each meeting, including those applications for which the IRB member is not the primary reviewer, in enough depth to be familiar with the application, in order to be prepared to discuss the application at the meeting and determine if the research meets the regulatory criteria for approval.

1.2.10 Consultants to the IRB may provide comments and/or recommendations in writing prior to the meeting, or attend the meeting to participate in the review of an application. Consultants’ written comments are distributed to all IRB members and maintained in the corresponding application file. For consultants attending a convened meeting, her or his comments and/or recommendations are recorded in the meeting’s minutes.

1.3 Review

1.3.1 A quorum of the primary IRB members, or their designated alternates, must be present in order to conduct business at a convened meeting. The quorum must include at least one non-scientific member as defined in IRB SOP OR 203.

1.3.2 When the meeting agenda includes the review of a research application involving a vulnerable population(s), as defined by regulation, or by the subjects’ susceptibility to coercion or undue influence, the IRB manager ensures that appropriate representation is present at the meeting for discussions.

1.3.3 The review of each application is initiated by the primary reviewer who summarizes the application and presents his/her assessment to the Board. The review is guided by the application’s content and the appropriate review guide sheet(s). The level of risk posed to subjects by the proposed research, as delineated in the application, is defined. Board members
and any consultants then have the opportunity to discuss the research and identify any additional concerns. The investigator is invited into the meeting room to discuss the proposed research, respond to Board members’ concerns and questions. After the departure of the investigator, the initial concerns are revisited, any controverted issues and their resolution are discussed and a final list of revisions is agreed upon prior to voting.

1.3.4 A member or consultant with a conflict of interest must recuse himself/herself and leave the room prior to the vote and only participate in the review process by providing general information about the application (e.g., respond to questions).

1.4 Review Outcomes

1.4.1 Once discussion has been closed, an IRB member makes a motion, which must be seconded by another member, and then the convened IRB members vote for or against, or abstain from one of the following actions:

- Approved: The research procedures and associated documents meet the criteria for approval with no further revision.
- Approved with Conditions: The research procedures and associated documents meet the criteria for approval; however, final approval is contingent upon receiving external documentation (i.e., school permissions, other committee approvals, second IRB approval documentation, etc.) and any minor revisions.
- Pending Revision: Minor revisions that do not involve substantive issues must be made before the research can be approved. The investigator must submit the revisions for review in order to secure approval.
- Tabled: The IRB withholds approval pending submission of major revisions to the application and/or additional information. The investigator’s response to the Board’s request for revisions is reviewed at a convened meeting of the IRB with a quorum present.
- Disapproved: Disapproval of an application usually occurs when the IRB determines the risk of the proposed procedures outweighs any benefit expected to result from the research, or if the proposed research does not meet the federal criteria for IRB approval.

Not research involving human subjects: The proposed activity does not meet the federal definition of research involving human subjects per 45 CFR 46.

1.4.2 The approval period for the application is determined at the time of approval at the convened meeting. The approval period will be appropriate to the degree of risk, but no longer than one year. The following factors are considered when determining the criteria for which applications require review more frequently than once per year and what the review frequency will be:

- probability and magnitude of anticipated risks to subjects;
- overall qualifications of the investigator and other members of the research team;
- specific experience of the investigator and other members of the research team in conducting similar research;
• nature and frequency of unanticipated problems or adverse events observed in similar research;

• inclusion of vulnerable populations; and

• any other factors the IRB deems relevant.

When the IRB conducts the initial review of an application at a convened meeting and approves the research without requiring changes to the application or the consent document(s), or without requesting that the investigator submit clarifications or additional documents, the effective date of the initial approval is the date of the IRB meeting at which approval is granted. In such circumstances, the expiration date of the initial approval period and the date by which the first continuing review must occur may be as late as one year after the date of the IRB meeting at which the application was initially approved (45 CFR 46.109(e)). Thus, the start of the approval period (i.e. the approval date) is the date of the convened IRB meeting at which approval is granted.

When an application is approved, the IRB Coordinator or IRB Manager will generate the approval letter for the IRB Chair’s signature and attach all recruiting, consent and debriefing documents with the IRB approval stamp affixed with the valid dates of IRB approval and the date IRB approval expires. The expiration date will be 365 days from the date of approval unless a shorter time frame is deemed appropriate by the reviewer(s) or the IRB.

The IRB Coordinator or IRB Manager will generate the approval letter using the IRB electronic tracking system. The IRB Coordinator or IRB Manager will send the signed approval letter to the investigator.

If an application is placed in pending revision status or is approved with conditions, the approval date is the date the IRB Chair (or any other member(s) designated by the IRB) reviews and accepts as satisfactory the revised application, and/or consent documents, and/or any other materials required by the IRB from the investigator. If the application is tabled, the approval date will be the date of the subsequent convened meeting at which approval is granted or when conditions for approval have been satisfactorily met, if approval is not granted at the subsequent IRB meeting.

1.4.3 The IRB Coordinator will document the approval status and any suggested revisions in the IRB electronic tracking system. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting at which it was reviewed.

1.4.4. When an application is approved by the IRB, the IRB Coordinator or IRB Manager will generate the approval letter for the IRB Chair’s signature and attach all recruiting, consent, and debriefing documents with the IRB approval stamp affixed, with the valid date of IRB approval and the date IRB approval expires. The expiration date will be 365 days from the date of approval unless a shorter time frame is deemed appropriate by the IRB. The IRB Coordinator or IRB Manager will generate the approval letter using the IRB electronic tracking system. The IRB Coordinator or IRB Manager will send the signed approval letter to the investigator.

1.4.5 When an application is approved with conditions by the IRB, the IRB Manager will generate an approved with conditions letter to be sent to the investigator stipulating the documents that are needed prior to final approval and/or any minor revisions that are needed. Upon receipt of the requested documentation and/or satisfactory revisions, an approval letter will be issued as described in 1.4.4.

1.4.6 When an application is placed in pending revision status, the IRB Coordinator will generate an email message to the investigator transmitting the revisions requested by the IRB. A summary of the IRB’s comments is generated by the IRB Manager or IRB Coordinator and emailed to each of the members who were present at the meeting at which the application was reviewed. The investigator is responsible for submitting any requested revisions to the IRB. The
IRB Chair may review and approve the revisions received under the pending revision status. The Chair may forward the response to the entire IRB for additional review or to a designated member(s), request additional information, or approve the revised application.

1.4.7 If the investigator’s response to the pending revision status is approved, the IRB Coordinator documents that the application has been approved in the IRB electronic tracking system and generates an approval letter that is sent to the investigator as described in 1.4.4.

1.4.8 When an application is tabled, the IRB Coordinator will generate a letter to the investigator transmitting the major revisions and/or the need for additional information, as requested by the IRB. The letter will stipulate if the investigator will need to attend the convened meeting at which her or his revisions will be reviewed. A summary of the IRB’s comments is generated by the IRB Manager or IRB Coordinator and sent to each of the members who were present at the meeting in which the application was reviewed.

1.4.9 When an application is disapproved, the IRB Coordinator or IRB Manager will generate a letter describing the reasons the IRB chose not to approve the application.

1.4.10 When the activity proposed in an application does not qualify as research involving human subjects, the IRB Coordinator or IRB Manager will generate a letter informing the investigator that IRB approval is not necessary.

1.4.11 If the investigator has concerns regarding the IRB’s decision/recommendations for changes in the research in order to secure approval, he/she may submit his/her concerns to the IRB Chair in writing that includes her or his justification for why the IRB decision should be reversed. The Board will consider the written justification and agree on a final resolution at a convened meeting.

1.4.12 A report of all applications that were approved via expedited review procedures since the previously convened meeting of the IRB are posted to the IRB members’ secure website prior to the next convened meeting of the IRB. The report also contains lists of applications approved under exempt status review and continuing review procedures, as well as those applications for which modifications were approved since the previously convened meeting of the IRB.

1.4.13 The Institutional Official (IO) is informed of IRB actions via the URC communications portal. When new information (i.e. meeting agendas and approved minutes) is available via the URC communications portal, the IO receives an email message from the IRB Manager, or his/her designee. Agendas for upcoming meetings are posted to the portal several days prior to each meeting. Minutes are posted to the portal shortly after they are approved by the IRB. By providing this information to the IO, the IRB satisfies its obligation to inform the institution of its actions.

2. SCOPE
This standard operating procedure applies to all research submitted to the IRB that qualifies for full board review.

3. RESPONSIBILITY
The investigator is responsible for submitting the IRB application and the appropriate supporting documents for full board review and for responding to any revisions requested by the IRB in a timely manner.
The IRB Coordinator is responsible for receiving applications requesting full board review, verifying completeness, determining the need for other committee review; entering the application into the IRB electronic tracking system; preparing and sending the review package to the Board member serving as the primary reviewer; making review materials available to all members via the IRB members’ secure website; tracking the review process and any revisions in the IRB electronic tracking system; sending the appropriate correspondence to the investigator and to Board members; and generating approval letters.

The IRB Manager or IRB Coordinator is responsible for providing a summary of the IRB’s comments and or recommendations to the Board members who attended the meeting at which an application was reviewed.

The IRB Manager is responsible for assisting in screening full board applications for completeness and determining the need for other committee review. The IRB Manager assists the IRB Chair in determining if additional expertise is needed for review and identifying potential consultants. The IRB Manager assists the IRB Chair in assigning a primary reviewer and in reviewing and approving investigator responses to revision requests.

The IRB Chair is responsible for oversight of the full board review process and provides advice and assistance as needed to other involved parties. The Chair evaluates the expertise needed for review of the application and directs the assignment of a primary reviewer or the identification of a consultant to provide the needed expertise. The Chair or her or his designee reviews and may approve all minor revisions received from the investigator in response to pending revision status. The IRB Chair or Manager receives all written concerns from investigators regarding IRB decisions and/or recommendations and coordinates meetings to assist in the resolution of the investigator’s concerns.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subparts B
45 CFR 46 Subparts C
45 CFR 46 SUBPARTS D

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

. ATTACHMENTS

None

. IMPLEMENTATION OF PROCEDURES

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<th>Task</th>
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<th><strong>IRB Coordinator</strong></th>
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<td>Receive submissions, review for sufficient information/need for other committee review, complete IRB electronic tracking system data entry, confirm that investigator has completed required training, prepare and send review packages, prepare and send appropriate correspondence. Prepare summary of all IRB review comments and send to each Board member who attended the meeting at which the application was reviewed. Following review, generate correspondence notifying investigator of application approval status (approved, approved with conditions, pending revision, tabled or disapproved). Document in the IRB electronic tracking system. If the application was placed in pending or approved with conditions status, upon approval of revisions, or receipt of requested documentation/information, update approval status in the IRB electronic tracking system and generate correspondence notifying investigator.</td>
<td>Assist with application screening. Assist the Chair with review expertise determinations, assignment of primary reviewer and identification of consultants as needed. Prepare summary of all IRB review comments and send to each Board member. Assist the Chair with reviewing revisions. Review and approve revisions. Receive and review written concerns from investigator regarding IRB decisions or recommendations. Coordinate meetings for resolution of investigator concerns.</td>
<td>Determine review expertise needed, assign primary reviewers, coordinate identification of consultants as needed. Review and approve revisions. Receive and review written concerns from investigators regarding IRB decisions or recommendations. Coordinate meetings for resolution of investigator concerns.</td>
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