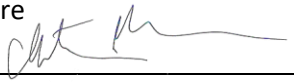
OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #303.7 Revision 7	**TITLE: Initial Full Review**	Effective Date: 5/8/2022
Approved By: OIRB Director	Signature 	Date 5/8/2022
Approved By: IRB Chair	Signature 	Date 5/8/2022

PURPOSE
To define policies and procedures for initial review by a fully convened IRB.

REVISIONS FROM PREVIOUS VERSION
Update references to electronic research administration (ERA) system

POLICY
The IRB conducts initial review for research that is greater than minimal risk at convened meetings regardless of funding source. See the procedures and requirements for conducting a convened meeting and the definition of *quorum* in the IRB Meeting Conduct SOP. The IRB only approves research that meets the federal criteria for approval as specified in 45 CFR 46.111 and/or 21 CFR 56.111. During initial full review, the IRB reviews the informed consent process and documentation as specified in SOP 501 Informed Consent.

RESPONSIBILITIES
Execution of SOP: IRB Chairs, IRB Members, Principal Investigator (PI)/Project Team, OIRB Staff.

PROCEDURE
Submission and Screening

1. The PI submits a complete submission package to the OIRB.
2. OIRB staff conduct intake and pre-review activities according to the Staff Processing of Submissions SOP and make an initial assessment whether the project is greater than minimal risk.
3. If the project is greater than minimal risk and/or if federally funded and does not meet exempt or expedited review criteria, it is scheduled on the agenda for the next available meeting. The IRB usually meets once per month. OIRB staff schedule protocols for review on a "first-come, first-serve" basis, limiting number of reviews as appropriate in order to permit adequate time for discussion and deliberation of agenda items.
4. OIRB staff screen the protocol to determine whether additional expertise is necessary to conduct the review. OIRB staff assign a primary reviewer based on the IRB member's background and expertise as necessary. If no IRB member has the appropriate expertise, OIRB staff may ask a consultant to serve as primary reviewer.
5. Consultant reviews are conducted as described in SOP 103 IRB Meeting Conduct and SOP 204 Use of Outside Expertise-Consultants.
6. OIRB staff screen all initial submissions to determine whether a protocol falls under regulations of the Health Insurance and Portability and Accountability Act (HIPAA) Privacy Rule and/or the Family Educational Rights to Privacy Act (FERPA). OIRB staff may consult with the OIRB Director on any protocol regulated by the Privacy Rule and/or by FERPA, who provides recommendations for each

protocol to ensure compliance with the Privacy Rule and/or with FERPA and forwards them to the IRB. See the HIPAA in Research SOP for additional information regarding HIPAA review procedures.

7. If the researcher indicates that the project involves an investigational device, OIRB staff confirm the validity of the investigational device exemption (IDE) number by ensuring that the researcher has included a copy of the detailed protocol from the sponsor (containing the number) and/or verification statement from the sponsor or the Food and Drug Administration (FDA). If the device does not have an IDE, OIRB staff verify that the PI submitted a Device Form that describes how the device meets IDE Exemption requirements or includes a justification for a nonsignificant risk (NSR) determination.
8. OIRB staff confirm that any applicable Institutional Biosafety and Conflict of Interest Committee approvals are in place. If applicable approvals are not in place, OIRB staff notify the researcher in writing, requesting the appropriate information. When the researcher submits the information, OIRB staff may then put the project on an agenda for review by the IRB.
9. OIRB staff also ensure that all listed researchers have completed the required training. If the researchers have not completed training, OIRB staff notify the PI in writing. The researcher must send the appropriate certifications of training before the IRB can issue approval or remove the individuals from the project team.

Assignment of Reviews to the IRB

1. Approximately seven days prior to each convened meeting, OIRB staff provide the meeting agenda and all review materials to voting IRB members. The documentation provided to IRB members includes all applicable sections of the application.
   - Research protocol;
   - Consent/assent process and forms including waiver requests;
   - HIPAA forms, including waiver requests;
   - COI Management plans, if applicable;
   - Device risk determination, if applicable;
   - Other committee reviews or final approval materials;
   - Additional documents, including recruitment materials, proposed data instruments (e.g. surveys, interview questions, etc.), materials/letters of support for off-site research.
2. All IRB members review all information in the agenda packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.
3. Consultants may provide comments or recommendations in writing to the IRB prior to the meeting or may be asked to attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports in the project file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant. (See IRB Meeting Minutes SOP.)

IRB Review

1. All IRB members attending the meeting receive materials listed in the *Assignment of Reviews to the IRB* section above, prior to the convened meeting, have the opportunity to discuss each research protocol during the convened meeting, and participate in the determination of whether the research meets the regulatory criteria for approval. IRB review occurs as detailed in the IRB Meeting Conduct SOP.

2. When the IRB reviews research that involves categories of individuals vulnerable to coercion or undue influence, OIRB staff ensure that adequate representation or consultation is present for discussions of the project. (See Protection of Vulnerable Participants SOP and IRB Membership SOP.)
3. When conducting the review of the proposed research, the IRB utilizes the appropriate Reviewer Checklists.
4. A member or consultant with a COI must leave the room during the vote and only participate in the review by providing information in accordance with the IRB Member and Consultant Conflict of Interest SOP.
5. During the convened meeting, the IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year (unless the IRB determines that the research is minimal risk and meets exempt or expedited review criteria, if federally funded). The IRB may set a shorter approval period for high-risk protocols or protocols with high risk/low potential benefit ratios.
6. For research involving an investigational device, the IRB determines what action(s) is needed (device meets IDE exemption criteria, device meets criteria for abbreviated requirements at 21 CFR 812.2(b)) or the PI needs to obtain an IDE from the FDA). The IRB reviews relevant information including, but not limited to, a description of the device, the proposed investigational plan and participant selection criteria. The IRB will also confirm the process described in the Device Form to ensure investigational devices are used only in approved research protocols and under the direction of approved researchers. If the IRB determines the device meets IDE exemption criteria or if the device does not meet the definition of significant risk (also called NSR), the project may be approved using criteria at 21 CFR 56.111. The determination is documented in the IRB meeting minutes.
7. When a protocol receives final approval, the OIRB considers the start of the approval period as the date of the convened IRB meeting. If a protocol is approved with conditions (see IRB Meeting Conduct SOP) and the PI completes the modifications, the approval period starts from the meeting date of the convened IRB on which the IRB initially reviewed the protocol. Should the project be deferred (tabled) requiring the convened IRB to complete its review and issue approval at a subsequent meeting, the approval period starts with the date of the subsequent convened IRB meeting.
8. If the research involves prisoners, OIRB staff check to determine whether the PI submitted the protocol for funding to any DHHS agency. If the project is federally funded and the protocol involves prisoners, OIRB staff prepares and submits a prisoner certification report to the Office for Human Research Protection (OHRP) in accordance with OHRP requirements and the Mandated Reporting to External Agencies SOP. The IRB will not issue a final approval letter under the OIRB has received final prisoner certification from OHRP.
9. Once the IRB approves a protocol, OIRB staff send an approval letter to the PI, which includes the approval period, a reminder to use only the approved consent/assent form, and a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.
10. If the PI has concerns regarding the IRB decision/recommendations for changes in the project, they may submit them to the IRB for consideration via a written document that includes a justification for changing the IRB decision.

REFERENCES

21 CFR 50.25
21 CFR 56.111
21 CFR 312

21 CFR 812
45 CFR 46.108
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subparts B, C, D