# Standard Operating Procedures

<table>
<thead>
<tr>
<th>SOP #303.3 Revision 3</th>
<th>TITLE: Initial Full Review</th>
<th>Effective Date: 7/7/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 8/31/2016</td>
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<tr>
<td>Approved By: IRB Chair</td>
<td>Signature</td>
<td>Date 9/1/16</td>
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</tbody>
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## PURPOSE
To define policies and procedures for initial review by a fully convened IRB.

## REVISIONS FROM PREVIOUS VERSION
Addition of IRB review of process to control use of investigational devices and clarification regarding OHRP prisoner certification process.

## POLICY
The IRB conducts initial review for non-exempt research at convened meetings unless the research is eligible for expedited initial review. (See Exempt and Expedited Initial Review SOPs.) See the procedures for conducting a convened meeting, the definition of quorum, and the requirements for conducting a full review meeting 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 21 CFR 56.111, and. Also, during initial full review the IRB reviews the informed consent process and documentation as specified in the Informed Consent SOP.

## RESPONSIBILITIES
Execution of SOP: IRB Chairs, IRB Members, Principal Investigator (PI)/Study Personnel, OIRB Staff.

## PROCEDURE

**Submission and Screening**

1. The PI or designee completes a submission package through IRBNet and submits it to the OIRB for initial review.
2. If the protocol 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.
3. OIRB staff conduct intake and pre-review activities according to the Staff Intake and Pre-Review of Submissions SOP.
4. OIRB staff screen the protocol to determine whether additional expertise is necessary to conduct the review. If so, OIRB staff may ask an ad hoc or cultural consultant who has appropriate expertise in the discipline or with non-English speaking populations or locations to participate in the review. The OIRB maintains a list of potential cultural consultants qualified by cultural and/or linguistic knowledge or training to assist the IRB, as appropriate, and may contact IRB members, UNM faculty, or department chairs for advice in identifying consultants.
5. The PI may also recommend cultural consultants provided that they are not directly involved in the study. These consultants may review consent forms, provide verifications of translations, and provide guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted.

6. OIRB staff ensure that ad hoc or cultural consultants do not have a conflict of interest in accordance with the IRB Member and Consultant Conflict of Interest SOP.

7. OIRB staff send the ad hoc or cultural consultants the same information as voting IRB members and a detailed protocol/grant application, if applicable.

8. OIRB staff assign a primary reviewer based on the IRB member’s educational background and expertise as necessary. If no IRB member has the appropriate expertise, OIRB staff may ask an ad hoc or cultural consultant to serve as primary reviewer.

9. OIRB Staff screens 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 forward any protocol regulated by the Privacy Rule and/or by FERPA to the OIRB Director, who writes 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.

10. If the investigator indicates that the research involves an investigational device exemption (IDE), OIRB staff confirm the validity of the IDE number by ensuring that the investigator has included a copy (containing the number) of the detailed protocol from the sponsor and/or verification statement from the sponsor or the Food and Drug Administration (FDA). If the device does not have an IDE, OIRB staff confirm that the Device Form has been submitted that includes a justification for a nonsignificant risk (NSR) determination.

11. OIRB staff confirm that all of the applicable Institutional Biosafety Committee 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 study on an agenda for review by the IRB.

12. 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.

**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 initial full review applications sent to the IRB members include all applicable sections of the application.
   - Project Information Form including research description;
   - Study protocol including Department of Health and Human Services (DHHS) approved protocol (e.g. NIH cooperative group trial), if applicable;
   - Consent/assent process and forms including waiver requests, any DHHS approved sample informed consent document, and translated consent document for non-English speaking subjects;
   - HIPAA forms;
   - Conflict of Interest Management plan;
   - Sponsor's grant application;
• Contract or device proposal;
• Device risk determination, if applicable;
• Other committee review or final approval materials;
• Additional materials, including advertisements, 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. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports in the study 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.

2. IRB review occurs as detailed in the IRB Meeting Conduct SOP.

3. When the IRB reviews research that involves categories of human subjects vulnerable to coercion or undue influence, OIRB staff ensure that adequate representation or consultation is present for discussions of research involving vulnerable human subjects. (See Protection of Vulnerable Subjects SOP and IRB Membership SOP.)

4. In conducting the initial review of the proposed research, the IRB utilizes the appropriate Reviewer Checklists.

5. A member or consultant with a conflict of interest 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.

6. 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. The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratios.

7. For research involving a device where the PI or the sponsor has not obtained an IDE, the committee determines what action(s) is needed (whether the PI needs to obtain an IDE or whether the device meets criteria for abbreviated requirements at 21 CFR 812.2(b). The IRB reviews relevant information including, but not limited to, a description of the device, the proposed investigational plan and subject 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 study is NSR, the study may be approved using criteria at 21 CFR 56.111. The determination will be documented in the IRB meeting minutes.

8. When a protocol receives final approval, the OIRB assigns 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 study be deferred (tabled) requiring the convened IRB to complete its review and issue approval of the study at a subsequent meeting, the approval period starts with the date of the subsequent convened IRB meeting.

9. If the research involves prisoners, OIRB staff check to determine whether the PI submitted the protocol for funding to any DHHS agency. If this is the case and the protocol involves prisoners, the OIRB Director 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.

10. 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.

11. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit them to the IRB via a written document that includes a justification for changing the IRB decision. The IRB reviews the request using the standard procedures.

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