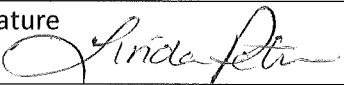





UNM

Office of the Institutional Review Board

Standard Operating Procedures		
<b>SOP #108.4 Revision 4</b>	<b>TITLE: IRB Member and Staff Training</b>	Effective Date: 11/30/2016
Approved By: OIRB Director	Signature 	Date 12/1/2016
Approved By: IRB Chair	Signature 	Date 12/13/16

**PURPOSE**

To describe the institution's programs for ensuring that all IRB members and OIRB staff are appropriately educated about the regulatory requirements and ethical considerations for the protection of human subjects involved in research.

**REVISIONS FROM PREVIOUS VERSION**

Clarify CITI training requirements for IRB community members

**POLICY**

The foundation for the effective implementation of all facets of the UNM human research protection program (HRPP) and for efforts to promote compliance with HRPP requirements lies in a comprehensive, mandatory education program for all applicable personnel, including IRB members and OIRB staff. UNM has a multifaceted human subjects' protection education program which is designed to provide essential training on ethics and regulations of research and local IRB policies/procedures as explained below.

**RESPONSIBILITIES**

Execution of SOP: OIRB Staff, IRB

**PROCEDURE**

*Initial Education for IRB Members*

Following appointment to membership on the IRB and prior to serving as reviewers, IRB members and alternate members receive the following training.

1. The OIRB requires each new member attend an in-person orientation session, which includes training on use of the IRBNet database.
2. Prior to acting as primary reviewers at fully convened IRB meetings, new members complete a "shadow review" of a new study along with the two primary reviewers. The OIRB Director reviews the shadow review and provides feedback and guidance to the member. Once a member demonstrates functional knowledge of federal human research regulations and institutional policies, they are signed off to serve as a primary reviewer.
3. Once an IRB member has completed three months of service, they may be selected to be an expedited reviewer. Designated OIRB staff conduct an Expedited Reviewer training to educate first-



- time reviewers on expedited and exempt applicability criteria and categories, criteria for IRB approval, and general responsibilities as an expedited reviewer.
4. The University requires all IRB members to be trained in the protection of human subjects. Members meet this requirement by:
    - Successful completion of the Public Responsibility in Medicine and Research (PRIM&R) Ethical Research Oversight Course (E-ROC) AND
    - Successful completion of the Collaborative Institutional Training Initiative (CITI) UNM Main Campus Researchers on-line training for IRB Members. Community members may substitute CITI IRB member training completed at another institution if they serve on multiple IRBs.
  5. In addition to the above training, members receive the following educational materials:
    - OIRB website, which includes OIRB/IRB SOPs, UNM IRB guidance, policy, and educational materials, and IRB forms
    - Institutional Review Board Member Handbook (Amdur & Bankert)
    - Trainings and educational opportunities as described in the HRPP Training and Education Program.

#### *Continuing Education of IRB Members*

OIRB staff offer the following continuing education opportunities to current members of the IRB.

1. Ongoing Protocol Specific Training: OIRB staff disseminate materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e. brain stimulation) or selected vulnerable subject populations (i.e. prisoners) to each IRB member, as needed. OIRB staff refer IRB reviewers to pertinent materials. Resource materials come from a variety of sources, including but not limited to: Office for Human Research Protections (OHRP) Guidance; handout materials prepared by the OIRB; journal articles.
2. IRB Member E-mail Lists: The OIRB maintains e-mail distribution lists which are used on an ongoing basis to send IRB members a variety of materials such as copies of pertinent articles, regulatory updates, web references to resource materials or government reports, or communication about a specific protocol review.
3. Presentations: As appropriate, the OIRB presents training on selected topics at IRB meetings or IRB in-service programs. OIRB may invite a specialist in a specific area to address the IRB as needed. OIRB subscribes to and makes available, applicable webinar presentations.
4. Dissemination of Articles or Educational Materials Collected at Professional Meetings or from Scientific Literature: Periodically, OIRB staff include copies of these materials in the IRB agenda packet. Also, the OIRB sends correspondence to the IRB members periodically informing them that the materials are available upon request.
5. OIRB subscribes to and distributes to IRB members a variety of publications.
6. Every three (3) years, IRB members must become re-certified in human subjects' protection training. The CITI on-line human subjects' protection training program offers a continuing education program which satisfies this requirement.
7. As available, UNM provides funds for an IRB Chair or other member to attend one national educational conference per year.
8. Unfulfilled training requirements may result in termination of membership on the IRB.

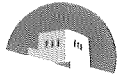


### *Initial Education for New OIRB Staff*

1. New OIRB staff members receive the OIRB Staff Orientation Checklist as a baseline orientation guide. New staff members check each section upon completion and provide a copy of the completed checklist to the OIRB Director.
2. New OIRB staff members receive the following educational materials or website links:
  - [45 CFR 46](#): Protection of Human Subjects (OHRP);
  - [21 CFR 56](#): Institutional Review Boards (FDA); [21 CFR 50](#): Protection of Human Subjects
  - [UNM OIRB Website](#);
  - UNM IRB Member Orientation training;
  - Institutional Review Board Member Handbook (Amdur & Bankert).
3. The OIRB Director establishes and implements a training plan for each new OIRB staff member, which includes direct hands-on training by designated experienced staff members.
4. New OIRB staff are provided with the OIRB COP (Common Office Practices) Manual. The manual includes general information and task specific step-by-step instructions, flow charts, and checklists which allow the new staff member to double check his/her work. The manual is also used by experienced staff when conducting direct hands-on training.
5. Other internal training documents that may be disseminated to new staff as needed.
6. New OIRB staff members review existing OIRB/IRB standard operating procedures (SOPs).
7. UNM requires that all OIRB staff be trained in the protection of human subjects. OIRB staff meet this requirement by:
  - Successful completion of the [Collaborative Institutional Training Initiative \(CITI\) on-line HSP training program](#), and
  - Successful completion of the Public responsibility in Medicine and Research (PRIM&R) Ethical Research Oversight Course (E-ROC).
8. New OIRB staff are assigned a mentor who is an experienced staff member who guides the new staff in his/her pre-review and processing of submissions, understanding of IRB policies and procedures, and federal, state, and University regulations.

### *Continuing Education of OIRB Staff*

1. The OIRB Director holds staff meetings weekly. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an ongoing basis at these meetings. The OIRB Director or other designated staff periodically provides training on selected topics. Also, experts in specific areas may provide specialized training on specific topics (e.g. CBPR) at staff meetings. Periodically, OIRB staff members give presentations on selected issues/topics/conferences at staff meetings.
2. The OIRB encourages and periodically requires its staff members to attend University, city, state, national, or regional IRB teleconferences, workshops, lectures or webinars.
3. OIRB staff receive all of the materials distributed to IRB members. Also, staff receive copies of selected compliance information/material distributed by the OIRB Director (e.g. OHRP publications such as the Engagement Memo, copies of innovative materials used by other IRBs/institutions,



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OHRP correspondence, training materials developed by external groups, PRIM&R Board educational e-mails).

5. The OIRB subscribes to and makes available to staff various newsletters and publications (e.g. Hastings Center's IRB Newsletter, Department of Health and Human Services ORI Newsletter).
6. If during the year designated OIRB staff revise SOPs or add information to an SOP, and the SOP is subsequently approved/signed by the Director of OIRB and IRB Chair. OIRB staff are notified upon implementation of the approved/signed revised SOP. For additional details, see the Standard Operating Procedure Management SOP. Also, internal training documents are re-disseminated to OIRB staff as deemed necessary to ensure procedural consistency.
7. Every three (3) years, OIRB staff must become re-certified in human subjects' protection training. The CITI Web-based human subjects' protection training program offers a continuing education program to satisfy this requirement.
8. Additional training and education opportunities as described in the HRPP Training and Education Program.
9. Unfulfilled training requirements may result in employee disciplinary action, up to and including termination.

#### **REFERENCES**

45 CFR 46.107

45 CFR 46.304

21 CFR 56.107