

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training		Page 1 of 6
Approved By: ORI Director	Signature	Date	Date First Effective: 06-30-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 05-29-09

OBJECTIVE

To describe the institution's programs for ensuring that all Institutional Review Board (IRB) members and Office of Research Integrity (ORI) staff are appropriately educated about the regulatory requirements and ethical considerations for the protection of human subjects involved in research

GENERAL DESCRIPTION

The foundation for the effective implementation of all facets of the University of Kentucky (UK) 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 research support staff in the ORI. UK 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.

RESPONSIBILITY

Execution of SOP: IRB members and Office of Research Integrity (ORI) staff.

PROCEDURES

Initial Education for IRB Members

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

1. ORI staff provide new IRB members an on-line training module titled "University of Kentucky IRB Member Orientation".
2. The ORI also offers an orientation session for each new member.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training	Page 2 of 6

3. ORI staff assign new IRB members a mentor who is an experienced IRB member who guides the new member in his/her reviews of protocols, IRB policies and procedures, and federal, state, and University regulations.
4. Upon initiation of an IRB member's assigned month as expedited reviewer for new proposals, designated ORI staff make available a one-on-one orientation to educate first-time reviewers on expedited applicability criteria and categories, criteria for IRB approval, and general responsibilities as an expedited reviewer.
5. Upon initiation of an IRB member serving for the first time as reviewer of protocols undergoing expedited continuation review, designated ORI staff make available a one-on-one orientation to educate him/her on the criteria for IRB approval, applying the expedited applicability criteria, and general responsibilities as an expedited continuation reviewer.
6. Upon initiation of an IRB member's assigned month as exemption reviewer, designated ORI staff make available a one-on-one orientation to educate first-time reviewers on applying the exempt categories, and general responsibilities as an exemption reviewer.
7. The University requires all IRB members to be trained in the protection of human subjects. Members may meet this requirement by one of two means:
 - Successful completion of the Collaborative IRB Training Initiative (CITI) on-line human subjects' protection training program; or
 - Successful completion of Dunn & Chadwick's *Protecting Study Volunteers in Research* training book and on-line assessment and certification.
8. In addition to the above training, members receive the following educational materials per website links:
 - University of Kentucky IRB Survival Handbook, which includes ORI/IRB SOPs, UK IRB guidance, policy, and educational materials, and IRB forms. The IRB Survival Handbook also includes the Protocol Specific Training (PST) materials. (See Item 1 in the Continuing Education section below.);
 - University of Kentucky IRB Resource Guide compiled by ORI staff and including sections on Ethics of Human Subjects Research, Basic IRB Regulations, Selected Auxiliary Regulations/Policy, IRB Review Mechanisms, Educational Materials and other useful references;
 - ORI website and contact information.

Continuing Education of IRB Members

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

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training	Page 3 of 6

1. On-going Protocol Specific Training: ORI staff disseminate materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e., gene therapy or tissue banking) or selected vulnerable subject populations (i.e., prisoners) to each IRB member. In the agenda or expedited review packet, ORI staff refer IRB reviewers to pertinent PST materials (e.g., if a research project involves children, ORI staff refer the reviewers to the PST materials on children). Resource materials come from a variety of sources, including but not limited to: *OPRR Guidebook, 1993; OPRR Reports; FDA Information Sheets*; handout materials prepared by ORI; journal articles.
2. Exempt/Expedited: IRB members serving as expedited reviewer or exempt reviewer receive specific guidance documents for the type of review upon initiation of his/her assigned month.
3. IRB Members E-mail Lists: The ORI maintains e-mail mailing lists which are used on an on-going 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. The few IRB members who do not have e-mail receive paper copies of this material.
4. Presentations: Upon request or as appropriate, the ORI presents training on selected topics or invites a specialist in a specific area to address the IRB.
5. Dissemination of Articles or Educational Materials Collected at Professional Meetings or from Scientific Literature: Periodically, ORI staff include copies of these materials in the IRB agenda packet. Also, the ORI sends correspondence to the IRB members periodically informing them that the materials are available upon request.
6. ORI subscribes to and distributes to IRB members a variety of publications.
7. ORI staff review, update, and distribute information in the IRB Survival Handbook and Resource Guide, as necessary.
8. 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. Other options are also available.
9. UK provides funds to send the Medical IRB Chair and the Nonmedical IRB Chair to attend one national IRB meeting per year.
10. Usually once a year, ORI co-sponsors a regional IRB conference. UK pays for IRB members' registrations.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training	Page 4 of 6

Initial Education for New ORI Staff

1. New ORI staff members receive the ORI 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 Research Education Specialist as documentation.
2. New ORI staff members receive the following educational materials or website links:
 - 45CFR46: Protection of Human Subjects (OHRP);
 - 21CFR50: Protection of Human Subjects (FDA);
 - 21CFR56: Institutional Review Boards (FDA);
 - FDA Information Sheets;
 - UK ORI website and Veterans Affairs (VA) Research website;
 - UK IRB Member Orientation Online Module;
 - IRB Survival Handbook (includes SOPs, guidance documents and educational materials);
 - Protocol Specific Training (PST) materials included in the IRB Survival Handbook;
 - IRB Resource Guide; and
 - HIPAA Educational Module.
3. ORI supervisory staff establish and implement a training plan for each new ORI staff member, which includes direct hands-on training by designated experienced staff members.
4. New ORI staff are also given internal training documents by experienced staff members as the applicable topic/task presents itself. For example, during training entailing compilation of IRB meeting agenda packets and primary reviewer packets, the document entitled “Primary Reviewer and Agenda Packet Checklists” is made available for the new staff member to double check his/her work. Other internal training documents that may be disseminated to new staff include, but are not limited to:
 - ORI New Employee Orientation Manual;
 - AA Responsibilities at IRB Meetings;
 - ORI Medical Full Review Agenda Packet Distribution for Medical Ex-Officio Members & Others;
 - ORI Customer Service Standards;
 - Primary Reviewer (PR) and Office of Research Integrity (ORI) Responsibilities Continuation Review (CR) Screening/Review;
 - Cultural Consultant Process;
 - Coding Sequence for Change in Review Type;
 - Continuation Review Coding Training;
 - Approval of Minor Revisions on a Full Review Protocol;
 - Prisoner Certification Letter Information.
5. New ORI staff members must read all existing ORI/IRB standard operating procedures.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training	Page 5 of 6

6. UK requires that all ORI staff be trained in the protection of human subjects. ORI staff may meet this requirement by one of two means:
 - Successful completion of the Collaborative IRB Training Initiative (CITI) on-line human subjects' protection training program; or
 - Successful completion of the Dunn & Chadwick *Protecting Study Volunteers in Research* training book and on-line assessment and certification.
7. ORI staff complete the on-line Office for Human Research Protections (OHRP) Assurance Module.

Continuing Education of ORI Staff

1. The ORI Director holds staff meetings approximately three times a month and half-day/full-day ORI planning meetings one to two times a year. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an on-going basis at these meetings. The ORI Director or Research Education Specialist periodically provide training on selected topics. Also, experts in specific areas provide specialized training on specific topics (e.g., gene therapy, occupational health safety) at staff meetings. Periodically, ORI staff members give presentations on selected issues/topics/conferences at staff or planning meetings.
2. The ORI encourages and periodically requires its staff members (professional and clerical) to attend University/VA, city, state, national, or regional IRB teleconferences, workshops or lectures.
3. ORI staff receive all of the materials distributed to IRB members. Also, staff receive copies of selected compliance information/material distributed by the ORI Director or senior staff (e.g., OHRP publications such as the Engagement Memo, copies of innovative materials used by other IRBs/institutions, Food and Drug Administration (FDA) and OHRP correspondence, training materials developed by external groups, Public Responsibility in Medicine & Research (PRIM&R) Board educational e-mails).
4. UK Sponsored Program Development distributes the *Federal Register* and *NIH Guide* announcements to ORI staff as appropriate.
5. Examples of educational materials that the ORI subscribes to and circulates to staff are as follows:
 - *Hastings Center's IRB*;
 - *Dennis Maloney's Human Research Report*;
 - *Department of Health and Human Services (DHHS) ORI Newsletter*;
 - *IRB Advisor*;

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-4 Revision #5	TITLE: IRB Members/ORI Staff Training	Page 6 of 6

- *Report on Research Compliance.*
6. If during the year designated ORI staff revise Standard Operating Procedures (SOPs) or add information to an SOP, and the SOP is subsequently approved/signed by the Director of ORI (and when applicable, other individuals, e.g., SOPs for coordination between units), ORI staff are notified by the designated ORI staff upon implementation of the approved/signed revised SOP. For additional details, see the Generation, Use, and Revision of Standard Operating Procedures SOP. Also, internal training documents are re-disseminated to ORI staff as deemed necessary for ensuring procedural consistency.
 7. Every three (3) years, ORI 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. Other options are available.

REFERENCES

Generation, Use, and Revision of Standard Operating Procedures SOP