University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #8	**TITLE: IRB Members/ORI Staff Training**		**Page 1 of 4**
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: 05-09-19

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 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. The ORI provides an orientation session for each new member.

2. ORI staff provide new IRB members with a training binder which includes the "University of Kentucky IRB Member Orientation Module" and access to online training tutorials.

3. The ORI Education staff assign an experienced IRB member to serve as a mentor to inexperienced new IRB members. The mentor guides the new member in his/her reviews of protocols, IRB policies and procedures, and federal, state, and University regulations.

4. Prior to serving as an expedited reviewer, an IRB member must serve on an IRB for three months or attend and observe at least one convened meeting, view at least two online training tutorials on the ORI website, and attend an expedited review session conducted by the ORI Research Education staff or online. Ongoing support from designated ORI staff is available, as needed, to educate reviewers on applying expedited categories, criteria for approval, and general responsibilities as an expedited reviewer.

5. Prior to serving as an exempt reviewer, designated ORI staff make available an orientation to educate first-time reviewers on applying the exempt categories and general responsibilities as an exempt reviewer.

6. The University requires all IRB members to be trained in the protection of human subjects. Members may meet this requirement by successful completion of Collaborative Institutional Training Initiative (CITI) Human Subject Protection (HSP) online training.

7. In addition to the above training, members have access to the following educational materials from the ORI website including the University of Kentucky IRB Survival Handbook, ORI/IRB SOPs, UK IRB guidance, policies, educational materials, and IRB forms.

Continuing Education of IRB Members

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

1. IRB Members E-mail Lists: The ORI maintains e-mail distribution lists which are used on an ongoing basis to send IRB members a variety of materials such as pertinent articles, regulatory updates, web references to resource materials or government reports, or communication about a specific protocol review.

2. Presentations: Upon request or as appropriate, the ORI presents training on selected topics at IRB meetings or IRB in-service programs. ORI invites specialists in a specific area to address the IRB as needed. ORI subscribes to and makes available applicable webinar presentations.

3. Dissemination of Articles or Educational Materials Collected at Professional Meetings or from Scientific Literature: Periodically, ORI staff include copies of these materials with the IRB agenda. Also, the ORI sends correspondence to IRB members periodically informing them that materials are available upon request.

4. ORI subscribes to and distributes a variety of publications to IRB members.

5. ORI staff review and update information in the IRB Survival Handbook, as necessary.

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. Other options are also available (e.g. attendance at the Regional Human Subject Protection Conference, PRIM&R conferences, etc.)

7. As available, UK provides funds for the IRB Chairs to attend one national IRB meeting per year.

8. Once a year, ORI co-sponsors a regional Human Subject Protection Conference. UK pays for IRB members' registrations.

Initial Education for New ORI Staff

1. New ORI staff members receive the ORI Staff Orientation Checklist as a baseline orientation guide.

2. The ORI Research Education Specialist and supervisory staff establish and implement a training plan for each new ORI staff member, which includes hands-on training by designated experienced staff members.

3. Other internal training documents that may be disseminated to new staff include but are not limited to ORI Staff Manual including ORI Customer Service Standards.

4. New ORI staff members review existing ORI/IRB standard operating procedures.

5. UK requires that all ORI staff be trained in the protection of human subjects. ORI staff fulfill this requirement with successful completion of the CITI on-line HSP training program.

Continuing Education of ORI Staff

1. The ORI Director holds staff meetings approximately two (2) times a month. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an ongoing basis at these meetings. The ORI Director or Research Education staff periodically provides training on selected topics. Also, experts in specific areas provide 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 meetings.

2. The ORI encourages and periodically requires its staff members (professional and clerical) to attend University, city, state, national, or regional IRB teleconferences, workshops, lectures or webinars.

3. ORI staff receive all of the educational materials distributed to IRB members. Staff also 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, FDA and OHRP correspondence, training materials developed by external groups, PRIM&R Board educational e-mails).

4. The ORI subscribes to and makes available to staff various newsletters and publications.

5. 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 person 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 disseminated to ORI staff as deemed necessary to ensure procedural consistency.

6. Every three (3) years, ORI staff must become re-certified in human subjects' protection training. The CITI on-line human subjects protection training program offers a continuing education program to satisfy this requirement. Other options are available (e.g. attendance at the Regional Human Subject Protection Conference, PRIM&R conferences, etc.).

REFERENCES

Generation, Use, and Revision of Standard Operating Procedures SOP