The University of Kentucky has a multifaceted human subject protection education program, which is designed to provide essential training to all constituents on ethics and regulation of research and local institutional review board (IRB) policies/procedures. The Office of Research Integrity (ORI) administers, records, and tracks mandatory initial and three-year refresher Human Subject Protection (HSP) training for study personnel, IRB members, and ORI staff. The following describes education offerings, initiatives, and procedures to promote and contribute to the qualifications and expertise of constituents involved in the human research protection program (HRPP).

**IRB Members Training Initiatives**

- **New IRB Member Orientation:** The Office of Research Integrity (ORI) provides new IRB members with a comprehensive orientation and introduction to IRB membership using multiple adult-learning modalities (e.g., group orientation session; web-based course; hard-copy self-study module; and mentor).
  - **Orientation Session:** The ORI Director and/or designated ORI staff provide an individual or small group orientation session and resource binder.
  - **PRIM&R Web-Based Course:** New IRB members are provided with the PRIM&R Ethical Research Oversight Course (E-ROC), online training course addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of human subjects research. Completion of the course qualifies as human subject protection (HSP) training if the individual’s HSP training is not current.
  - **The UK IRB Member Orientation:** This hard-copy self-study course consists of five modules and a quiz designed to describe how the University of Kentucky ORI and IRB operate to meet federal regulatory and institutional requirements. The course details nine basic IRB member responsibilities including conflict of interest, education requirements, and confidentiality.
  - **IRB Mentor:** New IRB members are assigned a mentor (i.e., experienced IRB member) to answer questions and provide advice in terms of the reviews of protocols, IRB policies, procedures, and regulations. ORI Staff and/or the IRB Mentor invite new members to attend meetings before they begin service in order to provide “play by play” commentary on the operation of the meetings.

- **Vice Chair Orientation:** The ORI Director and/or designated ORI staff provide an individual or small group orientation session and resource binder specific to the duties of the Vice Chairs. Specific instruction included continuing review issues, major-minor outcomes, ORI-IRB member role delineation, and dynamics of chairing meetings or other chair coverage duties.

- **Monthly Chair Meetings:** The ORI Director and Education Specialist meet monthly with the Medical IRB Chairs (or designee) to provide ongoing education, updates, and discuss ethical or protocol-specific review issues. The meetings provide an efficient means to provide identical education and encourage consistency among leadership of the three boards. Additional ORI staff members are invited to attend to share topic-specific expertise or reports.

- **Specialty Specific Training:** Additional training is provided as needed for specific or select IRB members (e.g., prisoner reviewer training by Robert Walker, Ph.D.; children’s reviews by visiting expert Bruce Gordon, M.D.; community member training by Belinda Smith, M.S.; NCI CIRB reviewer training by Helene Lake-Bullock, J.D.)
• **Continuing Education Initiatives:** Continuing education is provided to IRB members via **IRB In-Service** programs, (typically conducted on a quarterly basis), brief update presentations at the beginning of scheduled review meetings, and periodic **Webinars** (e.g. AAHRPP, OHRP, and PRIM&R).

• Funds are provided to send members to the **Annual IRB Regional Conference** co-sponsored with Schulman Associates IRB, University of Cincinnati, Cincinnati Children's Hospital and the University of Kentucky.

• Funds are provided as available to send the Medical IRB Chair(s) and Nonmedical IRB Chair to one national level IRB meeting a year. If funding permits, a limited number of IRB members are also sent to one national level IRB meeting.

• Every three (3) years, IRB members complete **human subjects’ protection** (HSP) refresher training. The CITI on-line human subjects’ protection training program offers a continuing education program which satisfies this requirement. Other options are also available.

• The **IRB Membership Website** provides announcements, rosters, meeting dates, training resources and quick links to key resources. Also included is information on the “nuts and bolts’ of serving on an IRB for prospective members.

• The University of Kentucky **IRB Survival Handbook** is provided to IRB members through the ORI website. This electronic web based document contains guidance/policy/educational documents on federal regulations and local institutional policies and procedures; protocol specific training materials; ORI/IRB standard operating procedures (**SOPs**); IRB applications and IRB forms; and IRB reviewer documents. Upon special request, an abbreviated paper copy of the handbook is provided to IRB members.

• On-going **Protocol Specific Training (PST):** When the Office of Research Integrity receives a protocol involving a specialized topic area (such as gene therapy or tissue banking) or selected vulnerable subject populations (e.g., prisoners), the ORI staff in the IRB agenda packet directs the IRB member to the pertinent information included in the Protocol Specific Training sections of the **IRB Survival Handbook**. The educational materials delineate ethical and/or regulatory issues that the IRB should consider in reviewing that specific protocol. The resource materials are selected from a variety of sources including but not limited to: OHRP IRB Guidebook; FDA Information Sheet Guidance: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; handout materials prepared by the Office of Research Integrity; journal articles. The ORI has termed the phrase “PST” (Protocol Specific Training) to refer to this training initiative.

• Since 2006, ORI has maintained the **Recent Changes at the Federal Level Impacting IRBs** table. The table includes the following for select draft and final guidance documents: release/comment date, initiating federal agency, web links, and summary description.

• IRB members are provided with updates in the **Standard Operating Procedures** that affect their activities.

• **UK IRB Review Newsletter:** The internal newsletter is a compilation of ‘need to know’ updates and announcements for UK IRB members, investigators, and others involved in human subject research. The newsletter is distributed to IRB Members via email.
The University of Kentucky IRB Resource Guide is provided to IRB members through the ORI website, CD ROM or paper copy upon request: The IRB Resource Guide consists of key human subject protection documents and references. It has five sections including:

1. Ethics of Human Subject Research;
2. 45CFR46 and 21CFR Parts 50 and 56;
3. Auxiliary Regulations and Policies;
4. IRB Review Mechanism;
5. Educational Material and Useful Resources.

ORI subscribes to and makes available to the IRB members various newsletters and publications (e.g., Hastings Center’s IRB Newsletter, Human Research Report)

IRB Members E-mail Lists: The ORI maintains e-mail distribution lists which are used on an on-going basis to send IRB members a variety of materials such as, announcements, education opportunities, copies of pertinent articles, regulatory updates, web references to resource materials or government reports, or communication about a specific protocol review. Hard copies of this material are available upon request.

Key Administrators, Principal Investigators, Research Staff, and Student Training Initiatives

Mandatory Human Subject Protection (HSP) Training: The University of Kentucky requires all study personnel on projects involving human subjects to complete initial mandatory HSP training available on the Collaborative IRB Training Initiative (CITI) web-based program provided with a biomedical or social/behavioral emphases and available in English and Spanish. The UK Human Subject Protection training mandate dictates that study personnel complete HSP refresher training every three years. The CITI on-line HSP training program offers a continuing education program, which satisfies this requirement. Other training options are also available including attendance at a PRIM&R or UK regional HSP conference, the web-based NIH HSP course, or other approved equivalent training. Study personnel who have completed equivalent HSP training at a separate institution may submit documentation to ORI for consideration in meeting HSP training requirements.

Community Engaged or Community Based HSP Training: As traditional HSP training may not be appropriate for members of the community involved in community engaged participatory research. ORI provides information on national programs available to educate nonscientific/nonprofessional community-based individuals (e.g., CERTification: Community Involvement in Research Training, Research Ethics Training Curriculum for Community Representatives; and Johns Hopkins Field Training Guide). ORI will accommodate alternative means to assess and document completion of training where applicable and approved.

Mandatory FDA Sponsor-Investigator Training: Investigators who also serve in a sponsor capacity for a FDA regulated product (hold an Investigational New Drug (IND), Investigational Device Exemption (IDE) or sponsor a non-significant risk device study) are required to complete a web based course (Drug or Device Development for Sponsor-Investigators) on CITI. The courses detail both investigator and sponsor regulatory requirements and International Conference on Harmonization (ICH) good clinical practice guidelines. In addition, the investigator may request or the IRB may suggest an individual consultation with the IRB chair or designee regarding the FDA regulated protocol.

The University of Kentucky CITI curriculum includes a number of additional trainings available to investigators and research staff including Health Insurance Portability and Accountability
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Act (HIPAA), Responsible Conduct in Research, Good Clinical Practice (GCP), and Humanitarian Use Device (HUD) Course.

- **Navigating the IRB Submission & Review Process:** This introductory seminar designed for students, faculty, or staff provides an overview of the ethical and regulatory framework for protecting human subjects. Guidance on the preparation and submission of an IRB application, accessing resources, and on-going investigator responsibilities is also covered. The session, provided periodically and upon request, is tailored to include issues and examples specific to the requesting research group or university class.

- The **ORI Workshops and Conferences** website provides announcements for upcoming programs and offerings available upon request to the University community such as guest lectures, workshops, and seminars on a variety of topics impacting ethical conduct of research.

- **New Faculty Orientation:** ORI and/or the designated Institutional Official presents at the University orientation for new faculty.

- **University of Kentucky Center on Clinical and Translational Sciences (CCTS)** serves as the resource center for faculty and staff conducting sponsored or investigator initiated translational research. The CCTS **Training, Education, and Mentoring (TEAM)** program offers research staff training programs and career-development degree programs. The ORI participate in the following CCTS training programs:
  - The “**Clinical Research Update Series**” is an accredited series that provides monthly presentations from local and regional experts. Content provides topical information and practical strategies for research coordinators, staff, and investigators. In addition, CCTS host various audio conferences on fiscal and clinical topics important to clinical and translational researchers.
  - “**Clinical Research Coordinator 101 Training Course**” is a multi-session, classroom based training appropriate for entry level positions, those new to the field, or anyone who is interested in learning about clinical trials. Currently conducted as an ORI and CCTS collaborative program, the course consists of 10 modules and encompasses trial conduct with emphasis on compliance with federal regulations and institutional policies, adherence with Good Clinical Practice guidelines, and the ethical conduct of clinical research.

- **Required Research Education:** The ORI required research education website provides research faculty and staff with information and links to various trainings offered or mandated based on protocol-specific needs or sponsor/funding agency requirements.


- **ORI What’s New** webpage page offers some of the most recent news-worthy topics, helpful regulatory tips, and updates to IRB/ORI policy, procedures, and guidelines as well as current and archived **IRB Review Newsletters**.

- **ORI Listserv:** The electronic listserv is sent to all research personnel with an active IRB approved protocol and selective administrators, research staff and/or IRB members (n = 6,300). The listserv is distributed on an “as needed” basis. Listserv announcements prior to June 2008 are available online on the ORI What’s New web page.
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- **UK IRB Review Newsletter**: The internal newsletter is a compilation of ‘need to know’ updates and announcements for UK IRB members, investigators, and others involved in human subject research. The newsletter is sent to research personnel via the ORI listserv and posted on the ORI What’s New webpage.

- The IRB Resource Guide lists several **video, broadcast recording and internet resources** that ORI makes available upon request to investigators, faculty and teachers including:
  - OHRP/OPRR Video Tape series, “Protecting Human Subjects”;
  - OHRP CD ROM, “Investigator 101”
  - Additional Video or Broadcast Recordings and Online Trainings

- The University of Kentucky Proposal Development Office (PDO) publishes a monthly “Grants Bulletin” which is available on the PDO website. UK Research also offers email notification via subscription that alerts subscribers that a new bulletin is available.

**ORI Staff Training Initiatives**

- **New Staff Member Orientation**: The ORI provides new employees with a comprehensive orientation including both regulatory education and hands-on task-specific training.
  - The ORI Director meets with new ORI staff to discuss ORI mission, customer standards, reporting lines, and regulatory framework.
  - New ORI staff complete the PRIM&R Ethical Research Oversight Course (E-ROC) online training, review IRB/ORI Standard Operating Procedures, and complete applicable supplemental training as needed (e.g., HIPAA). Completion of the E-ROC course qualifies as HSP training if the individual has not previously obtained HSP training.
  - Using the ORI Operations Manual as a guide, new ORI staff members circulate through the department to work with various individuals and learn all aspects of IRB administration. The manual provides guidance and instructions on standards, general, and task-specific operations.

- **ORI Continuing Education**: Staff meetings are held approximately twice a month. Periodically, ORI half-day/full-day planning meetings are held. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an on-going basis at staff and planning meetings. ORI Director, Research Education Specialist, and other staff periodically provide training and/or case presentations. Also, subject-area experts are invited to staff meetings to provide specialized staff training (e.g. occupational health and safety, radioactive drug research committee).

- ORI professional staff are provided an opportunity to attend one national/regional professional meeting approximately every other year.

- ORI professional staff attend the Annual IRB Regional Conference co-sponsored by Schulman Associates IRB, the University of Cincinnati, Cincinnati Children’s Hospital, and the University of Kentucky.

- ORI staff (professional and administrative) are encouraged to attend University, city, state or regional IRB teleconferences, webinars, workshops, or lectures presented by the CCTS, ORI Director, local hospitals or other University constituencies.

- All of the written and e-mail information/materials/updates/documents/YouTube/video tapes discussed in the two sections above are provided to ORI staff on an on-going basis. In
addition, staff are encouraged to read IRB Forum discussion group and the OHRP listserv. Also, staff receive copies of selected compliance information/material distributed by the ORI Director or other staff.

- Federal Register and NIH Guide announcements are distributed to ORI staff by Proposal Development Office (PDO) or the ORI Director, as appropriate. ORI maintains a Recent Changes at the Federal Level Impacting IRBs table which includes a listing, links, and summaries of draft and final guidance or regulations of importance to IRBs.

- ORI subscribe to and make available to staff various newsletters and publications (e.g. Hastings Center’s IRB Newsletter, DHHS ORI Newsletter) and webinars (e.g. AAHRPP, PRIM&R, and OHRP).

- New SOPs are circulated to ORI staff and revisions to existing SOPs are communicated as applicable to ORI staff via staff meeting presentation and/or written announcements.

Public and potential research volunteers education & outreach

- ORI Research Participants website provides information regarding participation in research in English and Spanish, clinical trial information, guidance for parents regarding research with children and contacts for concerns or suggestions. Education material regarding human subject protection, IRB, and accreditation are also provided. In addition, the site provides a brochure to guide Legally Authorized Representatives regarding their obligations in providing consent on an individual’s behalf.

- The CCTS, UK HealthCare, and Markey Cancer Center also share the mission to reach, educate, maintain a presence and engage the public via multiple venues including websites, confidential research interest portal, videos, brochures, wall mount exhibits, researcher spotlights and participation at outreach events.
  - CCTS Participate in Research website
  - UK Clinical Research: 5 part Clinical Trials Video Series
  - UK HealthCare Clinical Research website
  - Understanding Clinical Research Studies FAQ
  - UK Clinical Research Education Day - Research Education Day which is a free public event involving representatives from the ORI, IRB, and departments engaged in clinical research.
  - Markey Cancer Center Clinical Trials web site
  - Markey Cancer Center Cancer Research Day one-day event showcasing current cancer research projects at UK; registration is free for Patient Advisory Group members.