University of Kentucky Human Research Education Options
(Assurance # FWA 00005295)

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 Education Specialist and/or designated staff provide an individual or small group orientation session and resource binder.
  - **CITI IRB Member Module – "What Every New IRB Member Needs to Know":** addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of human subject 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 to provide "play by play" commentary on the operation of the meetings.

- **Vice Chair Orientation:** The Education Specialist and/or designated staff offer newly appointed Vice Chairs with an orientation session and binder on the specific duties of the Vice Chairs. Specific instructions 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 and Nonmedical 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 five boards. Additional ORI staff members are invited to attend and share topic-specific expertise or reports.

- **Specialty Specific Training:** Additional training is provided as needed for specific or select IRB members (*e.g., community members)*

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- **Continuing Education Initiatives**: Continuing education is provided to IRB members primarily by topical mini sessions held at the beginning of scheduled review meetings, periodic webinars (e.g. AAHRPP, OHRP, and PRIM&R), and scheduled presentations.

- Funds are provided to send members to the **Annual Human Research Protections (HRP) Conference** co-sponsored by the University of Kentucky, University of Cincinnati, Cincinnati Children's Hospital and the University of Kentucky, and Northern Kentucky University.

- 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 videos and quick links to key resources. Also included is information on the "nuts and bolts' of serving on an IRB for recruitment of prospective members.

- The University of Kentucky **IRB Survival Handbook** is provided to IRB members through the ORI website. This electronic web-based tool contains guidance/policy/educational documents on federal regulations and local institutional policies and procedures; ORI/IRB standard operating procedures (*SOPs*); and IRB forms.

- Since 2006, ORI has maintained the **Changes at the Federal Level Impacting IRBs** resource. The tool is now interactive and searchable by year or topic. Each entry includes 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** 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.

- 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 in Constant Contact. These are used to send IRB members a variety of materials such as announcements, education opportunities, copies of pertinent articles, regulatory updates, new resources, etc.

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

- **Getting Started Website**: Provides step-by-step instructions for initiating and submitting human research for IRB review. Includes links to resources and interactive tools. Also includes information on continued oversight and IRB interactions, as well as study closure information.

- **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 HRP conference, 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., CIRTification: 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.

- **Non-UK Study Personnel HSP Training:** Since CITI access is limited to individuals with single sign on credentials, UK ORI developed an HSP training course available publicly on the Coggno platform. The course is loosely based on the form NIH Protecting Human Research Participants with reference to sample cases and local context.

- **K-12 Teacher & Support Staff HSP Training:** UK ORI developed training specifically for this group to enhance protections for this particularly vulnerable population. The course covers all ethical principles and includes case studies to emphasize voluntariness, autonomy limits, rights, and welfare of K-12 students.

- **Mandatory FDA Sponsor-Investigator Training:** Investigators who also serve in a sponsor capacity for an FDA regulated product (e.g., *hold an Investigational New Drug (IND), Investigational Device Exemption (IDE)*) are required to complete sponsor-investigator training. Options include completion of the CITI Good Clinical Practice course for drug or device development, the ReGARDD Training Modules on IND Sponsor-Investigator Responsibilities [HTML] or other equivalent training.

- The University of Kentucky CITI curriculum includes several additional trainings available to investigators and research staff including **Clinical Research Coordinator, Good Clinical Practice (GCP), Mobile Apps, Artificial Intelligence, Single IRB Review, Advanced Issues in Informed Consent, Phase I research, Humanitarian Use Devices, etc.**

- **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 upon request, is tailored to include issues and examples specific to the requesting research group or university class.

- **Informed Consent Workshop: from Perception to Process**
  Co-sponsored by ORI & CCTS. Periodically offered as a four-hour, hands-on workshop or abbreviated session upon request, for research personnel provides tools to enable researchers to recognize and evaluate their own consent documents and process for compliance with basic

regulatory and ethical requirements. Engage attendees in interactive activities designed to improve research informed consent development. Includes mock practice to improve communication and meet the needs, motives, abilities, and goals of the potential research participant.

- **ORI Video Training & Interactive Tools:** The ORI training & Education website features numerous brief topical video trainings including *What Research Activities Need Institutional Review Board (IRB) Review; Getting Started with the IRB, Research Recruitment and Advertising; Short Form Consent, Gender Inclusive Language, Real World Data*, and more. In addition, the page provides interactive tools to aid investigators navigation of the regulatory framework including *FDA Drug and Device tool, Primary Research & Secondary Use, Automated Dictionary, Research vs. Quality Improvement, Exempt Categories*, etc.

- **Sample Applications and Protocol Development Resources** webpage provides sample IRB submissions, key participant information, tools templates, and more.

- 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:** The **Vice President for Research Orientation Website** provides a comprehensive orientation for new faculty to get you familiar with our research support offices, policies, procedures, and resources available to support research programs. This includes an **ORI Orientation Video** on the IRB and human research protections. ORI also attends and exhibits at in-person New Faculty Orientation events hosted by the Vice President for Research.

- The **University of Kentucky Center for 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 hosts various audio conferences on fiscal and clinical topics important to clinical and translational researchers.
  - The "**Clinical Research Coordination 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.

- The **ORI Web site** includes **Standard Operating Procedures**, the **IRB Survival Handbook**, **Getting Started**, **FDA-Regulated Research**, **Informed Consent**, and **numerous FAQs**. .

- **ORI News & Announcements** 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**.

- **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.

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 Education Specialist and/or Associate Director meet with new ORI staff to discuss ORI mission, customer standards, reporting lines, and regulatory framework.
  - New ORI staff complete a series of web-based training tailored to their role and job functions.
  - New ORI staff members circulate through the department to work with various individuals and learn all aspects of IRB administration and task-specific operations.

- **ORI Continuing Education**: Staff meetings are held approximately twice a month. New federal initiatives and interpretations of federal regulations and/or discussion of ethical issues occur on an on-going basis at staff meetings. The Research Education Team and other staff periodically provide training.

- ORI professional staff are periodically provided an opportunity to attend a national/regional professional meeting as funding permits.

- ORI professional staff attend the **Annual Human Research Protections Conference** co-sponsored by the University of Kentucky, University of Cincinnati, Cincinnati Children's Hospital and the University of Kentucky, Northern Kentucky University. 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.

- ORI maintains a **Recent Changes at the Federal Level Impacting IRBs** interactive tool which includes a links and summaries of draft and final guidance or regulations of importance to human research protections.

- 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, patient/community advisory groups, and participation at outreach events.

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- **CCTS Participate in Research Website**
- **UK Clinical Research: 5-part Clinical Trials Video Series**
- **UK HealthCare Clinical Research Website**
- **Understanding Clinical Research Studies FAQ**
- **Markey Cancer Center Clinical Trials Website**
- **Markey Cancer Center Cancer Research Day** one-day event showcasing current cancer research projects at UK; registration is free for Patient Advisory Group members.

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10/19/18; 2/8/2023 updated weblinks; 2/20/2024