

UNIVERSITY OF KENTUCKY

MANDATORY RESEARCH EDUCATION REQUIREMENTS

Human Subjects

Initial human subject protection (HSP) training: All personnel involved in human subject research must complete one of the two options below:

- **Collaborative Investigator Training Initiative (CITI):** readings and test online
Instructions at http://www.research.uky.edu/ori/ORIForms/42-CITI_instructions.pdf
Contact: Stephanie Morris, Office of Research Integrity – 257-0582 or samo222@uky.edu
- **Protecting Study Volunteers in Research a.k.a. (Dunn & Chadwick):** book with online test
Instructions at http://www.research.uky.edu/ori/ORIForms/43-Dunn_Chadwick_inst.pdf
Contact: Stephanie Morris, Office of Research Integrity – 257-0582 or samo222@uky.edu

Continuing HSP training: Continuing education in HSP must be completed at least every three years. There are several options for renewing your HSP training:

- **CITI web based human subjects protection training (refresher course option):** Enter the CITI website and register as a UK user. The course is a synopsis of the main biomedical or social/behavioral modules that are required as initial training. Web address: <https://www.citiprogram.org/default.asp>
- **VA Good Clinical Practice and Human Subjects Protection web based modules** (submit certificate of completion) Web address: www.citiprogram.org
- **Attendance at the UK annual human subject protection conference,** (submit certificate of attendance).
- **Attendance of an equivalent human subjects protection conference** (ex. PRIM&R) within the last six (6) Months (this does not include an isolated session on human subjects protection as part of a conference on another subject matter). Submit certificate of attendance.
- **NIH human subjects protection program web-based training** (only qualifies as a refresher course and not for initial human subjects protection training). Submit certificate of completion. Web address: <http://phrp.nihtraining.com/users/login.php>

Animal Care & Use

All personnel involved with the use and care of animals involved in research are required to complete initial training and continuing education. Depending on the species and/or proposed procedures, additional specialized training may be required. Please refer to the guidelines at the following link.

- **IACUC Policies & Procedures Training and Continuing Education**
Web address:
http://www.research.uky.edu/ori/univet/resources/sop/IACUC_106_Training%20and%20Continuing%20Education%20Requirements.pdf

Fiscal Compliance Training for Clinical Trials that Involves Third-Party Billing

This training is mandatory for principal investigators and clinical research coordinators who will conduct clinical trials involving third-party billing. This training may also be useful to business officers and other employees who deal with budgetary and billing issues related to clinical research.

- **Fiscal Compliance in Clinical Trials Education Program**
<http://mcsharepoint/evpha/ops/comp/rfc/Resources/Forms/AllItems.aspx>
 Classroom to be announced
 Contact: Rebecca Scott, 323-1478 or rmwalt00@email.uky.edu

Sponsor/ Investigator Mandatory Training

All individuals who functioning as the investigator and sponsor for a FDA regulated trial (drug or device).

- **[Sponsor-Investigator web-based training description](#)**
Title: ORI000-NC: Sponsor-Investigator Clinical Trials with FDA Regulated Products
 On-line modules and exams (drug or device specific) located on [UK's blackboard website](#). Contact: Belinda Smith, ORI Education Specialist, 323-2446 or belinda.smith@uky.edu

Environmental Health and Safety

The University requires safety training classes to be completed before beginning certain types of work. These requirements apply to all individuals involved in the covered work, including faculty, staff, students, post-docs, visiting researchers, and volunteers. To find out what classes you need to take, consult the Training Checklist.

- **Training checklist for Research Grants and Contracts**

Web address:

<http://ehs.uky.edu/ehs/checklist.html>

Classes are grouped under their respective EH&S departments on the training schedule including,

- Occupational Health and Safety (Chemical Hygiene/Lab Safety, Bloodborne Pathogens, Hazard Communications, etc);
 - Biological Safety (Biological Safety, Bloodborne Pathogens for Researchers, Autoclave);
 - Environmental Management (Hazardous Waste, DOT/IATA);
 - Radiation Safety (Basic, Advanced, Laser Safety); and
 - University Fire Marshal (Fire Extinguisher Use).
- **Training Schedule**
 Web address:
<http://ehs.uky.edu/ehs/classes.html>

Veterans Affairs Medical Center

University of Kentucky researchers who utilize VA facilities, recruit VA patients for UK studies, or who have joint appointments must complete mandatory education in any area applicable to the research being conducted. These VA requirements are in the following areas: Human Subjects, Animal Care and Use, Occupational Health and Safety, Hazardous Materials Management, Radiation

Safety, and Fire and Safety. For specific information, contact Lena Molen at the VA Research Service Office, 281-4927.

OPTIONAL EDUCATION RESOURCES

(Not mandated by UK but may be required by sponsor or funding agency)

Responsible Conduct of Research

The [National Science Foundation \(NSF\)](#) has implemented training in Responsible Conduct of Research as an integral part of preparation and development of current and future scientists. RCR training is also a requirement for various other funding opportunities such as postdoctoral fellowships.

- **UK CITI Curriculum RCR Training – choose from:**
 - Biomedical RCR
 - Social and Behavioral RCR
 - Physical Science RCR
 - Humanities RCR
 - Administrators RCR
 - Engineers RCR

For instructions refer to the RCR training section of [CITI Instructions](#)

Good Clinical Practice

Some industry sponsors of clinical trials require investigators to be trained in Good Clinical Practice (GCP) guidelines. UK CITI curriculum includes GCP training modules under optional trainings.

- **UK CITI Curriculum Optional GCP Training (English and Spanish)**

For instructions refer to the optional training section of [CITI Instructions](#)

Compiled by Ada Sue Selwitz and Jennifer Harris, Office of Research Integrity Updated 3/10/11
33-Mandatory_Research_Ed_Requirements.doc J:\Mandatory IRB Training\Educational Handouts\ and J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\