***TITLE: Required Training***

***SOP # RM XX.XX***

***Author(s):***

 ***Approved by Date***

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**I. SCOPE/PURPOSE**

The purpose of this SOP is to ensure individuals conducting clinical research at UAB are appropriately trained, to identify appropriate training mechanisms, and to ensure appropriate documentation of training.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

**III. RELEVANT REGULATIONS/GCPs**

Food and Drug Administration (FDA); ICH-GCP 4.1.3, 4.1.5, 4.2.4, 4.5

**IV. DEFINITIONS/ACRONYMS**

ICH – International Conference of Harmonisation

GCP – Good Clinical Practice

IRB – Institutional Review Board

eDES – Electronic Data Entry System

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following all research staff– Principal Investigators, Sub-Investigators, Study Coordinators, Data Management, Laboratory Technicians, Research Pharmacists, Regulatory Affairs, and sponsors.

**VI. DETAILS**

Training in clinical research is critical to assuring all aspects of good clinical practices are adhered to, from protecting human subjects to collecting rigorous data. An important part of training is to maintain a log of training for each protocol (see Appendix A) and to maintain a log for each employee (see Appendix B). Some training is required per the research office’s standard operating procedures and other training may be required per protocol.

 **I. Training Requirements**

a. The investigator will be aware of, and will comply with, GCP and the applicable regulatory requirements.

b. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

c. The sponsor will utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports. The sponsor will conduct the initial protocol training via the site initiation visit.

d. All key personnel are required to complete initial and continuing human subjects protection training and GCP training.

IRB HSP – Continuing IRB training is required once every 3 years. The [Continuing IRB Training](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/CotinuingIRBTraining.aspx) web page lists approved options. Individuals who plan to attend events not in that list but related to human subjects research may submit an agenda or synopsis of the event before attending so the IRB may determine if training credit can be given for that event. In 2000, the NIH enacted policy NOT-OD-00-039 requiring that study or "key" personnel involved in human subjects research complete education in the protection of those subjects. At **UAB**, study personnel are required to complete an approved “initial’ training option and to complete an approved "continuing" option once during every 2 or 3 year period.

IATA - All personnel who package and ship specimens must complete training and

become certified in accordance with Federal Regulations. IATA training will be required.

.GCP Training in ICH GCPs is required. All personnel will participate in the ICH-GCP training on Miami CITI training websites.

**II. Continuing Education/Training**

Additional training requirements may be necessary to meet the demands of particular protocols.

**Throughout the conduct of the study, training will be documented as follows:**

(Protocol specific training, amendments, consent forms, IB updates)

* The PI/study coordinator/regulatory manager will be notified of study specific updates from the sponsor
* Study specific updates will be disseminated to the study team electronically (slide decks, Summary of Changes, “redlined” and clean copies)
* The study team will document receipt/review of relevant documents by replying to the email
* If required, site specific training logs will be completed
* Documentation of training will be filed in the regulatory binder
* Key personnel are required to attend departmental meetings (e.g. CTMC) if applicable
* Applicable training certificates (eDES) will be filed in the regulatory binder

 **Acceptable / Recommended Training / Courses**

* Transcelerate
* CITI Online: [CITI Basic-Biomedical or Behavioral-Course in Human Research Protections](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/CITI-Courses.aspx), University of Miami
* NIH Online: [Protecting Human Research Participants](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/NIH-Training.aspx), National Institutes of Health
* UAB Online: [Investigator 101 UAB Course-Initial (requires BlazerID and RealPlayer)](http://www.uab.edu/learningsystem)
* UAB Course: [GRD 717: Principles of Scientific Integrity](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/IRBCoursesProgramsApproved.aspx)
* For New UAB Researchers: [Human Subjects Protection Training](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/IRBTrainingAlternatives.aspx), from your previous institution
* [Research Coordinator Training Program](http://www.uab.edu/research/administration/offices/IRB/Training/Pages/Research-Coordinator-Training-Program.aspx) (offered twice a year by UAB)
* ICH-GCP Training through CITI:

*Some sponsors require that protocols be conducted in accordance with guidelines from the International Conference on Harmonization - Good Clinical Practices (ICH-GCP). For these protocols, all staff members must complete ICH-GCP training in addition to Human Subjects Protections training.*

* IRB PRO100 - <http://sppublic.ad.uab.edu/policies/content/Pages/UAB-RA-PRO-0000277.aspx>
* UAB IRB WEBSITE - <http://www.uab.edu/research/administration/offices/IRB/Training/Pages/CotinuingIRBTraining.aspx>
* FDA Guidance for Industry – E6 Good Clinical Practice: Consolidated Guidance

**VII. QA**

Annually, each personnel record will be reviewed for completeness. Additionally, prior to each monitor visit, the training log will be reviewed for completeness.

**VIII. APPENDICES / RESOURCES**

Appendix A Training Log

Appendix B Per staff member Log

**IX. RELATED SOPS**

NA

Appendix A

Inservice and Training Log

Title of Inservice:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Conducted by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**My signature below attests to my attendance and understanding of the presented information:**

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Appendix B

Inservice and Training Log

Printed Staff Member Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**My signature below attests to my attendance and understanding of the presented information:**

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