Clinical Research Shared Service Standard Operating Procedure

SOP 123-ADM  Training and Education for Clinical Research Shared Service

Approval signature: ____________________________
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Purpose:
Research studies will be conducted according to Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) regulations to protect the safety and welfare of study subjects. The research team must be educated about current study protocols and the regulations governing investigational clinical trials.

Investigators and all key members of the research team who are working in or overseeing programs that conduct research with human subjects will receive initial training and continuing education about conducting research responsibly.

This standard operating procedure (SOP) describes the process and documentation required by the institution for the initial and continuing education of the principal investigator and research staff in Good Clinical Practices (GCPs), the ethical conduct of research conducted at this research site and other work-related continuing education.

References:
- 21 CFR 312.60  General Responsibilities of Investigators
- 45 CFR 46  46DHHS Part 46 Protection of Human Subjects
- 21 CFR 812  Subpart E Responsibilities of Investigators
- May 1997  ICH Good Clinical Practice: Consolidated Guideline (E6 4.2.4)
- September 1993  FDA Internal Compliance Program Guidance Manual for Clinical Investigators: 7348.811
- June 5, 2000  NIH Notice 00-00-029: Required Education in the Protection of Human Research Participants
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
This SOP applies to those members of the clinical research team involved in or overseeing programs that conduct research on human subjects at the Arizona Cancer Center (AZCC).
Tools:

Definition of Terms:
- Clinical Trial Office (CTO): Individuals responsible for the regulatory documentation, completion and distribution of clinical research projects as part of the Clinical Research Shared Service at the Arizona Cancer Center.
- Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- Oncore: Database used to store protocol and patient data at the Arizona Cancer Center.

Safety Issues:
This SOP delineates the training and continued education necessary for the safe conduct of clinical trials. Documentation of training is federally mandated.

Process Overview:
All clinical research staff is given the opportunity for continuing education as well as study-specific training for any research involving human subjects to which they are assigned, either by team structure or as required by Form FDA 1572.

Process Steps:
1) Human Subjects Training:
   a) All members of the research team involved in human subjects’ research must pass the exam based on the Collaborative Institutional Training Initiative (CITI) course in the Protection of Human Research Subjects, available at www.citiprogram.org. CITI training is valid for two years. CITI will email you a reminder one to two months prior to the expiration of your training. To maintain your training, you must complete the CITI refresher course prior to the expiration of your previous training.

2) Protocol-specific training:
   a) Investigators Meeting:
      i) The PI and/or their designee, Research Nurse Coordinator and/or Clinical Research Coordinator, may attend the investigators meeting at the request of the sponsor.
      ii) A copy of information provided for training should be provided for confirmation of training.
      iii) A copy of this documentation is forwarded to the CTO for incorporation into the regulatory binder.
   b) Additional and/or subsequent training:
      i) The primary assigned Research Nurse Coordinator and/or Clinical Research Coordinator are required to perform protocol specific cross training for
applicable CRSS staff to ensure adequate training on the protocol and/or any revisions/amendments.

ii) A copy of information provided for training must be provided to their supervisor for confirmation of training.

iii) A copy of this documentation is forwarded to the CTO for incorporation into the regulatory binder.

3) Site Initiation Visit:
   a) The PI, Research Nurse Coordinator, Clinical Research Coordinator, Investigational Pharmacist, IRB Coordinator, Regulatory Specialist, and CTO staff, QA/QC Program staff, DSMB Coordinator and the Clinical Research Technician, as necessary, attend the visit.
   b) The signature log (i.e., training signature log) is signed by all attendees for proof of attendance and/or training.
   c) A copy of the training documentation is forwarded to CTO for incorporation into the regulatory binder.

4) CCRC:
   a) The Arizona Cancer Center's CCRC occurs bi-monthly to present Phase I studies, to review on-going clinical trials and to announce new potential studies for drug development.
   b) New clinical trials are presented by the Principal Investigators, as applicable.
   c) Attendees are requested to sign the CCRC attendance log.
   d) CTO personnel maintain the attendance logs in the CTO office.

5) Continuing Education:
   a) Research staff members will document their attendance of additional research, oncology-related lectures, and other pre-approved educational programs (i.e., computer training, H.R. classes). Staff is also encouraged to supply records supporting the attendance/completion of such training to their departmental supervisor for incorporation into their departmental training file.