Human Subjects Research Staff Training List

Please see the PITT Training Table to ensure your staff member does all trainings required for their position: https://www.orp.pitt.edu/training/training-table-list*

GENERAL REQUIRED TRAININGS

CITI Trainings - http://www.citiprogram.org/*

- CITI Training Good Clinical Practice (GCP)
  - US FDA Focused (Biomedical)
  - Social and Behavioral
- CITI Training Human Subjects Protection (HSP)
  - Biomedical
  - Social, Behavioral, Educational
- CITI Training Financial Conflict of Interest (FCOI)
- CITI Training Responsible Conduct or Research
- CITI Health Information Privacy & Security
- CITI Revised Common Rule
- Citi-Modules-Instructions-HSR-Basic*

STUDY-SPECIFIC TRAININGS

- Protocol
- Protocol schedule of activities/procedures
- ICF training, overview, talking points, review
- SSP and MOP
- ECRF review, completion, quality control, and revision
- Study-specific source documents
- Study-specific shared drive format (file storage)

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SUPPLEMENTAL TRAININGS

REGULATORY & COMPLIANCE (GENERAL)

- PITT vs UPMC (decision-making tree for review)
- PITT PRO: access and Sandbox training
- Human Research Protection Office (HRPO) Guidance and Forms A-Z Index*
- OSPARS access and portal training
- OSPARS submission checklist/tool
- Pitt CTO Trial Registration*
- Clinicaltrials.gov overview

REGULATORY & COMPLIANCE (STUDY SPECIFIC)

- Preparing and maintaining the regulatory binder
- FDA form 1572 (discuss, complete, upkeep)
- Delegation of duties log (discuss, complete, upkeep)
- Tracking Study Staff Training and Documents (CV, License, GCP/HSP)
- Study Financial Conflict of Interest (FCOI)
- UPMC: obtaining unique Med-ID#
- Creating screening/enrollment link and study schedule tracking
- Study team meeting agenda and documentation
- Quality management plan training

COMPUTER PROGRAMS

- Shared Drive (PITT and UPMC)
- OneDrive (PITT and UPMC)
- INFONET (UPMC)
- Oncore* (PITT)
- MS Teams (PITT and UPMC)
- MS Outlook, Word, Excel, PowerPoint
- RedCap*: Standard vs 21CFR 11 Compliant
- Qualtrics (PITT)
- Access
- Division/group-specific databases
- Other: _____

ADMINISTRATIVE /FINANCE /BUDGETS

- Vincent (PITT and/or UPMC)
  - Complete Pitt Vincent training*
- OnCORE (clinical trials management system)
- Study budget (creation, review)
- Clinical Trial Agreement (CTA) review
- Creation of visit tracking and revenue reconciliation
  - What do we invoice for
  - Automatic payments
  - Revenue reconciliation
- Review fiscal year
  - PITT Fiscal/Academic Year: July 1-June 30
  - UPMC Fiscal/Calendar Year: January 1- December 31

LAB/SPECIMEN MANAGEMENT

- Study-specific lab evaluation and grading
- Autoclaving (ancillary service) – know how to use it
- Bloodborne Pathogens (BBP) for Laboratory Personnel | Office of Public Safety & Emergency Management (pitt.edu)*
- If you are shipping any specimens, you must take this training: Dangerous Goods Shipping | Office of Public Safety & Emergency Management (pitt.edu) (this would satisfy IATA training)*
- PITT Office of Public Safety training list: Training | Office of Public Safety & Emergency Management* (this includes many different types of trainings in lab and environmental safety that can be accessed).

PHARMACY

- UPMC IDS Documents (read and review)
- Study product transport and chain of custody
- Study product check, QC, documentation prep, and post-administration.

DOCUMENTATION AND CHARTING

- Source documentation training/discussion
- Informed consent training
- Preparing the source document table (why and how)

- Create and review study visit checklists
- Creating visit source documents
- Creating study participant charts

STUDY VISIT OBSERVATION

- Observe ICF discussion (with participant)
- Successful full screening visit (with participant)
- Successful full enrollment visit (with participant)
- Successful follow-up visit (with participant)
- IRB procedures

CLINICAL RESEARCH PROCEDURES and PARTICIPANT SAFETY

- Basic Life Support (BLS)
    - UPMC: Infonet learning portal* and register
    - PITT: AED Training | Office of Public Safety & Emergency Management*
- Advanced Cardiac Life Support (ACLS)
    - UPMC: Infonet learning portal* and register
    - Pitt: AED Training | Office of Public Safety & Emergency Management*
- Code cart discussion with Manager/Supervisor and procedures based on location ("how to call a code")
- WISER (courses for a fee) https://www.wisersimulation.org/*
- Phlebotomy training and/or Sign Off (assess interest)
- Participant Data
    - Vital Signs: BP, Pulse, Temp, Pulse Ox
    - Height and Weight
    - 12 Lead EKG
    - BMI Calculator*(NIH)
- Adverse Events (AE) and Serious Adverse Events (SAE) overview
- NIH Stroke Scale*
- Add others as needed

ADDITIONAL SUPPORTIVE TRAININGS

- CITI Clinical Research Coordinator
- CTSI Orientation to Research Operations - live provided twice per year
- DOM CRC Training (10 modules) - on demand
- EPIC Training (EMR) – job specific (require contingent worker status. See PITT Managers Guide*)
- NIH Research Coordinator Training: Introduction to the Principles and Practice of Clinical Research (IPPCR)*

SOP REVIEW

- Environmental Health & Safety*
- University of Pittsburgh EH&S Guidelines on Specimen Transport between Research Facilities*
- University of Pittsburgh EH&S Guidelines on Infectious Waste/Biohazardous Waste Disposal*
- DOM PITT Internal website* : go to Clinical Research tab

IMPORTANT RESOURCES:

- Pitt Research Offices | Pitt Research | University of Pittsburgh*
- Resources for Researchers | Pitt Research | University of Pittsburgh*
- Home | CTSI University of Pittsburgh*
- DOM PITT Internal Website*

REGISTRATION FOR COMMUNICATION and NEWSLETTERS

- Human Research Protection Office (IRB, etc.): https://www.hrpo.pitt.edu/sign-our-mailing-list*
- CTSI*

DISCUSSIONS

- Provide any disease-specific resources
- Review clinic schedules
- Who/what are FDA, HHS and their oversight of research
- What is the Code of Federal Regulations* (CFRs)

STUDY-SPECIFIC DISCUSSIONS

- Who is the Sponsor and what are their responsibilities?
- Who/what is the IoR/PI and what are their responsibilities?
- Understanding the financial process supporting your trial
- Describe the regulatory approval process and why it is this important.
- Becoming a project lead/project expert

OTHER DISCUSSIONS

- Obtaining parking passes for participant visits

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- Obtaining dry ice for study visits
- Coordinating study visits with study providers
- Scheduling study visits
- **indicates hyperlink*