


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	TRAINING CLINICAL RESEARCH PERSONNEL		
SOP#: 102	Effective Date:01/01/2015	Version: 1.0	Page 1 of 4

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to ensure that clinical research personnel in the CRC receive adequate training required by the principles of the International Conference on Harmonization (ICH), Guideline for Good Clinical Practice (GCP), and University of South Florida (USF) policies and procedures.

SCOPE: This SOP applies to all clinical research site personnel involved in the implementation and coordination of clinical research studies within the CRC. Each individual shall be qualified by education, training and experience to perform his / her tasks.

RESPONSIBILITY: The Principal Investigator (PI) and all members of the research personnel who conduct clinical trials at the CRC are responsible for complying with this SOP.

DEFINITIONS:

Belmont Report: Report created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that established ethical principles and guidelines for the protection of human subjects of research. It is based on three ethical principles that should guide research: respect of persons, beneficence and justice.

Declaration of Helsinki: A set of ethical principles developed by the World Medical Association (WMA) to provide guidance to physicians and other participants in medical research involving human subjects. It is widely regarded as the cornerstone document of human research ethics.

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.

International Conference on Harmonization (ICH): A joint collaboration between the United States, European Union (EU) and Japan that established the ICH GCP Guideline aimed to provide a unified standard to facilitate the mutual acceptance of clinical data by the regulatory authorities of these jurisdictions

Nuremberg Code: A set of ten research ethics principles for human experimentation established as a result of the subsequent Nuremberg Trials at the end of the Second World War.

EPIC: The electronic medical record (EMR) and scheduling/billing system that serves the University of South Florida Physician's Group (USFPG)

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PROCEDURE:

1. Initial employee training begins on the new employee's start date and continues throughout a training period determined by the department manager and/or designated department representative. Ongoing employee training will occur throughout employment at USF Health.
2. All new participating investigators and clinical research personnel will participate in training programs to acquaint them with the principles of Good Clinical Practices. The orientation program may include information on the following topics:
 - 2.1. Historical overview and global perspective of clinical research
 - 2.2. Glossary of terms and definitions
 - 2.3. SOPs of the investigative site
 - 2.4. GCP and ICH Guidelines
 - 2.5. Sponsor visits
 - 2.6. IRB bylaws, submission procedures and contact information
 - 2.7. Roles and responsibilities of the clinical research personnel
 - 2.8. Code of Federal Regulations (CFR)
 - 2.9. Declaration of Helsinki
 - 2.10. Belmont Report
 - 2.11. Nuremburg Code
 - 2.12. OSHA Universal Precautions
 - 2.13. Core competencies (ECG, phlebotomy, etc.)
 - 2.14. Informed Consent process and documentation
 - 2.15. Audits and inspections
 - 2.16. EPIC Scheduler training
3. Clinical Research Personnel will be trained on the Standard Operating Procedures prior to commencement of any clinical research activities at the CRC.
 - 3.1 Training will be documented on the Research Personnel Training Log (Appendix C)
 - 3.2 The training logs will be kept in the employee file within the department.
4. Required Training for Clinical Research Personnel
 - 4.1 Bloodborne Pathogens (BBP)- Prevention and Management of Occupational Exposures Biohazardous Waste Education: All personnel with a reasonable expectation of exposure to blood, body fluid, tissue or sharps must complete training within 90 days of acquiring said duties. Please visit USF Research Integrtiy and Compliance website for further information on Biosafety training.

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- 4.2 Communicable Disease Screening & Prevention Certification: All USF Health personnel with face-to-face patient contact and/or will be involved in direct patient care must complete certification prior to seeing any patients and/or study subjects within the first two weeks of employment. Please contact Associate Director, Medical Health Administration, Infection Prevention & Control, Employee/Student Health & Wellness for information or to schedule a screening appointment.
- 4.2.1 HIPAA Training: All clinical research personnel with either direct or indirect access to subjects or to their health information is required to take this one-time course prior to seeing any patients/study subjects and/or their health information. This includes access to computing systems which transmit, receive, create or store confidential patient information.
- 4.3 Human Research Subjects Protections Program (HRPP) Mandatory Education Training: All key study personnel (Investigators, Sub-Investigators, Research Coordinators, and personnel members) are required to maintain this training. Information is provided on the USF IRB and Research Integrity and Compliance website.
- 4.4 USF Division of Research Integrity and Compliance (DRIC) Biosafety Training Course: All study personnel who ship and/or receive biohazardous materials must complete this training course and continuing education required at USF within 90 days of hire.
- 4.5 EPIC Scheduler Training: Required for all research personnel responsible for scheduling research study visits in the CRC.
- 4.6 Responsible Conduct of Research (RCR): RCR Training is required for undergraduate and graduate students and post-doctoral research fellows supported on National Science Foundation (NSF) funded projects only. Training is required prior to submission of NSF proposal and can be accessed at: <https://www.citiprogram.org>
- 4.7 Interest Inventory for PHS Funded Research: All investigators who are funded by or anticipate funding by PHS and Certain Federal Agencies, Foundations or Extramural Sponsors are required to complete an interest inventory located within the arc system. The form provides information on disclosure of applicable interests and their relationship to institutional responsibilities as well as any currently required training.

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REFERENCES:	21 CFR 312; 45 CFR 46; ICH and GCP Guidelines 2.8, 4.1.3	
RELATED POLICIES:	USF HRPP Policies and Procedures	
APPENDICES:	Appendix C: Research Personnel Training Log	
REVISION HISTORY: A running history of all revision dates will be kept in a log		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	