Minimum Training Requirements for Clinical Research Staff

Catherine Jahrsdorfer, R.N., B.S.N.

Director of Clinical Services

Office of Clinical Research

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UNIVERSITY OF SOUTH FLORIDA

Learning Objectives

- Identify minimum training requirements for clinical research coordinators at USF

- Review a sample Orientation Checklist

- Discover a new strategic partnership initiative between USF OCR and a well-established global CRO

- Learn what changes are coming this fall for the USF CRC meetings

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Getting Started – USF and USF Health

- USF Onboarding
- Get systems access according to assigned duties
  - Health email account
  - USF NetID
  - ARC Registration
  - Internal Form system
    - Hint: if you will be creating Internal Forms on behalf of your PI then CRAN access should be requested
    - The system is being redesigned and training will begin this month - register through TRAIN

Getting Started – USF OCR

- Get systems access according to assigned duties, cont.
  - ClinCard
  - Merge CTMS Investigator
  - OCR SharePoint PI Protocol Library

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COMMUNICABLE DISEASE SCREENING & PREVENTION CERTIFICATION

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Applicable Staff

- Required for all employees working where there is contact with patients and/or exposure to blood or body fluids

- If you will have face-to-face patient contact and/or will be involved in direct patient care, this screening is required

- Patient contact will not be permitted until the communicable disease screening is complete.

Timeframe for Completion

- Within the first two weeks of employment
- Annual Tuberculin Skin Testing (TST) will be required during your employment
- Annual influenza vaccination is highly encouraged
- Affiliates may have additional requirements for research credentialing at their facility

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How

- Contact Medical Health Administration (974-3163) for a screening appointment
http://health.usf.edu/medicine/internalmedicine/infectious/medical healthadmin/index.html

- Complete the Communicable Disease Screening Form and Prevention Certification Form

- Provide documentation of immunizations: Hep B, MMR, Varicella, Td, Tdap and influenza or titers will be drawn

- No cost immunizations are provided to staff based on titer results

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Safety: Back to Basics

Privacy in Research

Reducing the Risk

ROLE-BASED TRAINING

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Applicable Staff

- Safety: Back to Basics is required for all employees working in clinical areas or other areas where there is contact with patients and/or exposure to blood or bodily fluids

- Privacy in Research is required for all employees involved in human subject research

- Reducing the Risk covers medical malpractice and risk management issues and was developed by the USF Self-Insurance Program

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Timeframe for Completion

- All required modules must be completed within 10 business days of hire date
- Training should be repeated annually

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How

- Training is online at USF Health Learn: https://learn.health.usf.edu/login/index.php
- From the drop down menu under Course Categories, select USF Health Training
- Select Role-based Training

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How, cont.

- Complete all of the modules within the course "Safety: Back to Basics" including the post tests
  - Applying Standard Precautions
  - OSHA Fit Testing for Particulate Respirators
  - OSHA Bloodborne Pathogen (BBP) Education
  - Preventing Occupational Exposure to Bloodborne Pathogens
  - Selecting and Using Personal Protective Equipment

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How, cont.

- Complete the course "Privacy in Research"
- Complete all of the modules within the course "Reducing the Risk" including the quizzes
- Print the Certificates of Completion and file with your site's training records

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USF HEALTH PROFESSIONAL INTEGRITY & COMPLIANCE

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Applicable Staff

- Professional Integrity, Compliance and Information Security training is required of all faculty, residents/fellows, students, staff and other members of the USF Health community

Timeframe for Completion

- All required modules must be completed within 10 business days of hire date
- Training should be repeated annually

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How

- Training is online at USF Health Learn: https://learn.health.usf.edu/login/index.php
- From the drop down menu under Course Categories, select USF Health Training
- Select USF Health Professional Integrity & Compliance – Required Training

How, cont.

- This course includes the following modules:
  - Professional Integrity at USF Health
  - False Claims Acts and USF Health Standards
  - Professional Compliance - This course is chosen by Role. Select "Research staff with duties related to human subjects, patients or PHI"
  - HIPAA Compliance - This course is chosen by Role. Select "Research staff with duties related to human subjects, patients or PHI"
  - Computer & Information Security
- Print the certificate of completion and file with your site's training records

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Unlawful Harassment Prevention

USF REQUIRED TRAINING

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Applicable Staff

- The USF Required Training course is comprised of training that USF Administration has determined to be required of all faculty and staff

Timeframe for Completion

- All required modules must be completed within 10 business days of hire date

- Training should be repeated annually

How

- Training is online at USF Health Learn: https://learn.health.usf.edu/login/index.php

- From the drop down menu under Course Categories, select USF Health Training

- Select USF Required Training

- This course currently includes the following modules:

  – Unlawful Harassment Prevention

- Print the certificate of completion and file with your site's training records

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HUMAN SUBJECTS PROTECTION EDUCATION

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Applicable Staff

- All faculty, staff and students directly involved in the conduct of clinical research

- This includes individuals who:
  - collect or enter data
  - conduct study procedures (including informed consent) or interventions with human subjects
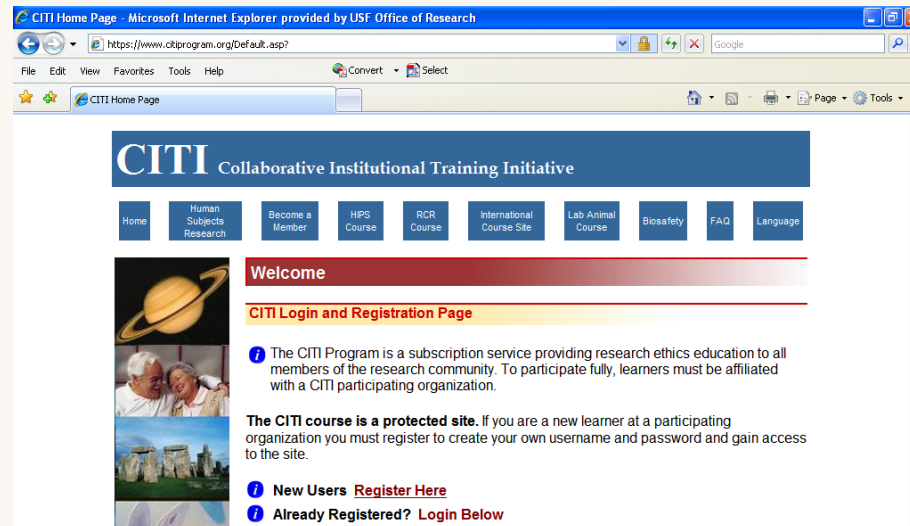 - use or have access to private information that can be linked to research subjects

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Timeframe for Completion

- Prior to engaging in the conduct of clinical research with human subjects and every two years thereafter

How

- IRB mandatory educational requirements: http://www.research.usf.edu/dric/hrpp/education.asp

- CITI (Collaborative Institutional Training Initiative) training registration and login page: https://www.citiprogram.org
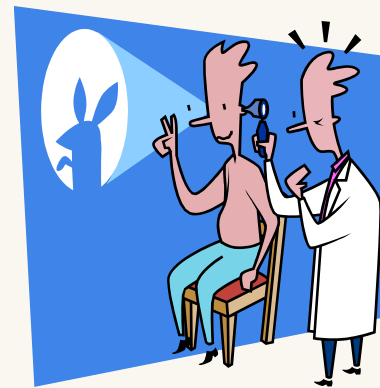
How, cont.

- Complete the Biomedical Investigators and Key Personnel – Basic Course if this is the first time taking HSP education

- Complete the Biomedical Investigators and Key Personnel – Refresher Course if the Basic Course has already been completed

- Print the certificate of completion and file with your site's training records

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GOOD CLINICAL PRACTICE (GCP)

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Applicable Staff

- All faculty, staff and students directly involved in the conduct of clinical research

- This course is intended for use by research personnel involved in conducting drug, device or biologic studies

Timeframe for Completion

- Prior to engaging in the conduct of clinical research with human subjects

- While not mandatory at this time, it is recommended that this course be completed every two years

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How

- CITI provides on-line training modules that can be accessed at: https://www.citiprogram.org

- It is strongly recommended that all modules be included and that they be completed in the order listed in the GCP introduction

- Print the certificate of completion and file with your site's training records

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USF RIC BIOSAFETY COURSE: *COMPREHENSIVE GUIDE TO SHIPPING INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS*

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Applicable Staff

- All USF staff who ship and/or receive potentially biohazardous materials

- The DOT defines hazardous material as substances that are capable of posing an unreasonable risk to health, safety, and property when transported in commerce

- This includes diagnostic specimens, infectious agents, biological products, and dry ice

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Timeframe for Completion

- Within 90 days of hire into a position that requires the shipping/ receipt of biohazardous materials and biannually thereafter

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How

- Course information is available at: http://www.research.usf.edu/dric/biosafety/shipping.asp

- The training is completed on an individual basis and is an interactive, computer-based, self-paced training program

- Average allotted time to complete training is about 2 to 3 hours

How, cont.

- Testing is conducted at 3702 Spectrum Blvd., University Technology Center, Suite 155

- There is an open-book exam at the end of the training and you must score 85% or better to earn your certificate

- The training is good for two years

- File your certificate of completion with your site's training records
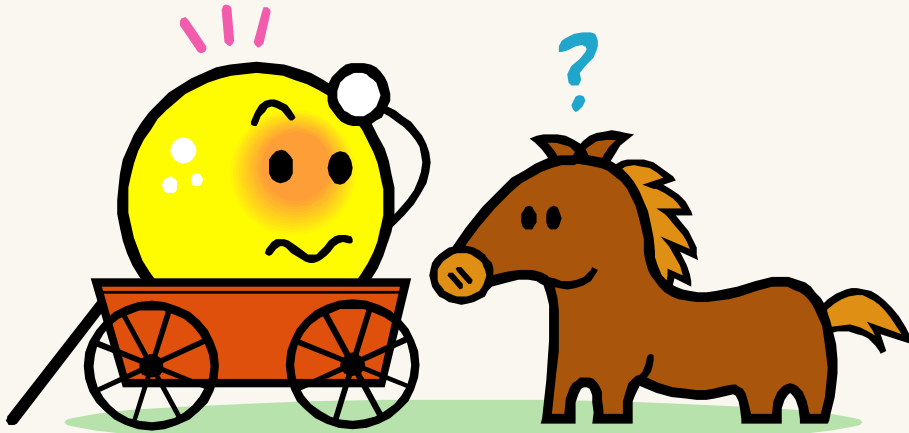
RESPONSIBLE CONDUCT OF RESEARCH

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Applicable Staff

- Effective January 4, 2010 the National Science Foundation (NSF) requires that all undergraduate and graduate students, as well as post-doctoral research fellows, who are submitting new proposals for NSF funding receive training in the Responsible Conduct of Research (RCR)

- Effective January 25, 2010, the National Institutes of Health (NIH) also adopted and expanded this requirement to include scholars

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Timeframe for Completion

- Prior to submission of NSF proposal and/or prior to being appointed to an NIH funded grant

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How

- CITI provides on-line training modules that can be accessed at: https://www.citiprogram.org

- CITI offers RCR training for biomedical sciences, social and behavioral sciences and other disciplines

- NIH specifies that 8 hours of training must be completed every 4 years. A substantive amount of this training must be in person.

- Refer to the RIC FAQ – Institutional Requirements for Training on RCR: http://www.research.usf.edu/dric/docs/RCR-FAQ-final.pdf

- Print the certificates of completion and file with your site's training records

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SAMPLE ORIENTATION CHECKLIST

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Sample Orientation Checklist

Nurse Researcher/Clinical Research Coordinator
Orientation Checklist

Activity	Completed (date & initial)	Confirmed (date & initial)
USF Onboarding		
Online benefits orientation		
Discover USF orientation: Welcome to USF – 1.5 days (Day 1: 8-4, Day 2: 8:30-11:30)		
Systems Access		
Email Account		
USF NetID		
ARC Registration		
Electronic Internal Form System Username and Password		
ClinCard Access		
Merge CTMS Investigator Access		
SharePoint		
Training Courses		
USF Health Learn: https://learn.health.usf.edu/login/index.php		
• USF Health Professional Integrity & Compliance – Required Training Professional Integrity, Compliance and Information Security training that is required of all faculty, residents/fellows, students, staff and other members of the USF Health community.		
o Professional Integrity at USF Health		
o False Claims Acts and USF Health Standards		
o Professional Compliance This course is chosen by Role. Please select "Research staff with duties related to human subjects, patients or PHI"		
o HIPAA Compliance This course is chosen by Role. Please select "Research staff with duties related to human subjects, patients or PHI"		
o Computer & Information Security		
• Role Based Training The Role-based Training course contains modules that are required for employees with certain roles or functions.		
o Safety: Back to Basics Required for all employees working in clinical areas or other areas where there is contact with patients and/or exposure to blood or bodily fluids This section includes the following modules: • Applying Standard Precautions • OSHA Fit Testing for Particulate Respirators • OSHA Bloodborne Pathogen (BBP) Education • Preventing Occupational Exposure to Bloodborne Pathogens • Selecting and Using Personal Protective Equipment		
o Privacy in Research Required for all employees involved in human subject research		
o Reducing the Risk		

Checklist is found on the OCR Education & Training page:
http://health.usf.edu/research/ocr/education.htm

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QUINTILES PARTNERSHIP WITH USF OFFICE OF CLINICAL RESEARCH

Quintiles Partnership with USF
Office of Clinical Research

Kim Davis, Strategic Site Relationship Manager (SSRM)

clinical | commercial | consulting | capital

CHANGES…

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Something Old

- Started monthly CRC meetings in October 2008
- We've executed **52 meetings** and covered **50 topics** since that time
- Trainings have been provided by **14 unique units**
- Attendance
  - Davis Islands = 951 (58.6%)
  - Main campus = 672 (41.4%)
  - Total attendance = **1623**
- *Thank you for your attention and support!*

Something New

- Starting next month Sadaf Aslam, as part of her new responsibilities as the Director of Communications, Education & Training in the USF OCR, will coordinate the CRC meetings

- Sadaf will be sending a short survey to get feedback on the frequency and topics for the meetings moving forward

- Please join me in welcoming Sadaf and supporting her in her new role with the USF OCR!

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Questions, Concerns, Comments?

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