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Title:	Clinical Research Coordinator Orientation	SOP #: 10.05.3
Date First Effective: June 1, 2002	Revision Date: April 26, 2010	

OBJECTIVE

This standard operating procedure (SOP) describes the process of orienting qualified personnel to the role of Clinical Research Coordinator.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator record keeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.68	Inspection of investigator records and reports
May 9, 1997	International Conference of Harmonisation; Good Clinical Practice: Consolidated Guidelines
January, 1988	Guidelines for the Monitoring of Clinical Investigations FDA Internal Compliance Program Guidance Manual 1994; 7348.811: Clinical Investigators
UVA IRB website	Online Training http://www.virginia.edu/vpr/irb/hsr/index.html
OHRP website	Office for Human Research Protection http://www.hhs.gov/
IATA	International Air Transport Association dangerous goods regulations

REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are applicable to this SOP

ATTACHMENTS

Attachment:	University of Virginia Health System Skills Checklist – Clinical Research Coordinator
Attachment:	Clinical Research Coordinator Post-Orientation Assessment

PROCEDURES

• Clinical Research Coordinator	1. Attend UVa centralized orientation sessions as required for new personnel. (Sessions are organized through the Center for Organizational Development (COD)).
	2. Satisfy all testing requirements established by COD for new personnel (including research on-line training modules).
• Clinical Research Coordinator's supervisor	3. Assign a preceptor who will be responsible for the oversight of the Clinical Research Coordinator specific orientation.
• Preceptor	4. Describe the reporting relationship to the Associate VP for Nursing if the CRC holds a nursing licensure (RN, NP).
	5. Describe the credentialing requirements if the CRC holds a Nurse Practitioner or MD licensure.
	6. Recommend attendance at the next scheduled IRB research

	coordinator educational session.
	7. Recommend participation in the mentoring program provided by the SOM Clinical Trials Office.
	8. Recommend viewing of the online education learning shots located on the IRB website
	9. Provide CRC with a personal copy (or access to a central copy) of regulations governing clinical trial activities (must include but not be limited to 21 CFR Part 50, 21 CFR Part 54, 21 CFR Part 56, 21 CFR Part 312, 21 CFR Part 812, 45 CFR Part 46, ICH Guidelines: E6). Utilize these during the orientation process.
	10. Provide CRC with access to standard operating procedures (SOPs) governing clinical trial activities within the SOM at UVa. Utilize these procedures throughout the orientation process.
• Clinical Research Coordinator • Preceptor	11. Develop a position-specific training plan tailored to the expected job duties of this new employee (utilize the University of Virginia Health System Skills Checklist – Clinical Research Coordinator).
• Clinical Research Coordinator • Preceptor	12. Initiate the CRC skills checklist. 13. Provide (or arrange for) the review or training necessary for each skill itemized on the CRC skills checklist.
• Clinical Research Coordinator	14. Complete the IRB online "Protection of Human Subjects in Research" CITI program.
• Clinical Research Coordinator • Preceptor	15. Document the CRC's progress of the orientation process by finalizing the clinical research coordinator skills checklist.
	16. Identify areas/tasks that require additional training. Develop a plan to assure this training is completed.
	17 Ealuate the orientation process. (May complete Clinical Research Coordinator Post-Orientation Assessment to document evaluation.)
• Clinical Research Coordinator's Supervisor	18 File orientation documentation, curriculum vitae, copy of current licensure (if applicable), copy of all completed training, and skills checklist in CRC's training file.