



Procedure Number: 105

Title: IRB Office Staff

Adopted: 8/2012

Revised: 09/2015

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Human Research Protection Program Procedure

HUMAN RESEARCH PROTECTION PROGRAM STAFF

DESCRIPTION

All University of Cincinnati (UC) Human Research Protection Program (HRPP) staff must have sufficient qualifications, background and training to effectively protect human research participants and maintain appropriate documentation of IRB activities.

RESPONSIBILITY

The HRPP Director is responsible for assuring that HRPP staff meet and maintain qualifications as described in this policy.

PROCESS

BASIC QUALIFICATIONS

All HRPP staff must have basic qualifications in order to function effectively, including the following.

- Experience interpreting and applying regulations
- Ability to accurately interpret and apply UC HRPP policies and procedures
- Ability to identify incomplete or inaccurate elements of submissions to the IRB
- Ability to educate others on federal regulations and UC HRPP policies and procedures
- Ability to educate others on the preparation of submissions to the IRB
- Ability to identify and implement process improvements
- Ability to work in a fast-paced environment
- Good database and computer skills
- Excellent written and oral communication skills
- Ability to think critically
- Willingness to pursue professional development through continuing education

Specific responsibilities for each level of employee in the HRPP are listed in the appropriate job descriptions, which are maintained by the HRPP Director or designee.

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NEW OFFICE STAFF ORIENTATION AND TRAINING

All newly hired HRPP staff must undergo orientation to the UC HRPP, including the following topics.

- General orientation regarding UC's HRPP
 - Types of research done at UC
 - Organizational structure and responsibilities of the Office of Research Integrity (ORI)
 - Responsibilities of Quality Control/Quality Improvement and how it intersects the IRB
 - UC HRPP policies, procedures and work instructions
- Specific orientation regarding UC IRB operations
 - Procedures, work instructions and forms relating to submission and processing of human subject research (HSR) proposals
 - Job-specific instruction by the HRPP Director or designee.

All newly hired HRPP staff must demonstrate their knowledge of human research subject protections by completing required CITI training and UC specific training about FDA regulated research as described in Policy I.04 *Demonstrating Knowledge of Human Research Protection by HRPP Staff*.

CONTINUING EDUCATION

All HRPP staff must maintain current CITI certification, FDA regulated research, and Veterans Administration (VA) training as described in Policy I.04 *Demonstrating Knowledge of Human Research Protection by HRPP Staff*. Additional training and continuing education may be required by the HRPP Director.

PERFORMANCE EVALUATION

Performance evaluation of each HRPP staff member will be conducted as required by UC Human Resources (HR) policies. Additional evaluations may be done as determined to be necessary by the HRPP Director or designee.



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Applicable Regulations and Documents:

Policy I.02 *IRB Office Staff Employment*

Policy I.04 *Demonstrating Knowledge of Human Research Protection by IRB Office Staff*

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
8/2012	C. Norman	04/2014		Revisions to reflect organizational changes
3/2015		3/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 Signature signed copy on file