GUIDELINE FOR TRAINING RESEARCH PERSONNEL

In accordance with federal regulation and guidance, Office for Human Subject Protection (OHSP) Policy 901 Investigator Responsibilities states that it is the responsibility of the Principal Investigator (PI) to oversee the conduct of all research activities, including the training and education of research staff. Regulatory authorities, as well as OHSP policy, further recognize that this responsibility (or activities related to this responsibility) may be delegated to other appropriately trained and capable staff, based on departmental/division resources and infrastructure. The purpose of this guideline is to assist Investigators, Research Staff, Department Chairs, Administrators and other Senior Leadership within the University of Rochester (UR) in navigating training-related requirements, opportunities and best practices for onboarding and training personnel engaged in human subject research.

Note: The composition of a study team can vary considerably across teams, departments, and the University. The use of the terms ‘research personnel’, ‘study team members’ and ‘staff’ in this guidance is inclusive of all individuals engaged in human subject research, including but not limited to: Investigators (Principal, Co- and Sub-Investigators), Coordinators, Project Managers, Research Assistants, Research Nurses, Lab Managers, Data Managers and Student Researchers.

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Basic Training Requirements
As described in OHSP Policy 201 Education Program, all research personnel are required to complete basic Human Subject Protection (HSP) training prior to engaging in the conduct of human subject research. This training is foundational; it provides an overview of major topic areas related to the protection of human subjects that are broadly applicable to all types of research (e.g., ethical obligations related to the conduct of human subject research, informed consent, vulnerable populations, institutional review board, and regulatory requirements). Internal research personnel are required to complete this training through the Collaborative Institutional Training Initiative (CITI); refresher training is required every 3 years. External research personnel who collaborate
with UR study teams on human subject research are also subject to this training requirement, as stated in the aforementioned policy and corresponding [OHSP Guideline on Human Subject Protection Training for External Research Personnel](#). Additional training, as described in the [Quick Reference Guide: Human Research Protection Program (HRPP) Training Requirements](#), may further be *required* based on the nature of the research, an individual’s role in conducting the research, and/or the funding source.

**KEY POINT #1: Training beyond the basic HSP course is necessary for research personnel to meet their day-to-day responsibilities effectively.** The nature of basic training requirements are just that – basic; this type of training should only be treated as a starting point for trainees. The content is not all encompassing or exhaustive, nor is it study/protocol-specific.

### Best Practices for Training Research Personnel

Thoughtful planning for the training and onboarding of research personnel is a critical step for ensuring the success of the trainee, the study team and any given study protocol. Individuals can enter the research workforce from a wide array of roles, with varying responsibilities, and a range of prior research experience. Failing to adequately consider prior experience (or lack thereof) and delegated responsibilities when creating a training plan for incoming research personnel, can result in considerable ramifications for the study team, as well as the institution at-large. The inability to meet study aims (e.g., based on low enrollment, protocol non-adherence, and/or poor data quality) and jeopardizing subject safety are just two potential consequences of poor training. Inadequate preparation and onboarding can also result in job dissatisfaction, low productivity and turnover, which ultimately costs the study team in lost time, money and resources.

*Competency-Based Training*

Historically, individuals overseeing human subject research (PIs or otherwise) have relied largely on ‘on-the-job’ training, in addition to the basic training requirements described above, as a mechanism for training new research personnel. ‘On-the-job’ training, however, is typically only as effective as the experiences a trainee encounters and the experience of the mentor providing job oversight, which may or may not be accurate, complete, and/or comprehensive. Moreover, as the nature of research continues to intensify in complexity, the shortcomings related to approaching training in this manner have become increasingly problematic.

In light of these challenges and the continued need to produce a highly skilled and qualified workforce, several professional organizations have published articles and white papers supporting a competency-based training approach among clinical research professionals. Briefly, competency-based training is learner-centric; which focuses on what trainees need to *know* and *do* to meet their job responsibilities. Additional characteristics of competency-based training include structuring training in a manner that allows trainees to move, at their own pace, through a
sequential, hierarchy of training modules and assessing progress in settings that mimic real-world scenarios (1, 2).

In 2013, the Joint Task Force (JTF) for Clinical Trial Competency was convened to align and harmonize existing clinical research competency frameworks (e.g., from the Consortium of Academic Programs in Clinical Research, Academy of Physicians in Clinical Research, Association for Clinical Research Professionals, and Regulatory Affairs Professionals Society). One of the aims of the resulting harmonized competency framework is to support training initiatives and workforce development by identifying a comprehensive set of skills necessary for conducting safe, ethical and high-quality clinical research (8). The JTF framework has since been updated and a ‘leveled’ version published to reflect increased competence through career advancement (7). Additional competency statements, building off the JTF framework, have also been published through the Clinical and Translational Science Award (CTSA) Consortium’s Enhancing Clinical Research Professionals’ Training and Qualification project, including suggested edits to accommodate social-behavioral research (1).

From a training and onboarding standpoint, these publications can be utilized to identify competencies required for a given role. Once identified and prioritized, training and onboarding plans can be developed and structured in a way that supports staff in achieving the desired competencies. Training resources that are readily available to aid research personnel in meeting these competencies are identified below.

**KEY POINT #2: Have a plan.** Investigators have protocols in place to carry out their research systematically; training and onboarding should be approached in the same manner. Plans should be specific to the individual, based on their responsibilities and prior experience. Evidence further supports the utilization of a competency-based training curriculum for workforce development. Research-related competency standards can assist investigators in identifying what training may need to take place and how training should be structured.

**Knowledge & Skill Development**

As mentioned above, training should focus on both ‘knowing’ and ‘doing’ (1, 3). Staff training is often centered on knowledge development, without a useful balance of applying that knowledge in meaningful settings to foster skill development.

A common methodology for skill development is the four step process of **LEARN, SEE, PRACTICE** and **DO**, whereby a trainee learns about a specific skill or procedure by acquiring knowledge, sees the skill/procedure demonstrated, practices the skill/procedure with correction and reinforcement, and then performs the skill/procedure. More recently proposed skill development frameworks expand this process to include the additional steps of **PROVE** and
MAINTAIN. In this manner, once a trainee has practiced a skill, they undergo objective assessment to ensure a certain skill level has been obtained prior to performing the skill/procedure independently. The trainee is then further expected to maintain skill level through regular practice (4, 6).

As such, to the extent possible, building in opportunities for trainees to observe, practice and prove a trainee’s skill achievement, prior to independent performance of a given skill, will be of mutual benefit to both the trainee and supervisor/PI.

**KEY POINT #3: Knowing ≠ doing.** Trainees are not typically able to successfully apply new information automatically. Skill development requires multiple opportunities for observation, practice and feedback.

**Ongoing Training, Support & Performance Monitoring**

Trainees are not capable of retaining all the information they are exposed to in one sitting. Deliberate re-exposure of information and continued opportunities for skill observation and practice through continued monitoring and training activities are necessary, at appropriately spaced intervals, in order to enhance retrieval of the information (5, 6). Similarly, as research and the regulatory climate continue to evolve, it is essential for workforce members to remain up-to-date on developments and best practices. To accommodate continued training, support and performance monitoring:

- Set specific, measurable onboarding and training goals based on the needs/role of the individual, e.g., set goals for each quarter of the trainee’s first year based on prioritized competency statements.
- Meet regularly with trainees to review progress, discuss milestones and provide feedback. As goals are reached, create new goals or consider how to advance original goals, accordingly.
- Incorporate quality checks and/or formal quality assurance processes to assess trainee performance and proactively. Performance errors that are not identified cannot be corrected, nor prevented. Incorporating a Quality Management Plan (QMP) into an onboarding and training plan (or by protocol), using the Plan-Do-Check-Act approach, will ensure the success of your team, as well as the research.
- Use ‘teachable moments’ to enforce requirements and/or best practices. Errors and ‘outlier’ or ‘one-off’ incidents (that aren’t necessarily performance-related) are going to
happen over the course of research. Utilize such incidents to encourage trainees to reference/re-train on applicable regulations, policies and/or good practices.

- Monitor shifts in responsibilities or workload as research protocols progress through their lifecycle (i.e., start-up, implementation and closeout). Shifts in responsibility often require re-evaluation of staff training needs and time commitments. Time commitments, particularly when staff are engaged in multiple studies, with multiple PIs, can easily be overlooked and underestimated, especially as existing research protocols are completed and new ones are initiated. Overburdened staff are less likely to be able to dedicate an appropriate amount of time to continued training and are at risk for burnout and failures in performance, which can ultimately put the research, and the subjects enrolled, at risk.

- Set forth expectations for trainees to participate in continuing education opportunities and safeguard time for them to do so, e.g., set a goal for staff to participate in at least 8 hours of continuing education each performance cycle. Local continuing education opportunities, that are available at no-cost, are regularly offered thru OHSP, the Clinical & Translational Science Institute, the Study Coordinators Organization for Research & Education and several external organizations (e.g., Advarra and WIRB-Copernicus Group [WCG]).

- Financially support trainee membership in research-related organizations (e.g., Association for Clinical Research Professionals [ACRP]; Society for Clinical Research Associates [SOCRA]) and attendance at local or national research-related conferences.

### KEY POINT #4: ‘Good’ training takes time. Trainees need time to digest the information they are provided and repeated exposure to information to successfully retain and apply information. Phased (or spaced out) training, provided at an appropriate pace, will further aid retention and application.

### OHSP Training Resources
The OHSP Division of Research Education & Training, in collaboration with other UR Human Research Protection Program (HRPP) personnel, has developed online training courses available at no cost to all UR employees and students. Components of the framework were designed to align with key JTF Core Competencies (‘key’ meaning competences commonly applicable among research-related roles within the UR). These courses are meant to provide a framework of tiered training for research personnel to utilize as needed, e.g., for training, onboarding and/or remedial training purposes. Investigators, Department Chairs, Administrators and other UR Senior Leadership may utilize, require and/or recommend completion of these courses as they see fit, based upon staff roles and/or needs. A summary of the training framework, including additional recommendations for utilizing the framework are provided in the OHSP Explains...The OHSP Training Framework guidance.
Additional OHSP resources that may assist/supplement research personnel onboarding & training include:

- **Study Team Member Onboarding & Training Guide** – This document is meant to supplement the tools and resources provided by the Office of Human Resources (including the New Employee Onboarding Checklist) and provides suggestions for general orientation tasks, research-related training, systems access and training, as well as protocol-specific onboarding activities. The document is fully customizable; contents should be modified per applicable institutional, departmental, and sponsor/funding agency requirements, as well as trainee roles/responsibilities and prior experience. Sample tools, with contents tailored for generic biomedical and social-behavioral research support positions (e.g., study coordinator, research assistant) with limited experience are also available for reference.

- **Quick Reference Guide: Human Research Protection Program (HRPP) Training Requirements**

- **OHSP Explains…The OHSP Training Framework**

- **Recordings from the UR-HRPP Educational Forums** – The UR-HRPP Educational Forum is a monthly seminar series hosted by OHSP on salient HRPP topics. Sessions are routinely recorded and available for later viewing (with closed captioning) via the ‘UR-HRPP Educational Materials’ course in Blackboard (self-enrollment instructions are available here). An index of recorded sessions (with aligned JTF Core Competencies) is posted on the OHSP website.

- **OHSP Help** – OHSP Help is a comprehensive index of OHSP resources, including OHSP policies, guidelines, FAQs and written reference materials on research-related topics.

- **Click® IRB Video Vignettes** – These short video recordings are available through the ‘UR-HRPP Educational Materials’ course in Blackboard (self-enrollment instructions are available here). The videos demonstrate various roles and activities in the Click® IRB system.

- Customized, small group training – Customized training, conducted by OHSP staff, is available upon request for small groups. OHSP staff will tailor training based on your needs/circumstance (e.g., an informed consent refresher for a study team following incidents of non-compliance, an overview of the IRB review process for departmental research fellows). Please note that, due to limited resources, regular/routine one-on-one training and mentorship with individual staff is not feasible.

Note: The resources listed above are routinely updated. Staff are encouraged to reference the materials utilizing the hyperlinks available here (or via the OHSP website) rather than downloading documents.

**Additional Training Resources**
The UR’s Clinical and Translational Science Institute (CTSI) offers multiple educational programs/opportunities for a wide range of staff/roles engaged in research. A complete listing of programs is available on the [CTSI website](https://www.ctsi.urmc.rochester.edu/). Of particular note:

- **The Human Subject Research Coordinator Trainee Program** is a 1-year, competency-based workforce development program aimed at preparing individuals with little to no research experience for roles in research coordination. The program involves three months of full-time training (inclusive of shadowing experiences), followed by 80% effort engaged in research conducted (within designated departments) and 20% effort on continuing education. Departments/Investigators can utilize the program to: a) hire CTSI-employed trainees to work on research conducting within their department (this service is available on a ‘first come, first serve’ basis; or b) train planned new hires that will be employed within their department.

- **The Study Coordinators Organization for Research & Education (SCORE)** is a training, support and networking organization for research coordinators and staff. Meeting on salient research topics are provided monthly, as well as an annual half-day training symposium. Informal mentorship is also available. Additional details are available on the [SCORE website](https://www.scoreonline.org/).

The following electronic textbooks are also available online through University of Rochester Libraries:


Additional resources, external to the UR, that may be of assistance in the training and onboarding process include:

- [ACRP Course Catalog](https://www.acrp.org/courses) (Note: Courses available through ACRP are fee-based. Their training opportunities are also searchable by competency domain.)

- [Barnett International Training Courses](http://www.barnettinternational.com/) (Note: Training opportunities available through Barnett International are fee-based.)

- [Coursera.Org Courses](https://www.coursera.org/) (e.g., Design and Interpretation of Clinical Trials; Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials; Data Management for Clinical Research; Understanding Clinical Research: Behind the Statistics; Community Engagement in Research and Population Health)
• Department of Health and Human Service (HHS) Office of Research Integrity (ORI) ‘The Research Clinic’ Training
• Global Health Training Centre e-Learning Courses
• SOCRA In-Person & Online Courses (Note: Courses available through SOCRA are fee-based. Information regarding course alignment with competency domains is also available here.)
• Transcelerate Biopharma, Inc./Society for Clinical Research Site’s Informational Programs for Site Staff
• Text/E-Text Resources:

References: