

University of Florida Health Cancer Center Clinical Research Office Gainesville, FL 32610 trials@cancer.ufl.edu

GUIDANCE: Onboarding and Training New Staff

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) Standard Operating Procedure (SOP) ET-001 Training and Education of Clinical Research Staff describes the initial and ongoing training requirements for UFHCC CRO staff and Investigators engaged in research conducted through the UFHCC.

The purpose of this document is to provide new staff, managers, and the Education and Training Specialist with a detailed process to verify that all required training has been completed and documented within a given timeline prior to engaging in their role in the clinical research process.

The Training Process

ET-001, section 6.1 lists the minimum required training and certifications for new CRO staff. In addition to institutionally-mandated trainings, the UFHCC CRO requires the completion of essential trainings that provide an overview of the goals and processes of the UFHCC CRO and provide introductory, content-specific education on topics necessary to the conduct of clinical research in oncology.

When a new staff member is hired, the unit manager will email the following information to the Education & Training Specialist:

- Staff Name
- UF email address
- UFID
- Start Date

The Education and Training Specialist will enroll the new staff member into the online training course and will send a welcome email with instructions for logging in, a description of course content, and expected completion date(s). The Education and Training Specialist will also offer to meet with each staff member for a brief meeting to review the training requirements and the online learning platform.

Training Content

The UFHCC CRO Orientation is divided into three parts:

Institutionally-mandated trainings and certifications which must be completed within the first
week (for example, Privacy Training: HIPAA, UF-IRB-01 Training, Good Clinical Practice Training,
etc.) Without these trainings and certifications, clinical staff cannot be added to studies. Non-

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clinical staff may also find their ability to complete tasks blocked until this institutionally mandated training has been completed.

- Required UFHCC CRO Trainings which should be completed within the first 5 weeks and no later than 3 months from the date of hire. Without these trainings and certifications, clinical staff should not be assigned as primary coordinator to studies.
- Billing Compliance Training should be completed within the first six months of hire. Due to
 class availability, these training sessions may be more difficult to schedule. When possible and
 deemed necessary, these trainings may be scheduled specifically for UFHCC CRO as a refresher
 for experienced staff and to allow new staff to meet the requirements.

During Training

The Education and Training Specialist will monitor progress and grade assessments for the self-paced, online portion of the training. As the essential documents are received, they will be added to OnCore and the Regulatory folder in SharePoint.

Managers will monitor their new staff member's progress during this time. To assist with this, at the end of 5 weeks, the Education and Training Specialist will send a reminder to the new staff member and the manager to complete any remaining training. Other reminders may be sent before or after this time as needed.

After Training

After the trainings are complete or at the end of 3 months, whichever comes first, the transcript for the Orientation training will be generated with any missing activities highlighted. The Education and Training Specialist will send the transcript to the manager and new employee for review and signature if trainings are complete. If the staff member has not completed all trainings, it will be the responsibility of the manager to follow-up with any missing items. These items will be uploaded to the applicable assignments in the online training modules. The manager will inform the Education and Training Specialist when these items are complete and a transcript will be created and sent to the manager and employee to sign. If the training has not been completed within the first 5 months of employment, the Education and Training Specialist will send a reminder to the manager and staff member.

Other opportunities for mastering the content may be offered through the CRO Monthly Education Series, co-mentoring sessions, manager led training, etc.

Exceptions

Employees may transfer to CRO from other internal units or other institutions. In these situations, the new staff member may be excused from the required training if it can be verified that these have been

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completed at the previous position. This verification may be in the form of a training transcript, certificate of completion, or by manager approval.

NOTE: Employees transferring to different positions within the CRO may require additional training; the manager will work with the Education and Training Specialist to determine which trainings are required.

Recommendations:

- Employees who do not complete the first two parts of training should not be added to studies (Clinical Staff). The content within the first 3-5 weeks of the orientation contains vital information relevant to the UFHCC CRO staff responsibilities in research, and as such, should be taken prior to taking part in research studies.
- Managers may consider making finishing the orientation training a goal in the employee's quarterly check-ins.
- Managers may consider working with HR to extend the probation period for new employees who do not complete all required Orientation Training within the first six months of hire.

Publication Date: 3/3/2022 | 4:51 PM EST

Effective Date: 3/15/2022

Approved By:

disack 3/3/2022 | 4:51 PM EST

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