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GUIDANCE: Onboarding and Training New Investigators

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 all UFHCC CRO staff and Investigators engaged in research conducted through the UFHCC.

The purpose of this document is to provide new investigators, CRO staff, and the Education and Training Specialist with a detailed process regarding verifying 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 6.1.1 lists the minimum required training and certifications for new investigators. In addition to these mandatory trainings, the UFHCC CRO requires the completion of essential trainings which provide an overview of the goals and processes of the UFHCC CRO and which provide introductory, content-specific education on topics necessary to the conduct of clinical research in oncology at UFHCC.

When a new investigator is hired, the following information will be sent to the Education and Training Specialist:

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

The Education and Training Specialist will enroll the new investigator 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 request a welcome meeting to be scheduled with the new investigator, Associate Director of Clinical Research, and relevant CRO Unit managers for a welcome meeting within the first two weeks of the new investigator's start date. The Education and Training Specialist will also be available to meet with each new investigator for a brief meeting to review the training requirements and the online learning platform.

Training Content

The UFHCC CRO New Investigator training provides the following content:

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- Mandatory institution-required training and certifications which must be completed as soon as possible (for example, Privacy Training: HIPAA, UF-IRB-01 Training, Good Clinical Practice Training, etc.) Without these trainings and certifications, investigators **cannot** be added to studies.

- Modules which review Standard Operating Procedures of UFHCC that are aligned with Association of Clinical Research Professionals (ACRP) competency guidelines for Primary Investigators. Each module has an assessment which must be passed with at least 80% accuracy before the module is deemed complete. Investigators **should not** be added to studies until this is complete as verified by the signed transcript.

During Training

The Education & 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 saved in the investigator's Regulatory folder in SharePoint.

The Education and Training specialist will monitor the investigator's progress. Reminders will be sent as needed with the ADCR copied.

After Training

After the training is complete, the transcript will be generated and sent for signature to the ADCR and the investigator. The signed transcript will be saved in the investigator's training file on the shared drive and in the corresponding Regulatory folder in SharePoint, and an email will be sent to the cro-regulatory@ufl.edu, pmo@cancer.ufl.edu, and the appropriate unit manager. At this point, the new investigator can be added to studies.

Recommendations

There is no official deadline, but since investigators cannot be added to studies until all training is complete, the onboarding process should be completed within the first two weeks of the investigator's start date. If possible, investigators are urged to complete all UFHCC specific training prior to their official start date. Other mandatory items may need to wait until the investigator has obtained their official role(s).

References

- ACRP Functional Competency Guidelines for Principal and Sub-Investigators

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