

## OFFICE OF CLINICAL RESEARCH

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### **Policy: RESEARCH TEAM TRAINING, QUALIFICATIONS, AND DELEGATION OF AUTHORITY**

1. **PURPOSE:** To define requirements for training programs for Research Teams (RTs). To ensure the qualifications of RT members are reviewed and documented. To establish a clear delegation of authority to qualified and trained staff.
2. **POLICY:** These policy requirements apply to all members of RTs involved in conducting human subject research and are in support of the institution's Human Research Protection Program (HRPP).

[The RT includes **all individuals engaged in human subject research as determined by research role rather than title**. In addition to the Principal Investigator (PI), the team may include the following research professionals: sub-investigator, research fellow, resident, research nurse, clinical research coordinator/associate, research manager, study pharmacist, data manager, business administrator, lab manager, and regulatory documents manager.]

- a. **Training** – Health Science Center (HSC) RT members will receive training on applicable federal, state, and local regulatory requirements, and institutional policies for human subject protection. Training programs will encompass the elements described in this policy, to include sufficient content, clear statement of the required frequency of training, appropriate continuing education for the RT, and procedures for documentation of training.
  - b. **Qualifications** - The PI will affirm that all RT members are qualified via education, training, and when appropriate, licensure, to execute the human subject research protocol requirements as assigned and within their research scope of practice.
  - c. **Delegation of Authority** – The PI is responsible for the overall conduct of a research study and may delegate defined study activities and procedures to members of the RT. The delegation of the research tasks and responsibilities must be documented. No RT member may perform medical and protocol procedures outside their medical qualifications or licensures, i.e., any delegated activity must be within the employee's scope of practice [See section 3.b.(3)].
3. **RESPONSIBILITY:** The overall responsibility for the RT training, qualifications, and delegation of authority resides with the PI. Qualified investigators will obtain information verifying the RT's training, licensure, and experience. The department chairperson attests to the competency of the investigator(s) to conduct the research project in the Institutional Review Board (IRB) application. As determined by individual schools, departments, centers, or divisions, some aspects of these policy requirements may be fulfilled under policy or procedural guidance at organizational levels other than the RT.
    - a. **Training Program Development** – The PI and all members of the RT will have formal training for conducting human subject research at HSC. The RT should understand the institution's HRPP and the activities it encompasses. The PI or designee confirms that the RT training and experience is sufficient for the study-specific requirements of each protocol. Training programs may include conferences, lectures, institutional forums, workshops, online programs, applicable readings, and on-the-job training. The required elements for a training program are as follows:
      - (1) **Content**
        - (a) Good Clinical Practice training will be required for all NIH funded clinical trials, regardless of phase.

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- (b) Individual training (e.g. Sponsor-Investigator regulatory responsibilities and FDA IND/IDE application process) provided by the Office of Clinical Research (OCR) at the request of investigators or research staff.
  - (c) Human Subjects Protection and Ethics Education training per HSC OCR Policy for all research personnel conducting human subjects research.
  - (d) Applicable procedural training on the policies and procedures at the institution (e.g., applicable research HOPs and OCR/CTO/OSP/Office of the IRB policies), department, center, or division levels for each employee.
  - (e) Training programs for each team member will encompass the functions necessary to perform research activities based upon defined job description roles and responsibilities. Provide training for any areas in which the employee is not already proficient. The following areas may be considered for each RT member's orientation program in addition to the above:
    - i. Roles and responsibilities of the research staff
    - ii. Core Competencies as applicable (e.g., screening procedures, ECG, phlebotomy, CPR)
    - iii. Environmental Health and Safety Training (e.g., OSHA Universal Precautions, IATA, blood borne pathogens)
    - iv. RT Standard Operating Procedures (SOP), Work Instructions (WI), routine checklists, etc.
    - v. Informed consent process and documentation practices
    - vi. Conduct of sponsor monitoring visits
    - vii. Sponsor Clinical Research Organization (CRO) audits, institutional audits, and FDA inspections
- (2) **Frequency** - Provide specific time requirements for completing orientation training of new employees. Ensure refresher training, as appropriate, to include clear guidance for frequency of refresher training in specified areas (e.g., departmental and RT SOPs, WIs, checklists). Establish guidelines for the timeliness of training new/revised policies and procedures (e.g., required within 2 weeks of implementation).
- (3) **Documentation** - Implement procedures to properly maintain and to organize training documentation, to include a periodic review of the training program. Record the key training information, e.g., date completed, the name(s) of those who conducted and received the training, and a brief description of the training. Official, current training

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records should be readily available for each employee who is conducting human subject research.

- (4) **Study-Specific Training** – All RT members will have adequate training to perform the study-specific activity(ies) based upon the protocol and as defined by their study-related roles and responsibilities. Ensure that any study-specific training necessary is provided and documented to include training on the study Data Safety Monitoring Plan (DSMP) for the specific study.
- b. **Qualifications** – Maintain current documentation of qualifications for all RT members. If departmental or other organizational level requirements are in place for documentation concerning personnel qualifications as described, this policy is not intended to supersede or to duplicate such requirements.
- (1) **Curriculum Vitae (CV)** - Each RT member will provide an updated CV or similar statement of experience, professional qualifications, employment, training, teaching experience, publications, current employment address and position, etc., within their orientation period. Each RT member should sign and date his/her CV and update his/her CV at least every two years.
  - (2) **Licensures** - As applicable (M.D., D.O., D.D.S., R.N., P.A., M.T., etc.), each licensed RT member must show proof of professional licensure with the actual license at initiation of employment and at subsequent renewal dates. Establish procedures to identify license expirations, to temporarily suspend the employee from study participation on that date, and to reinstate the employee once a current license is provided and verified. (Texas State Boards governing licensures have online mechanisms for verifying licenses and licensed practice agreements with other states' governing boards.)
  - (3) **HSC Research Scope of Practice for Study Personnel Policy** – Provide a Scope of Practice form for each applicable RT member (see HOP 7.2.3). Upon communicating study-specific RT assignments to a sponsor or to the IRB, the PI must confirm that all applicable employees have a current Scope of Practice form on file to support the assignments.
- c. **Delegation of Authority** – The PI may not delegate overall responsibility and will ensure that the RT is qualified to perform the delegated tasks as assigned.
- (1) **Typical responsibilities** – as delegated by PIs assuming adequate training, experience, and PI oversight, may include, but are not limited to the following:
    - (a) Screening and enrolling participants
    - (b) Managing subject participation per the protocol
    - (c) Obtaining informed consent
    - (d) Maintaining regulatory/study files
    - (e) Communicating with the IRB
    - (f) Assuring proper administration of investigational product
    - (g) Reporting adverse events/UPIRSOs
    - (h) Meeting with sponsor representatives/monitors

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- (i) Overseeing study closure and reporting
- (j) Supervising other RT members
- (k) Training other RT members
- (l) Managing/coordinating the business aspects of the clinical trial
- (m) Developing/negotiating budgets
- (n) Tracking Clinical Trial Agreement (CTA) approval
- (o) Planning/coordinating the clinical trial billing
- (p) Developing/performing recruitment strategies
- (q) Tracking study enrollment
- (r) Data entry and data management
- (s) Data analysis
- (t) Manuscript writing

(2) **Study-Specific Requirements** – The PI will make sure each RT member is qualified to perform the study-specific procedures and tasks that the PI delegates and that the delegation is clearly documented.

- (a) Implement procedures to capture changes in delegation and roles as they occur throughout the course of the study. The Step-2 Institutional Research Application Form and Inst M or Form B-2, captures this information and should be updated with any changes.
- (b) In addition to the research application forms, retain a record of valid signatures (e.g., witnessed signatures) for the RT and a Delegation of Authority Log form. Keep an updated record of handwriting samples (e.g., printing, cursive, numbers) for each RT member and the dates of their participation in the study (i.e., document the beginning and end dates). Update approval as personnel changes occur throughout the course of the study.
- (c) The delegation of authority documentation is required as part of the study document files.

**d. Staff not under direct PI Supervision** – Delegation of authority extends to third parties that may not be under the direct supervision of the PI, e.g., clinical, nursing, pharmacy, laboratory or radiology services. If direct training on the protocol is warranted, the PI will ensure that it is completed and documented. The PI should take action to verify that the third party has suitable training and qualifications