

CLINICAL RESEARCH FELLOWSHIP Policy on Supervision of Fellows

Incoming fellows are residency-trained physicians, and are required to become credentialed providers at BAMC. All patient care conducted by trainees during their fellowship is coordinated by the specific clinical department associated with the trainee's certification or training. The fellows practice within the scope of their privileges. Since the research fellows are credentialed providers, they do not require PD supervision for clinical practice in contrast to other clinical fellowships.

The Program Director is responsible for ensuring that fellows work with their clinical Chief to develop a plan that allows the trainee can practice within the scope of their clinical training and fulfill their fellowship requirement to remain clinically active.

The supervision of research fellows consists of administrative functions within the Department of Clinical Investigation, as members of the Institutional Review Board at BAMC, and as research investigators.

- I. Supervision as part of the Department of Clinical Investigation.
 - a. Research Consultation Service
 - i. Protocol Reviews
 1. Fellows will have direct supervision for the scientific and regulatory review of research protocols submitted to the BAMC IRB.
 2. Fellows will present the proposal and their review of the proposal to the PD, designated program key faculty, or IRB Chair for discussion prior to representing the BAMC IRB as a reviewer.
 3. Fellows may draft and sign memoranda approving exempt or expedited research protocols, but memoranda will require a staff co-signature.
 4. After the first 6 months of the fellowship, the reviewer performance of the fellow will be assessed. The program key faculty and PD can decide to allow the fellow to review protocols independently (no longer requiring faculty approval as implied in item number 2 above). IRB approval memoranda will still require a secondary staff signature.

- ii. Administrative Functions
 - 1. Fellows may not sign administrative documents representing the BAMC IRB other than that of a protocol reviewer and IRB Member as outlined above.
- II. Supervision as a Member of the Institutional Review Board (IRB).
 - a. Review of research proposals for the “full-board” IRB Committee as an IRB member.
 - i. The fellow must become a member of the BAMC IRB within the first 60 days of fellowship.
 - 1. A memorandum of appointment to the IRB from the Commanding General or his/her designee is required.
 - 2. The Trainee must complete all required training for IRB Members.
 - 3. The trainee must attend one IRB meeting as a non-voting member prior to being able to attend as a voting member.
 - a. This requirement can be waived if the trainee has sufficient prior experience as determined by the IRB Chair and PD.
 - ii. Trainee reviews of proposals also being reviewed at the monthly IRB meeting do not have to be discussed with program faculty or PD prior to the trainee contacting the PI and representing the IRB as a member/reviewer.
 - iii. Trainees may draft approval memoranda for full-board protocols reviewed at the monthly meetings, but these memoranda must be reviewed and signed by an IRB Chair.
- III. Supervision as Clinical Research Investigators.
 - a. Trainees must complete CITI training to conduct clinical research at BAMC. This training must be renewed annually. Good Clinical Practice (GCP) training will be required for FDA regulated studies.
 - b. Trainees must have all protocols approved by the PD prior to submission to the IRB for review.
 - c. Trainees must have the PD listed on all protocols as either an Associate Investigator or as the Staff Monitor.
 - d. All human research protocols conducted must be reviewed and approved by the BAMC IRB.
 - e. Trainees will be monitored in the conduct of clinical research by the PD as staff monitor or as an associate investigator.
 - f. Trainees must submit the results of their research in manuscript form to the PD prior to graduation.

- g. Trainees must have approval of the PD for research results to be submitted to peer-reviewed journals or for research conferences.
 - h. Trainees must have PD approval of any research grant applications to prior to submission.
- IV. Supervision as graduate students in the MSCI Program.
- a. All trainees must have a supervisory committee consisting of the PD and two other MSCI Program faculty (or BAMC faculty as agreed upon by the MSCI Program).
 - b. All trainees are evaluated by the PD and Supervisory Committee semi-annually.
 - c. All trainees must have their clinical research project approved by the Committee on Graduate Studies at UTHSCSA.
 - d. Attendance at MSCI Courses is monitored by the UTHSCSA MSCI staff.