
Clinical Research Enterprise (CRE)

Standard Operating Procedure for

Scope of Practice and communication workflows for Orthopaedic Research Fellows

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	1.0	11/2023	
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Purpose

The purpose of this SOP is to explain the scope of practice and the accepted communication practices and workflows for the Orthopaedic Research Fellows.

Scope

This SOP applies to all CRE Regulatory staff, CRE Education team, CRE Administration, and Orthopaedic Research Fellows.

I. Accepted Scope of Practice for Orthopaedic Research Fellows

- a. The following activities fall under Orthopaedic Research Fellows scope of practice:
 - i Consenting
 - ii Data collection, analysis, and entry into pre-approved electronic databases
 - iii Manuscript composition and submission with PI approval
 - iv Study Concept form Completion. Please note direct IRB submissions without usage of the study concept form and involvement of the CRE regulatory team is expressly prohibited.
 - v Other observational activities under the direct supervision of Investigator
- b. Any other activities that do fall into the above categories are prohibited unless prior approval has been received by both the Orthopaedic Vice Chair of Research and CRE Compliance team.

II. Orthopaedic Study Personnel Additions Process

- a. The CRE will not process study personnel addition requests being made by anyone other than the Primary Investigator (PI) on the study. If the PI of a study would like to add a new person to a protocol, they need to reach out to me directly to the CRE regulatory team, copying the Orthopaedic Vice Chair of Research on this communication. This
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request will need to include the name of the study, IRB number, proposed personnel's role on the study, length of time that person will be involved with study activities, and oversight plan. Please note students are not permitted to conduct consenting activities.

III. Consenting workflow for Orthopaedic Research Fellows

- a. Once an orthopaedic research fellow has been cleared for consenting activities by the CRE Education team it is their responsibility to reach out to the CRE Research Nurse Educator no more than 1 week after consenting a patient and plan for the review of the consent(s) for accuracy. After you have completed a few consents and there have been no issues it is at the discretion of the Research Nurse Educator to move to monthly reviews.

IV. Access to Ortho Research Fellows Folder in ChairDOM shared drive

- a. Upon completion orthopaedic research fellows training program, CRE Education team will reach out to DOM IT to provide new onboarding orthopedic research fellows with access to Ortho Research Fellows Folder on the main ChairDOM shared drive. This will be the only folder they will have access to.
- b. Upon granting of this access, the CRE Education team will reach out to the orthopaedic research fellows with instructions for mapping the shared drive to their computers.

V. Adding Studies to Ortho Research Fellows Folder in ChairDOM shared drive

- a. Only those on the CRE Education team are allowed to add or edit study folders within the shared drive folder.
- b. Only those on the CRE Education team can add study documents to study folders within the shared drive folder.
- c. Orthopaedic research fellows are not to change names/labels of folders
- d. Orthopaedic research fellows are not to create additional folders or add studies.
- e. Orthopaedic research fellows are not to delete any information in the study folders of the shared drive folder. If an error is discovered, the orthopedic research fellow should reach out to the CRE Education team email address at CRE-education@uabmc.edu for guidance and resolution.
- f. Orthopaedic research fellows may only edit and add to the Fellows documents folder within study folder. This folder is the appropriate location for any study spreadsheets, data, or other documents that the fellow may use for data related analysis.

VI. Communication and study document dissemination

- a. The process for communication and providing orthopaedic research fellows with study documents is outlined below:
 - i. Any requests for study documents, new studies, or IRB related changes that are needed
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should be directed to the main CRE regulatory email at CREregulatory.uabmc.edu, with the CRE Education team (CRE-education@uabmc.edu) included on the communication.

- ii. When a request involving an orthopaedic research fellow has been completed, the regulatory team will respond back to those listed on the study and let them know that the request has been completed and send relevant related documents. The regulatory team will include a blurb at the bottom of the email pertaining to the placement regulatory documents in the orthopaedic research fellows shared drive folder and the need for communication of clearance by the CRE education team prior to conducting study activities.
 - iii. Only study documents from the Ortho Research Fellows Folder are to be used for used for study activities such as consenting by the Orthopaedic research fellows.
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