

STANDARD OPERATING PROCEDURE

Title: Onboarding Clinical Research Administrator (CRA) Temporary Personnel

Responsible Parties:

Principal Investigators (Clinical Faculty)
Office of Research Administration (Sponsored Programs)
Office of Compliance and Audit Services (OCAS)

Effective Date: November 17, 2020

Intent: The office of the SVPR has signed a contract with a temp agency to enhance our clinical research enterprise by providing temporary CRAs for researchers conducting extramurally funded clinical trials. Approval will depend on several factors such as availability of extramural funding, duration of study, years of experience etc. The CRA may only begin work once all requirements assigned by OCAS and/or IRB have been met. Failure to timely complete any training required thereafter may result in suspension of CRA until such requirements have been met.

Process: The following steps are designed to ensure responsible parties have properly requested and/or reviewed training requirements prior to onboarding a temporary CRA. The cost of the temp will be based on the years of experience and services required (i.e. phlebotomy, ECG, etc.) The CRA will not be allowed to start any work until requisite training is completed and verified by OCAS and the IRB, therefore we encourage requests are submitted well in advance. Note – Temporary CRA's are not eligible for assignment as 'Investigators' and are excluded from holding positions of responsibility for design/conduct/reporting of research for purposes of COI Management.

Step 1: The PI should submit an unsigned Confidentiality Disclosure Agreement (CDA) to [Sponsored Programs Administration](#) (SPA) for review, negotiation and signature.

Simultaneously, the PI will prepare and [submit](#) a completed CRA Request form.

Step 2: Upon approval, the PI will be asked to meet with potential candidates to determine suitability for the study.

Step 3: The Clinical Trial Agreement (CTA) will be reviewed and negotiated by Sponsored Programs. Once finalized, the Director of Sponsored Programs will execute the contract.

Simultaneously, the internal budget will be prepared by the study team.

Step 4: Once the candidate has been selected and the executed Clinical Trial Agreement (CTA) is in place, the sponsored award will be established.

Simultaneously, SPA will finalize the CRA request form and forward it to the Office of Compliance and Audit Services (OCAS) to ensure any and all required compliance trainings are assigned and completed. The PI/Requesting Department's Administrator will be responsible for any communications/follow-up regarding the CRA's course requirements.

Simultaneously, the PI will amend their IRB protocol to update the personnel. The IRB is responsible for contacting the CRA to complete all applicable IRB training.

Step 5: The PI/Requesting department must promptly notify SPA of any changes to the CRAs responsibilities or status of employment.