

Clinical Trials Radiology Support Core (Role and Fee Structure)

The Vanderbilt Clinical Trials Radiology Support Core provides administrative imaging support services to the Vanderbilt clinical trials community. The Department of Radiology and Radiological Sciences has made a broad set of resources available for clinical trial protocol review, study design consultation, imaging acquisition, and post-processing. In order to provide a wide range of imaging support to clinical trials, our team consists of personnel from each imaging modality. Our collaborative study review processes help to ensure more accurate billing of study procedures and performance of appropriate imaging.

The services of this support core are designed to aid Vanderbilt researchers with clinical trial initiation, image acquisition, and image data submission. This core is intended to be used as a resource for the investigator, and will in no way replace any of the functions of the investigator's research staff. The department of Radiology has worked closely with the Hospital department of Charge Integrity and the School of Medicine Office of Research to document an appropriate cost recovery plan for providing these services.

Typical Clinical Trials Radiology Support Core services:

- Review of study protocol and imaging guidelines for feasibility and determination of exact imaging exams required for trial
- Consultation on scientific merit and imaging correlatives
- Resolution of protocol implementation issues with radiologists, physicists, study coordinators and sponsors
- Close collaboration with VUMC Finance/CTBC office regarding specific exam types and exam codes expected for each trial
- Loading specialized (i.e., non-standard of care) imaging protocols onto scanners
- Completion of sponsor required training
- Phantom or volunteer scanning for study qualification
- Completion of sponsor required documents for study qualification
- Participation in Site Initiation Visits if required by sponsor
- Resolution of sponsor queries related to image acquisition
- Image de-identification and archival to CD/DVD for transmission to sponsor
- Completion of imaging data transmittal forms as requested
- Creation of study-specific Clinical Trials Imaging Instructions (CTII) forms

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Due to the varied complexity of each clinical trial, core charges may vary greatly. A current rate chart is available in the “Fees” section of our [website](#). Clinical Trials Radiology Support Core rates will be reviewed by the Office of Research on a regular basis.

NOTE: Core fees in no way affect the pricing for clinical imaging procedures. Clinical imaging exams/procedures are charged using the current VUMC billing mechanisms.

Upon iLab submission of application and study documents, a brief review will be done at no charge to provide a quote for our services. Most core charges are incurred during our trial review and setup processes. Fees are charged for full radiology review, scanner set-up, fulfillment of sponsor qualification requirements, and for creation of study-specific Clinical Trials Imaging Instructions (CTII) forms at the time of study start-up/initiation. There is no recurring “maintenance” fee associated with our services. Once a study is open for accrual and has already undergone the radiology review process, the only fees incurred would typically include the following: disc creation, recurring sponsor-required phantom scanning for quality assurance of equipment, re-review for study amendment/revision, query response, delayed qualification requests, etc.

If all of the imaging for your trial is paid via Routine Care (no sponsor-paid imaging at any time-point), and there are no special imaging acquisition guidelines or imaging qualification requirements, then Radiology review/setup (and payment of associated core charges) is usually not required.

Per VUMC Office of Research policy, charges will be billed via iLab at the end of every month for all serviced rendered during that month. We understand that the study's cost center number may not be available at the time of our review/setup process, so an interim cost center number will need to be supplied to our core until such time that the study's cost center number is available.

In order to remain compliant, all support core services will include a fee regardless of the study's status. Rates are not subject to discount and core fees will be rendered regardless of study funding. Please ensure that the budgets for your clinical trials with an imaging component are negotiated to include core fees.