Clinical Trials Radiology Support Core
New Trial Workflow Basics

Does trial have an imaging component being performed in an imaging facility that is under Clinical Trials Radiology Support Core purview (VUH Radiology, VCH Radiology, Cardiac MRI, VOI, TVC, CWI or OHO Breast Center)?

**YES**

Are any imaging exams sponsor-paid, or are there special image acquisition instructions or sponsor-mandated imaging qualifications?

**NO**

If any of the trial imaging (that will be performed in an imaging facility that is under core purview) has sponsor paid or has sponsor mandated imaging acquisition guidelines, then core review IS required.

(Please contact other imaging facilities directly to determine their trial review/setup processes.)

**YES**

How is core made aware of trial?

Ideally, researcher will submit iLab request for new trial Radiology review/setup as soon as study documents are available.

Core receives eSMART email notification regarding the new trial with imaging component. Core will request iLab submission from researcher if iLab submission has not yet been received.

**NO**

If all of the clinical trial imaging is ordered, performed and paid Standard of Care (SOC), then core review is NOT required.

(Please contact other imaging facilities directly to determine their trial review/setup processes.)

If all clinical trial imaging is performed outside of these facilities, then core review is NOT required.

Researcher submits iLab request for new trial Radiology review/setup and includes all study documents and qualification requirements.

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At this stage, Radiology Support Core review/setup processes will be placed on hold if the eSMART ID# is not yet available.

After receipt of iLab submission, the Radiology Support Core manager will perform an initial review of all study materials provided by researcher. After initial review, core manager will create a service quote for the trial. Researcher must then “agree” to the quote in iLab before core work on the trial can begin.

After quote is approved in iLab by the researcher, the core manager will perform a thorough review of all trial documents provided, upload all study materials and qualification requirements to the Radiology Protocol Review SharePoint site, and assign review and qualification completion to each modality research lead as needed.

After thorough review of study documents by modality leads, and completion of any required trial qualifications, the Radiology Support Core manager will compile all information gathered during review.

Radiology Support Core manager will submit a “pricing request” to CTBC via eSMART. This “pricing request” will include a list of all imaging exam types identified during Radiology review.

CTBC will complete the eSMART “pricing request” by entering exam CPT/CDM codes and prices. (The exam codes and prices added by CTBC to the pricing request are not actually needed by Radiology, but the “pricing request” is how the core communicates it’s review findings with CTBC.)

The CTBC team will compare the imaging exams list provided by Radiology with the eSMART billing plan provided by the researcher, and seek resolution to any discrepancies.

Core manager will work with contracts office, CTBC, and clinical researchers regarding any discrepancies found during CTBC imaging exam reconciliation process.

Core manager will create draft Clinical Trials Imaging Instructions (CTII) form for the trial. CTII form will include scheduling notes, recommended imaging exams, and technical instructions for Radiology staff.

Draft CTII forms will be sent to all modalities for review/approval as needed. Modalities will review draft CTII form and send approval to core manager.

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At this stage, Radiology Support Core review/setup processes will be placed on hold if the IRB# is not yet available.

Core manager will finalize CTII form for the trial, complete eSMART imaging and links tabs for the trial, send finalized CTII form to shared CTII drive, and send CTII form to researcher. **NOTE** for all clinical trials with a Radiology component that is sponsor paid or has specialized imaging acquisition: the CTBC team will NOT set up the trial in EPIC until the Radiology review/setup processes are complete.

After draft CTII forms are approved by all modalities, Core manager will request and verify ImageCast modifier setup for the trial.

Study is set up in EPIC by CTBC, and opened to accrual.

**The clinical researcher associates patient to trial and updates enrollment status**

Patient must be associated to trial in eStar with “active” enrollment status before study orders are entered.

Electronic imaging order is placed by clinician in eStar, and linked to trial prior to scheduling. (VUH Interventional procedures also require consult request.) EPIC then places imaging order in scheduling queue.

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