# **Emory Saint Joseph’s Hospital (ESJH) and Johns Creek:**  Procedure for Emory University (EU) faculty and Emory Healthcare (EHC)-employed physicians/staff to conduct clinical trials/research or perform diagnostic services for research purposes at ESJH and/or Johns Creek site

# Clinical trials/research involving treatment and/or diagnostic services conducted at **ESJH or Johns Creek site**:

## Update the name and address of the following on the 1572, if applicable:

### Medical school, hospital or other research facility

### Clinical lab facility

### IRB

## Submit to EU Institutional Review Board (IRB) & HIPAA Privacy Board for review & approval. Fill in Clinical Research Key Points in eIRB for Office for Clinical Research (OCR) to upload in the Emory electronic medical record (EeMR) upon an electronic notice of award (eNOA).

## Submit to EU Conflict of Interest Committee (COIC) per Emory policy.

## Submit in EPEX (or OCR listserv if not funded) for:

### OCR to develop PRA if any EHC or Grady CPT codes & to develop/negotiate budget for non-federal clinical research.

### OTT/OSP to negotiate contract or approve grant.

## Forward copy of the informed consent form and protocol to***Rebecca Heitkam***at St. Joseph’s Hospital for review per the Catholic ethical & religious directives (ERD’s) and credentialing (applies to both St. Joseph’s and Johns Creek sites). Must be approved prior to commencing research at those sites.

## If PI-initiated and/or subjects on Medicare, contact OCR to register in clinicaltrials.gov prior to enrolling first subject. If meets the definition of an applicable clinical trial (ACT) or intend to publish in an ICMJE-governed journal, contact OCR to register in clinicaltrials.gov prior to enrolling first subject.

## After eNOA issued, OCR will upload study & study level documents to EeMR, e.g. PRA, IDS Drug Data Sheet, Clinical Research Key Points.

## Register subject in Emory Research Management System (ERMS) on same day as consented for OCR to set clinical trials flag in EeMR. Fax signed consent document to OCR to upload in EeMR on same day as consented. Perform ERMS Visit Tracking on same day as subject’s visit.

## After eNOA issued for industry-supported clinical research if SOM faculty as PI, OCR will perform invoicing, accounts receivable, accounts payable, patient stipends, & travel reimbursements.

# Clinical trials/research conducted at **other Emory sites** (e.g. EUH) but isolated diagnostic services performed at ESJH or Johns Creek for research purposes due to patient convenience or equipment availability:

## If any services are billed to an Emory grant account **or** require additional equipment settings/documentation related to the research,

### Complete items A-E & G-J above under I. above.

### ***Submit request for service agreement & attach IRB approval letter via email to rebecca.heitkam@emoryhealthcare.org.***

### Does not require review for Catholic ethical & religious directives (ERDs).

## If all services are billable to third party payor according to the PRA & do not require additional settings/documentation related to the research,

### Complete items A-E & G-J above under I. above.

### Does not require review for Catholic ethical & religious directives (ERDs).

# Chart review studies conducted at **ESJH site**:

## Requires EU IRB approval.

## ***Request ESJH medical records access via email to*** ***vickie.cook@emoryhealthcare.org*** ***or*** ***patricia.wilson@emoryhealthcare.org*** ***with the following information:***

### Name

### Network ID

### IRB approval letter

### Signed EHC privacy & security awareness attestation

### List of patients or category of patients for review

## Does not require review for Catholic ethical & religious directives (ERDs).