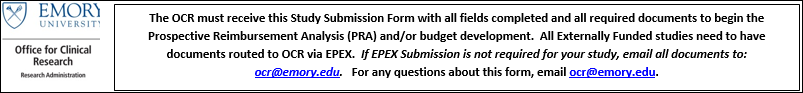
Office for Clinical Research (OCR) Study Submission Form



NEW SUBMISSION:  Y  N AMENDMENT SUBMISSION:  Y  N BUDGET ONLY SUBMISSION:  Y  N

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Required Documents and Information* | | | | | | | | | | | | |
| Completed OCR Study Submission Form  Emory IRB number  Final Protocol  Emory Draft Consent Form OR sponsor version & EU checklist | | | | | Sponsor Budget – editable version, prefer Excel  Draft Clinical Trial Agreement or Award Letter  PI Effort Sheet(s) (For funded submissions)  If amendment, tracked changes or summary of changes of protocol & ICF | | | | | | | |
| *Other Documents (If available/applicable)* | | | | | | | | | | | | |
| Y  N Draft Budget Prepared by Department  Y  N GCRC/ACTSI Budget/Cost Analysis  Y  N Radiology Checklist with Radiology Fee & Authorized  User Fee if Nuclear Medicine  Y  N Investigator Brochure | | | | | Y  N IND/IDE Exemption Letter  Y  N Lab Manual  Y  N EHC Device Form  Y  N Grady OGA Financial Clearance Form  Y  N CHOA LOI Budget | | | | | | | |
| *Principal Investigator and Department Information* | | | | | | | | | | | | |
| Name: | | | | | Office Phone #: | | | | Cell Phone #: | | | |
| School: | | Dept: | | | Division/Working Group: | | | | Email: | | | |
| *Clinical Research Coordinator Information* | | | | | | | | | | | | |
| Name: | | | | | Office Phone #: | | | | | | | |
| Email: | | | | | Cell Phone #: | | | | | | | |
| *Department/Research Administrator (DA/RA), RAS Information or Regulatory Specialist* | | | | | | | | | | | | |
| Name: | | | | | Office Phone #: | | | | Email: | | | |
| *Additional Contacts (who need to be copied on emails or sent the PRA and/or budget)* | | | | | | | | | | | | |
| Name: | | | | | Name: | | | | | | | |
| Email: | Office Phone #: | | | | Email: | | | | | | Office Phone #: | |
| *Study Information* | Protocol Title: | | | | | | | | | | | |
| Short Title/Acronym/Protocol number: | | | | | Protocol Version and Date: | | | | | | | |
| IRB#: | | | | | EPEX #:       (if applicable) | | | | | | | |
| Type of IRB: | CTA Target Enrollment #: | | | | PI-Initiated?:  Y  N | | | Estimated Study End Date: | | | | |
| Registered with ClinicalTrials.gov?: Y  N  Unknown  ClinicalTrials.gov (NCT) #: | | | | | | | | | | | | |
| *Drug or Device Information (Check all that apply)* | | | | | | | | | | | | |
| Drug Study?:  Y  N  NA IND#: | | | | IND Exempt?:  Y  N  NA IND Holder: | | | | | | | | |
| Device Study?:  Y  N  NA IDE#:  Category:  A  B | | | | IDE Exempt: (FDA approved, 510K, PMA, HDE, or Abbrev IDE): | | | | | | | | |
|  | | | | IDE Holder: | | | CMS Approved:  Y  N  NA  Pending | | | | | |
| Emory Purchasing Notified?  Y  N  NA (see form on <https://ocr.emory.edu/guidelines/forms-templates.html> then click on Investigational Devices and then the form hyperlink: View EHC Request for Investigational Device Pricing (DOCX) | | | | | | | | | | | | |
| If device not provided free, is price approved by Emory Healthcare Purchasing?  Y  N  NA | | | | | | | | | | | | |
| Name of Drug/Device (If more than 5, list on bottom of next page)-List all drugs that will be used in the study (including pre-meds) | | | | | | | | Emory/EHC/Grady to Purchase drug/device? | | | | Provided Free by Sponsor? |
|  | | | | | | | | Y  N | | | | Y  N |
|  | | | | | | | | Y  N | | | | Y  N |
|  | | | | | | | | Y  N | | | | Y  N |
|  | | | | | | | | Y  N | | | | Y  N |
|  | | | | | | | | Y  N | | | | Y  N |
| *Funding Sources (Check all that apply)* | | | | | | | | | | | | |
| Industry  Federal  Sub-Contract  Foundation  Internal  Unfunded  Other (Specify): | | | | | | | | | | | | |
| Has the budget been pre-negotiated?:  Y  N  NA | | | | | Received the Notice of Award?:  Y  N  NA | | | | | | | |
| *Sponsor Information* | | | | | Sponsor Name: | | | | | | | |
| Budget Contact: | | | | | Contract Contact: | | | | | | | |
| Email: | | | | | Email: | | | | | | | |
| Phone #: | | | | | Phone #: | | | | | | | |
| *Contract Research Organization (CRO)* | | | Y  N  NA | | CRO Name: | | | | | | | |
| Budget Contact: | | | | | Contract Contact: | | | | | | | |
| Email: | | | | | Email: | | | | | | | |
| Phone #: | | | | | Phone #: | | | | | | | |
| *Check all Facilities where Subjects will be seen* | | | | | | | | | | | | |
| Emory Clinic (TEC)  Emory University Hospital (EUH)  Emory University Hospital Midtown (EUHM)  Emory John’s Creek Hospital  Emory Saint Joseph’s Hospital  Emory Decatur Hospital  Emory Hillandale Hospital  Emory LTACH  Emory Wesley Woods Hospital | | | | | | Emory Proton Therapy Center  Emory Vaccine Center (Hope Clinic)  Emory Children’s Center (ECC)  Emory Orthopedic & Spine Hospital  Grady Health System  Grady-Ponce Center  Children’s Egleston  Hughes Spalding  Scottish Rite  Atlanta VA Medical Center (VAMC)  Other (Specify): | | | | | | |
| *Protocol Required Study Items/Services – Regardless if SOC/Routine Care – Check all that apply* | | | | | | | | | | | | |
| Physical Exam/Office Visit  Y  N | | Research Room - no EHC billable  Y  N | | | CPT code used | | No CPT code used (Effort only) \*Approved by Dept Administrator?  Y  N | | | | | |
| Use of Ancillary Department Services? | | Y  N  Has ancillary department approved participation in study?  Y  N | | | Ophthalmology  Dermatology  EPIC – Emory Personalized  Immunotherapy Core | | | | | Cellular Therapy Lab  Cardiology  List other services: | | |
| Electrocardiogram (ECG) | | Y  N | | | Sponsor provided ECG machine  Study Staff will perform  Cardiology will perform | | | | | Cardiology will read  Study staff will read  Tracing to Central Lab | | |
| Pregnancy Test | | Y  N | | | Test sent to Emory Lab  Test sent to Grady Lab  Test sent to Central Lab | | | | | Kits provided by sponsor  Kits bought by department  POC (Point of Care Testing) | | |
| Radiology/Imaging | | Y  N | | | Emory Radiology  CSI/WW  FERN  Sibley Heart Center | | Grady  CHOA  BITC  Other (Specify): | | | | | |
| Laboratory Testing | | Y  N | | | Emory Medical Lab (EML)  Emory Pathology Lab  Central Lab  Emory Research Lab  Grady Laboratory | | | | | Emory Genetics Laboratory  Other (Specify):  POC (Specify):  Additional lab preparatory fees,  provide cost: | | |
| Hospital Services | | Y  N | | | Overnight stay  PACU | | | | | Operating Room  Other: | | |
| Anesthesia/Sedation | | Y  N | | | General Anesthesia  Conscious/MAC Sedation | | | | | Local  Time required (min): | | |
| Infusion Center | | Y  N | | | Winship Phase I unit  Winship Plaza Level  Executive Park  Other: | | | | | TEC-6B  TEC-3A  GCRC | | |
| Ambulatory Surgery Center | | Y  N | | | Executive Park  EUHM | | | | | TEC-Building B-Tunnel  Other: | | |
| GCRC | | Y  N | | | Overnight stay  Infusions | | | | | Pediatric Research Center  Other: | | |
| Other CORE facilities | | Y  N | | | BITC  FERN | | | | | CSI  Other: | | |
| Patient Compensation/Lodging or Transportation? | | Y  N | | | Amount(s): | | | | | | | |
| *Comments – Additional Information or Items/Services Not Addressed Above* | | | | | | | | | | | | |
|  | | | | | | | | | | | | |

Signature of person completing the form with date:

Signature:       Date: