Office for Clinical Research (OCR) Study Submission Form



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

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| *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 <http://www.ocr.emory.edu/forms/index.html>  |
| 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 | [ ]  LocalTime 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: