

# Request for Clinical Trial Activation in ERMS for Subject Enrollment Notification ONLY

Complete all fields and submit to OCR@Emory.edu.

If you have any questions, please contact OCR at OCR@Emory.edu or 404-778-4960.

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| What is a clinical trial (CT)?A clinical trial, per the NIH, is *a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes*. A CT is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions such as drugs, treatments, behavioral modifications, devices, or new ways of using known drugs, treatments, or devices. Research with human subjects to develop or evaluate clinical laboratory tests or imaging might be considered a clinical trial if the test will be used for medical decision making or if the test itself imposes more than minimal risk for subjects.  Important: * Please do not submit this form until your study has IRB approval.
* Only submit this form if study meets the definition of a clinical trial and does not have billable items or services that may enter the EHC or Grady billing systems.
* OCR is responsible for tracking the number of clinical trials and number of active participants for reporting purposes, so these clinical trials need to be in ERMS.
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CLINICAL TRIAL: [ ]  Y [ ]  N OCR INVOICING ONLY: [ ]  Y [ ]  N

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| Study Team Information |
| Principal Investigator’s Name:        |
| PI SOM Faculty? [ ]  Yes [ ]  No  |
| Primary Clinical Research Coordinator’s Name:       |
| Additional Coordinators Needing Access to ERMS:       |
| Department:       | Division:       |

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| Study Information |
| Emory IRB Number:        | Emory IRB Approval Date:        | External IRB: [ ]  Yes [ ]  No | IRB Sensitive Study Status: [ ]  Yes [ ]  No |
| Sponsor:       | Study Acronym/Short Title:       |
| Official Protocol Title: (as it appears on the Protocol)       |
| Funding Source? (check all that apply): [ ]  Industry [ ]  Federal [ ]  Sub-Contract [ ]  Foundation [ ]  Internal [ ]  Unfunded [ ]  Other (Specify):       |
| PI-Initiated by Emory PI?: [ ]  Y [ ]  N  | EPEX # (if applicable):       |
| Use of Emory Investigational Drug Service (IDS)? [ ]  Yes [ ]  No |
| Drug Study?: [ ]  Y [ ]  N [ ]  NA IND#:       Drug Phase?       or Device Study?: [ ]  Y [ ]  N [ ]  NA IDE#:        |
| IND/IDE Holder: [ ]  Sponsor [ ]  Principal Investigator [ ]  Other:        |
| Target Enrollment # (per IRB):       | Target Enrollment # (per CTA, if applicable):       | Estimated Study End Date:       |
| Registered with ClinicalTrials.gov?: Y [ ]  N [ ]  Unknown [ ]  ClinicalTrials.gov (NCT) #:       |
| 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):       |