**ClinicalTrials.gov Database Requirements**

ClincalTrials.gov allows the registration of trials that:

1. are required to register under FDAAA 801 and the Final Rule (42 CFR part 11); or,
2. are funded by the NIH and qualify as a clinical trial under the NIH definition

**NIH Definition of a Clinical Trial**

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.

**ClinicalTrials.gov database requirements**

**General Instructions**: Please do not use any pronouns, as your submission will not be accepted. For example, please change “we” to “the investigators” and “you” to “participants.”

**Study Identification**

*Unique Protocol ID (GT protocol number):*

*Brief Title (lay language, must be sufficiently descriptive):*

*Acronym (if any):*

*Official Title:*

*Secondary IDs (NIH grant or Contract Award Number):*

*Study Type:* [Select one] Interventional / Observational / Patient Registry / Expanded Access

**Study Status**

*Record Verification Date:*

*Overall Recruitment Status:* [Select one]

Recruiting / Enrolling by invitation / active, not yet recruiting / Complete/Suspended / Terminated (halted permanently) / Withdrawn (no participants enrolled)

*Study Start Date:* MM/DD/YYYY [Select one] Actual / Anticipated

*Primary Completion Date:* MM/DD/YYYY [Select one] Actual / Anticipated

*Study Completion Date:* MM/DD/YYYY [Select one] Actual / Anticipated

**Sponsor/Collaborators**

*Responsible Party:* [Select one] Sponsor (Georgia Tech) / Sponsor-Investigator (PI)

*Sponsor:* Georgia Institute of Technology

*Collaborators:*

**Oversight**

*U.S. FDA-regulated Drug:* [Select one] Yes / No

*U.S. FDA-regulated Device:* [Select one] Yes / No

*U.S. FDA IND/IDE:* [Select one] Yes / No

*Human Subjects Protection Review:*

*Board Status:*

*Approval Number:*

*Board Name:* Georgia Institute of Technology Central IRB

 *Board Affiliation:* Georgia Institute of Technology

 *Phone:*

 *Email:* irb@gatech.edu

 *Address:*

Office of Research Integrity Assurance

 Georgia Institute of Technology

 Dalney Street Building

926 Dalney Street NW, Atlanta, GA 30332-4025

*Data Monitoring Committee:* [Select one] Yes / No

*FDA Regulated Intervention:* [Select one] Yes / No

**Study Description**

Please do not use any pronouns, as your submission will not be accepted. For example, please change “we” to “the investigators” and “you” to “participants.”

*Brief Summary (lay language):*

*Detailed Description:*

**Conditions**

*Conditions or Focus of Study (you must select these from the following database:* [*https://meshb.nlm.nih.gov/search*](https://meshb.nlm.nih.gov/search)*):*

*Keywords:*

**Study Design**

*This section varies on the type of study. Therefore, after you provide the information requested in this form, we will then follow-up to ask the variable questions that are presented in this section (please see either Observational Supplemental Questions document or Investigational Supplemental Questions document).*

**Outcome Measures**

*Instructions: Please ensure that each outcome measure only describes one unit of measure, such as weight or height. Assessments with different Units of Measure must be presented in separate Outcome Measures.*

*Instructions: Please ensure that the outcome measure explicitly include the NAME OF THE MEASUREMENT and/or MEASUREMENT TOOL used to assess the measure. Please specify the measurement (e.g. "Incidence of...", "Rate of...", "Concentration of...", "% of patients with...", etc.) and the measurement tool (e.g., descriptive name of scale, physiological parameter, questionnaire, etc.) that will be used to assess this outcome measure.*

*Primary Outcome Measure(s):*

 *Outcome 1:*

 *Title:*

 *Description:*

 *Time Frame:*

 *(Add additional Primary Outcome if needed)*

*Secondary Outcome Measure(s) (If Any):*

 *Outcome 1:*

 *Title:*

 *Description:*

 *Time Frame:*

 *(Add additional Secondary Outcome if needed)*

*Other Pre-specified Outcomes (If Any):*

**Eligibility**

*Sex:* [Select one] All / Male / Female

*Gender Based:* [Select one] Yes / No

*Age Limits:*

 *Minimum Age:*

*Maximum Age:*

*Accepts Healthy Volunteers:* [Select one] Yes / No

*Eligibility Criteria:*

 *Inclusion Criteria:*

 *Exclusion Criteria:*

**Contacts/Locations**

*Overall Contacts:*

*Central Contact Person:*

 *First Name: MI: Last Name: Degree:*

 *Phone: Ext. Email:*

*Central Contact Backup:*

 *First Name: MI: Last Name: Degree:*

 *Phone: Ext. Email:*

*Overall Study Officials:*

 *First Name: MI: Last Name: Degree:*

 *Organizational Affiliation:*

*Official’s Role:* [Select one] Study Principal Investigator / Study Chair / Study Director

 *(Add any additional Study Officials if needed)*

*Locations:*

*Facility:*

 *Name: (Lab)*

 *City:*

*State/Province: ZIP/Postal Code:*

*Country:*

*Site Recruitment Status:* [Select one]

Recruiting / Enrolling by invitation / active, not yet recruiting / Complete /Suspended / Terminated (halted permanently) / Withdrawn (no participants enrolled

*Facility Contact:*

 *First Name: MI: Last Name: Degree:*

 *Phone: Ext. Email:*

*Facility Contact Backup: (if applicable)*

 *First Name: MI: Last Name: Degree:*

 *Phone: Ext. Email:*

*Investigators:*

 *First Name: MI: Last Name: Degree:*

 *Role:* [Select one] Site Principal Investigator / Site Sub-Investigator

 *(Add Additional Investigators if applicable)*

**IPD Sharing Statement**

*Plan to Share IPD:* [Select one] Yes / No / Undecided

*Plan Description: (if applicable)*

**References**

*Citations:*

*Links:*

*Available IPD/Information: (References to de-identified individual participant data (IPD) sets and supporting information)*

**Document Section**

*Only certain studies need to have study documents uploaded.*

* *Full study protocol and statistical analysis plan -- required with results information submission for studies with a Primary Completion Date on or after January 18, 2017*
* *Informed consent forms - optional for all studies*

*Upload as PDF/A Documents*

|  |  |
| --- | --- |
| **Results Section**  | *Results submission is required by FDAAA 801 for certain* [*applicable clinical trials*](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered) *of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.* *[Record must have a ClinicalTrials.gov ID (NCT number) before results can be entered.]* |
| [*Delay Results*](https://register.clinicaltrials.gov/prs/app/template/DelayedSubmission.vm?uid=U0001CJU&ts=31&sid=S00084BH&cx=x640mj) | *For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.*  |