# STUDY REGISTRATION FOR CLINICALTRIALS.GOV

**GCO#**

**Brief Title**

**Acronym (if any)**

**Study Title**

| Secondary ID | Secondary ID Type | Grantor or Funder/Registry Name/Issuing Organization |
|---|---|---|
| | -- Select -- | |
| | -- Select -- | |
| | -- Select -- | |
| | -- Select -- | |
| | -- Select -- | |
| | -- Select -- | |

**Study Type** -- Select --

## STUDY STATUS

**Today's Date**

**Overall Enrollment Status** -- Select --

**Why Study Stopped**

**Date of 1st Enrollment** **Type** -- Select --

**Primary Completion Date** **Type** -- Select --

**Study Completion Date** **Type** -- Select --

## SPONSOR/COLLABORATORS

**Responsible Party** -- Select --

*The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements: is responsible for conducting the study; has access to and control over the data from the study; has the right to publish the results of the study; and has the ability to meet all of the requirements for submitting and updating clinical study information. When a clinical study is conducted under an IND or IDE, the IND or IDE holder is considered the sponsor.

**Investigator Name**

**Investigator Official Title**

**Investigator Affiliation** Icahn School of Medicine at Mount Sinai

## COLLABORATORS – Agencies & Organizations – NOT INDIVIDUALS

**Collaborator**

**Collaborator**

**Collaborator**

**Collaborator**

## OVERSIGHT

**Studies a US FDA-regulated Drug Product** -- Select --

**Studies a US FDA-regulated Device Product** -- Select --

**Device Product Not Approved or Cleared by US FDA** -- Select --

**Post Prior to US FDA Approval or Clearance** -- Select --

**Pediatric Postmarket Surveillance of a Device Product** -- Select --

## OVERSIGHT - CONTINUED

**US Food and Drug Administration IND or IDE Study** -- Select --

**FDA Center** -- Select --

**IND/IDE Number**

**IND Serial Number**

**Availability of Expanded Access** -- Select --

**Expanded Access Record NCT Number**

**Data Monitoring Committee** -- Select --

**FDA Regulated Intervention** -- Select --

**Section 801 Clinical Trial** -- Select --

## HUMAN SUBJECTS REVIEW

**Human Subjects Protection Review Board Status** -- Select --

**Board Approval Number**

**Board Name** -- Select --

**Board Affiliation** -- Select --

Provide the following information if other than Sinai IRB or BRANY.

**Board Name**

**Board Affiliation**

**Phone** **Extension**

**Email**

**Address**

## IPD SHARING STATEMENT

**Plan to Share IDP** -- Select --

**Plan Description – What data in particular will be saved?**

- ○ All of the individual participant data collected during the trial, after deidentification.
- ○ Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).

**IDP Sharing - Supporting Information (Check all types of supporting information that will be shared.)**

- ☐ Study Protocol
- ☐ Statistical Analysis Plan (SAP)
- ☐ Informed Consent Form (ICF)
- ☐ Clinical Study Report (CSR)
- ☐ Analytic Code

**Time Frame**

- ○ Immediately following publication. No end date.
- ○ Beginning 3 months and ending 5 years following article publication.
- ○ Beginning 9 months and ending 36 months following article publication.
- ○ **Specify Other Time Frame**

## ACCESS CRITERIA

**With whom?**

- ○ Anyone who wishes to access the data.
- ○ Researchers who provide a methodologically sound proposal.
- ○ Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose.

**For what type of analysis?**

- ○ Any purpose.
- ○ To achieve aims in the approved proposal.
- ○ For individual participant data meta-analysis.

**By what mechanism will data be made available?**

- ○ Data are available indefinitely at (*Link to be included in the URL field below)*.
- ○ Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (*Link to be included in the URL field below).*
- ○ Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (*Link to be included in the URL field below*).
- ○ **Specify Other Mechanism**

**URL**

## Available IPD/Information

**References to deidentified individual participant data (IPD) sets and supporting information.**

**Data/Information Type** -- Select -- **Other**

**URL**

**Identifier**

**Comments**

**Data/Information Type** -- Select -- **Other**

**URL**

**Identifier**

**Comments**

**Data/Information Type** -- Select -- **Other**

**URL**

**Identifier**

**Comments**

**Data/Information Type** -- Select -- **Other**

**URL**

**Identifier**

**Comments**

## STUDY DESCRIPTION

**Brief Summary**

**Detailed Summary**

* For Patient Registries

Also describe the applicable registry procedures and other quality factors (for example, third party certification, on-site audit). In particular, summarize any procedures implemented as part of the patient registry, including, but not limited to the following:

- Quality assurance plan that addresses data validation and registry procedures, including any plans for site monitoring and auditing.
- Data checks to compare data entered into the registry against predefined rules for range or consistency with other data fields in the registry.
- Source data verification to assess the accuracy, completeness, or representativeness of registry data by comparing the data to external data sources (for example, medical records, paper or electronic case report forms, or interactive voice response systems).
- Data dictionary that contains detailed descriptions of each variable used by the registry, including the source of the variable, coding information if used (for example, World Health Organization Drug Dictionary, MedDRA), and normal ranges if relevant.
- Standard Operating Procedures to address registry operations and analysis activities, such as patient recruitment, data collection, data management, data analysis, reporting for adverse events, and change management.
- Sample size assessment to specify the number of participants or participant years necessary to demonstrate an effect.
- Plan for missing data to address situations where variables are reported as missing, unavailable, non-reported, uninterpretable, or considered missing because of data inconsistency or out-of-range results.
- Statistical analysis plan describing the analytical principles and statistical techniques to be employed in order to address the primary and secondary objectives, as specified in the study protocol or plan

## CONDITIONS AND KEYWORDS

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study Use appropriate descriptors from NLM's MeSH-controlled vocabulary thesaurus or terms from another vocabulary, such as the SNOMED CT that has been mapped to MeSH within the UMLS Metathesaurus.

**Condition**

**Condition**

**Condition**

Keywords - Words or phrases that best describe the protocol. Be as specific and precise as possible. Avoid acronyms and abbreviations

**Keyword**

**Keyword**

**Keyword**

**Keyword**

**Keyword**

**Keyword**

## STUDY DESIGN – INTERVENTIONAL STUDY

**Primary Purpose** -- Select --

**Study Phase** -- Select --

**Intervention Model** -- Select --

**Model Description**

**Number of Arms**

**Masking (Check all Roles that are masked or check None)**

- ☐ Participant
- ☐ Care Provider
- ☐ Investigator
- ☐ Outcome Assessor
- ☐ None (Open Label)

**Masking Description**

**Allocation** -- Select --

**Enrollment – Number of Subjects** **Type** -- Select --

## STUDY DESIGN – OBSERVATIONAL STUDY

☐ **Patient Registry**

**Study Model** -- Select --

**Time Perspective** -- Select --

**Biospecimen Retention** -- Select --

**Biospecimen Description**

**Enrollment** **Type** -- Select --

**Number of Groups/Cohorts**

**Target Follow-up Duration** -- Select --

## STUDY DESIGN – EXPANDED ACCESS

**Expanded Access Status** -- Select --

**Type:**

☐ **Not Applicable**

☐ **Individual Patients**

☐ **Intermediate-Size Popultation**

☐ **Treatment IND/Protocol**

## ARMS, GROUPS & INTERVENTIONS

**1. Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

**2. Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

## ARMS, GROUPS & INTERVENTIONS - CONTINUED

**3.** **Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

**4.** **Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

## ARMS, GROUPS & INTERVENTIONS - CONTINUED

**5.** **Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

**6.** **Arm Name**

**Arm Type** -- Select --

**Arm Description**

**Intervention Type** -- Select --

**Intervention Name**

**Other Intervention Name**

**Intervention Description**

# OUTCOME MESSURES

## PRIMARY OUTCOME MESSURES

**Title**

**Description**

**Time Frame**

## SECONDARY OUTCOME MESSURES

1. **Title**

   **Description**

   **Time Frame**

2. **Title**

   **Description**

   **Time Frame**

## SECONDARY OUTCOME MESSURES - CONTINUED

**3. Title**

**Description**

**Time Frame**

**4. Title**

**Description**

**Time Frame**

**5. Title**

**Description**

**Time Frame**

## SECONDARY OUTCOME MESSURES - CONTINUED

**6. Title**

**Description**

**Time Frame**

**7. Title**

**Description**

**Time Frame**

**8. Title**

**Description**

**Time Frame**

## ELGIBILITY

**Sex** -- Select --

**Gender Based** -- Select --

**Gender Eligibility Description**

**Age Limits**

**Minimum Age** **Unit of Time** -- Select --

**Maximum Age** **Unit of Time** -- Select --

**Accepts Healthy Volunteers** -- Select --

**Eligibility Criteria**

## FOR OBSERVATIONAL STUDIES ONLY

**Study Population Description**

**Sampling Method**

-- Select --

## CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

### CENTRAL CONTACT

**First Name** | **MI** | **Last Name** | **Degree**

**Phone** | **Ext** | **Email**

### CENTRAL CONTACT BACKUP

**First Name** | **MI** | **Last Name** | **Degree**

**Phone** | **Ext** | **Email**

### OVERALL STUDY OFFICIAL - 1

**First Name** | **MI** | **Last Name** | **Degree**

**Organization Affiliation**

**Official's Role** -- Select --

### OVERALL STUDY OFFICIAL - 2

**First Name** | **MI** | **Last Name** | **Degree**

**Organization Affiliation**

**Official's Role** -- Select --

### OVERALL STUDY OFFICIAL - 3

**First Name** | **MI** | **Last Name** | **Degree**

**Organization Affiliation**

**Official's Role** -- Select --

## LOCATION - 1

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## LOCATION – 2

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## LOCATION – 3

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## LOCATION – 4

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## LOCATION – 5

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## LOCATION – 6

**Facility Name**

**City** **State** -- Select -- **Zip** **Country** -- Select --

**Site Recruitment Status** -- Select --

### FACILITY CONTACT

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

**Phone** **Ext** **Email**

### FACILITY CONTACT BACKUP

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

**Phone** **Ext** **Email**

### INVESTIGATOR

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

**Role**

## REFERENCES

### CITATIONS

| | | |
|---|---|---|
| **PMID#** | **PMID#** | **PMID#** |
| **PMID#** | **PMID#** | **PMID#** |
| **PMID#** | **PMID#** | **PMID#** |
| **PMID#** | **PMID#** | **PMID#** |
| **PMID#** | **PMID#** | **PMID#** |

### LINKS

**URL**

**Description**

**URL**

**Description**

**URL**

**Description**