

Inspiring New Science In Guiding Healthcare in Turner Syndrome (INSIGHTS) Data Request and Use Policy

OVERVIEW

This document provides guidelines for requesting data from the InsignTS Registry. The goal is to establish a national, multicenter, prospective, longitudinal clinical data registry to improve clinical outcomes in individuals with Turner syndrome (TS).

INSIGHTS DATA SYSTEM

InsignTS data includes all registry, questionnaire, and biobank data for individuals with Turner syndrome participating in InsignTS at one of the consortium clinics. Registry data includes demographic information, diagnostic information, medications, vital sign parameters, laboratory values, and select patient reported data. Data are entered into a secure online application, Research Electronic Data Capture (REDCap), housed at the University of Colorado. Contact insights@ucdenver.edu for specific data elements.

NATURE OF DATA PROVIDED

Requests may be for a subset of de-identified raw data or summary statistics. More complex analyses will be considered, but may not be possible depending on the available resources. Requests for identifiable data will not be provided.

For studies proposing using InsignTS to contact and recruit participants, the proposed process to contact potentially eligible individuals should be made through InsignTS.

DATA REQUESTS

Requests for Data Access from Non-InsignTS Registry Member Investigators/Individuals

Requests for InsignTS Registry data access from non-member investigators and/or individuals must be accompanied by written verification of sponsorship by an investigator who is a member of the InsignTS consortium. It is expected that the sponsor will work closely with the investigators and/or individuals for use of data to ensure it remains within the goals of the InsignTS Registry.

Submitting a Request

Investigators may submit data requests using the template attached. Requests should be no longer than 3 pages.

Approval of Requests

Data use requests will be reviewed by the Steering Committee within one month of submission. The committee will consider the applicability and priority of the study question, the ability of the study team to appropriately use the data, the workload and feasibility for the InsignTS

study team, and the impact of this study on the TS community. Priority for requests will be given to teams actively contributing data to the registry. If you plan to publish or present results, you will be expected to follow the InsignTS Publication Policy.

Anticipated Timeline

TEMPLATE FOR PROPOSAL FOR DATA USE

Table of Contents

- A. Requestor Information
- B. Specific Aims
- C. Background and significance
- D. Study design and analytic plan
- E. Community engagement
- F. Dissemination
- G. Project team
- H. References

A. Requestor Information

Requestor name: _____

Project team lead: _____

Requestor contact information (include institution, mailing address, email address, phone #): _____

InsighTS Sponsor (if requestor is not part of the InsighTS consortium): _____

Is this request associated with a funded project or grant proposal: _____

If yes, provide the name of the project/proposal and details on the funding source(s) and grant number(s) if applicable: _____

Main purpose of this request:

- Analysis of data for peer-reviewed publication
- Analysis of data for presentation
- Recruitment of individuals/families into a new research project
- Summary statistics for use in proposal or report
- Other (please specify):

If presentation or publication, requester must agree to the publication policy.

B. Specific Aims

State the goals of the proposed project and hypotheses/research questions you aim to answer using InsighTS data.

C. Background and significance

Describe the impact of the proposed project for patients with Turner syndrome and/or their families. Identify gaps in the literature and how this project will fill them. Describe how the proposed project focuses on questions that affect outcomes of interest to patients/families.

D. Study design and analytic plan

Describe the methodologic/statistical approach including a conceptual model or theory that anchors the background/significance of the project and informs the study design.

D.1 Variables

Describe the key variables and relationships being tested, including a list of variables needed from the registry.

Dependent Variables: List the variables that are the main outcomes of interest and state which items in the InsignTS data dictionary will provide information on these outcomes. Include form name and item number.

Independent Variables and Covariates: List all other variables that are necessary for the analysis, including demographic information. Include form name and item number.

D.2 Statistical Analysis

Describe a priori plans for data analysis that correspond to the project's aims. Provide the sample size and power, if applicable. If using a sub-set of registry participants, list inclusion and exclusion criteria.

E. Community engagement

Describe the plan to engage patients and stakeholders meaningfully in the project. Describe what stakeholders will be engaged, at what stages of the project they will be engaged, and what level of engagement they will have. If you have multiple stakeholder groups involved, describe the role of each in the project.

Every project should have some level of community engagement. If you need assistance putting this into action or generating ideas, the InsignTS Steering Committee can help.

F. Dissemination

Describe how you will make project findings available to: the InsignTS Steering Committee, InsignTS registry participants and their families, patients with Turner syndrome and their families broadly, and clinicians working with Turner syndrome patients. All results will be posted on the InsignTS website.

G. Project team

Describe the team's capacity to accomplish the goals set forth in this project, including each team member's expertise in relation to the proposed project. Include proposed authors for any publication or presentation is to come from this request.

H. Timeline

Describe the timeline for completion of your project.

I. References

List the source material cited in this proposal using an accepted and consistent citation style.