The Turner Syndrome Research Registry

A Project of the Turner Syndrome Society of the United States

Turner Syndrome Research Registry Data Utilization General Information

Mission Statement: Promote research excellence in Turner syndrome by providing a central, private, and secure patient-powered online registry where individuals with Turner syndrome can share health information with researchers to improve their health and well-being

Dear Investigator,

Thank you for contacting the Scientific Advisory Board (SAB) of the Turner Syndrome Research Registry (TSRR). The TSRR was developed to allow scientists, clinicians, patients and families an opportunity to better understand Turner syndrome. Data in the TSRR is a collection of individual registry participants' self-reported health information. Permission for data use is controlled by the participant. We have also established the Turner Syndrome Research Repository-Northwest (TSRR-NW), that will include genotyping data. TSRR-NW data can be used in concert with TSRR data (see appendix). The overarching goal of the SAB is to allow researchers to utilize this data while also protecting registry participants' privacy.

The SAB periodically reviews and selects data utilization projects that appear to be most promising for advancing knowledge within the Turner syndrome field. This may include any research project, protocol, or pilot study being conducted by an investigator who is considered by the SAB to be studying a topic that is relevant to understanding Turner syndrome. For more information about the SAB and or the Turner Syndrome Society of the United States (TSSUS), please refer to www.turnersyndrome.org and a recently published paper.[1]

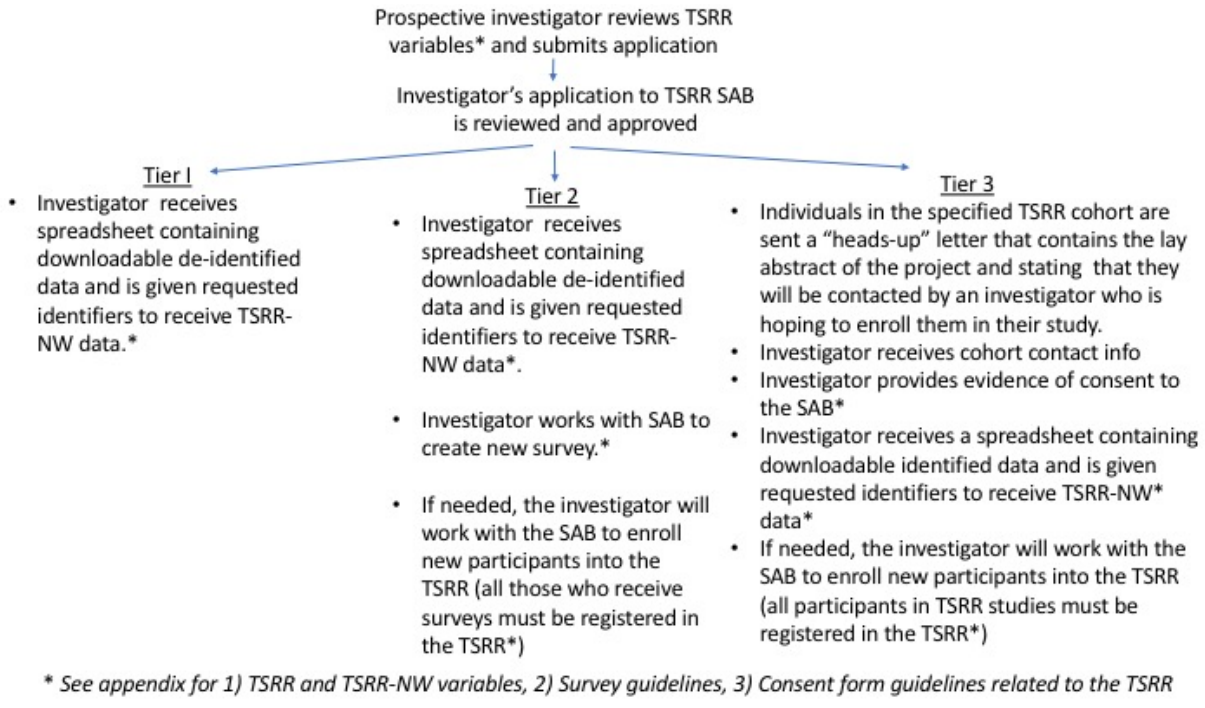
Data utilization research using the TSRR is categorized as follows

- Tier 1
  - Investigators receive access to de-identified data in the TSRR.
- Tier 2*#
  - Investigators request the collection of de-identified data that does not currently exist within the TSRR. This involves working with TSRR staff to create a new survey. #
- Tier 3*#@
  - Investigators request identified data and invite qualified participants to enroll in new research (IRB approval and signed consent is mandatory)
  - Study cannot be done within the scope of the TSRR (for example the collection of neuroimaging data or bio specimens.)
  - Investigators will submit new data generated for Tier 3 projects to the TSRR.

∗ *Approval for Tiers 2 and 3 automatically allows access to Tier 1data.*
\# *TSRR will support survey development and provide requested data.*
@ *The SAB will work with the investigator to specify which data will be eventually submitted to the TSRR.*

Turner Syndrome Research Registry

Prospective applicant work flow:



** See appendix for 1) TSRR and TSRR-NW variables, 2) Survey guidelines, 3) Consent form guidelines related to the TSRR*

Minimum Requirements for TSRR Data Utilization

- The research proposal must advance knowledge about health care conditions associated with Turner syndrome.
- If approved by the SAB the researcher must:
  - Acknowledge the TSRR in all publications, grant proposals, presentations, or discussions with the media.
  - Provide updates and or final summary/findings of the study to the SAB annually.
  - Agree that study materials or new study findings will be made available by the applicant to the TSRR as agreed upon. The time-frame and the mechanism through which new information will be incorporated into the TSRR will be determined on a case-by-case basis. "Materials" or "New findings" may include but are not limited to information obtained from the medical record, annotated genetic information (DNA or RNA sequencing), other biomaterials (blood, saliva, etc.), images, or other materials. What constitutes "materials" or "new findings" will be determined by the SAB in collaboration with the investigator prior to study approval.
  - IRB consent will outline what materials and new findings will be shared with the TSRR.
  - For Tier 3 projects demonstration of IRB approval is required prior to the SAB final review.
  - Contact information, new findings or materials may not be shared outside of the TSRR without the express permission of the TSRR Scientific Advisory Board. "Sharing data" includes but is not limited to sharing with other investigators, registries/repositories/databases.

- IRB-approved consent forms for Tier 2 (if necessary) and for all Tier 3 projects must state that participation is contingent upon joining the TSRR. https://www.turnersyndrome.org/research-registry (see appendix for information about how a potential study participant can join the TSRR)

Standard Information Required for TSRR Data Utilization Application Review

- Completed research proposal application
- Description of how the proposed study will be funded
- Financial disclosures for all involved investigators
- NIH Biosketch for the Primary Investigator and all Sub Investigators http://grants.nih.gov/grants/forms/biosketch.htm
- Full proposal, including hypothesis, background and significance, methods (length not to exceed five pages excluding references)

- Copies of proposed new surveys (if applicable). Surveys must:
  - Request new information (surveys and questions which duplicate existing TSRR data will need to be revised)
  - Ask questions that are reliably self-reported.
  - Conform to survey guidelines (see appendix including common data instrument, CDI)

The SAB review process

Applications for data utilization projects will be reviewed by the SAB on a rolling basis. Review will be a staged process. Those that are not triaged and are considered likely to be approved will be assigned an SAB member who will serve as a proxy on behalf of the Board and the Registry Participants. This board member begins a more detailed vetting process that will further assess the feasibility of the project, and provide guidance regarding creation of surveys and the portions of the consent form that relate specifically to the TSRR (see appendix for details). There will then be a second meeting of the SAB to consider final approval. Every effort will be made to complete this process within 120 days of receipt of the application. Responses from the Board will be “Yes”, “Yes with modifications” or “No.”

Questions about the application or process may be directed to Michael Silberbach MD, Chairman, TSRR Scientific Advisory Board (silberbm@ohsu.edu)

Turner Syndrome Research Registry Data Utilization Investigator Application Form

Title of Proposed Project:

Primary Investigator:

Title and Affiliation of Primary Investigator:

Institution of Primary Investigator:

Email:

Address:
Address1

Address2

Address3

City State Zip Code Country Postal Code

Phone:

Fax:

Names, Titles, Affiliation, and email address of all sub investigators:

Research category - Select only one (See page 1 of application for description of Tiers):

___ Tier One ___Tier Two ___Tier Three

1. Provide an abstract of the research to be performed (language should be at the level of a clinical scientist who has general knowledge of Turner syndrome health; < 300 words).

2. Study Population: In addition to a brief general description of the group of TS participants you wish to study, list the survey variables from the existing TSRR dataset (see appendix). This information will help the SAB work with you to specify your study cohort.

3. Provide a detailed description of the research to be performed including background, rationale, hypothesis, methods, expected results, statistical considerations, and quality assurance/quality control to be followed (limit to 5 pages).

4. Describe the funding and resources that will allow you to successfully complete this project.

5. For Tier 3 projects specify what new materials or data you will acquire as a result of your study. New materials or data may include: biological samples (urine, cheek cells, blood, or other tissues) or new data (psychological tests or other medical test results, laboratory results. State the format for collected new data (medical records, spreadsheets, standardized tests, word/text files, echo, MRI or other imaging, Highlight any new materials or new data that you think will be important to share with the TSRR.

6. Summarize the potential impact of your study. What important questions will your study solve or contribute to understanding?

7. Provide a short abstract of the proposed project and its significance using lay language (<150 words) that can be sent to participants. This will be used to promote your study and will also be included in the "heads-up" letters (see "Tier 3 work flow above) that will be sent to participants before you contact them for consent.

8. Provide a timeline from initiation of study to publication/release of study results.

9. Result summaries must be available to the SAB for review in an annual report of research progress. Please initial to confirm that you agree to this. _____

10. Are you willing to:
    - Allow import of certain new materials or data into the TSRR? Please initial to confirm that you agree to this. _____
    - Provide a lay summary (< 500 words) as well as a scientific summary (1 page that can be made available to TSRR participants, their community and the scientific community? Please initial to confirm that you agree to this. _____
    - Allow publications listed on the TSRR website? Please initial to confirm that you agree to this. _____

11. State what information or documents your funding source(s) and institution will require from the TSRR.

12. IRB approval must be active for the duration of your research study. Please initial to confirm that you agree to this. _____

13. The IRB consent form must include acknowledgement that new information including new materials and/or data will be placed in the TSRR

14. IRB-approved consent forms for Tier 2 (if necessary) and for all Tier 3 projects must state that participation is contingent upon joining the TSRR. https://www.turnersyndrome.org/research-registry

15. Final acceptance will depend on demonstration of IRB approval of the study.

16. Proof of consent for Tier 3 projects is required before receiving identfied data from the TSRR.

17. Attach the following additional information:

- NIH Biosketch for PI (and mentor if applicable) :
- NIH Biosketch for all sub investigators, if applicable:
- Financial disclosures for PI:
- Financial disclosures for all sub investigators, if applicable:

18. How did you hear about the TS Research Registry?

By signing below, I certify that the statements made in this application are accurate, true, and complete to the best of my knowledge.

_____

Signature of Primary Investigator Date

Reference cited:

1. Prakash SK, Lugo-Ruiz S, Rivera-Davila M, Rubio N, Jr., Shah AN, Knickmeyer RC, Scurlock C, Crenshaw M, Davis SM, Lorigan GA, Dorfman AT, Rubin K, Maslen C, Bamba V, Kruszka P, Silberbach M and Scientific Advisory Board of the T. The Turner syndrome research registry: Creating equipoise between investigators and participants. *Am J Med Genet C Semin Med Genet*. 2019;181:135-140.