

Document ID WSTR008	Title Publications	Effective Date 11/1/2019
Version 1.0	Prepared by Ally Avery, Manager	Date prepared 11/1/2019
	Approved by Glen Duncan, Director	Date approved 2/12/2020

Policy Investigators using data from the Washington State Twin Registry (WSTR) must adhere to publication policies for all abstracts and manuscripts derived from analyses of the data.

Purpose To ensure the integrity of publications using data from the WSTR.

Scope All manuscripts and abstracts submitted for presentations and publications derived from WSTR data obtained from WSTR participants, including survey, biologic, and objectively collected data, must be submitted for scientific review by the WSTR. Submission to the WSTR must occur at a minimum of 2 weeks prior to the journal or conference deadline.

Responsibilities

The Director will provide final approval for manuscripts and abstracts.

The Scientific Operations Manager (SOM) will keep track of all abstracts and manuscripts in progress, abandoned (i.e., no longer planned for submission), and published.

Procedures

1.0 Manuscript Proposals

- 1.1 Manuscript proposals must address specific hypotheses that can generally be completed within a period of 24 months. If the proposal takes longer than 24 months, an extension can be requested for an additional 6 months. Authors should not proceed with a manuscript (i.e., writing up the results in a format that would subsequently be submitted to a peer reviewed journal for consideration of publication) without an approved manuscript proposal (**WSTR008.1**).
- 1.2 For each new manuscript proposal, a writing group will be determined by the proposer, with input from the WSTR if requested by the proposer or suggested by the WSTR.
- 1.3 The first author will generally be the proposer, unless that proposer indicates in writing that he or she nominates another member of the writing committee to be lead author (e.g., a student).
- 1.4 If the first author is a student, a mentor sponsorship letter must be included with the manuscript proposal that includes information about the purpose of the project and the student’s role, a statement describing the mentor’s support of and commitment to the proposed project, and the projected timeline for completion.
- 1.5 Proposals must include an analysis plan as well as the information of the individual who will conduct the statistical analysis. If this person does not have previous experience with twin analyses, they will be required to consult with the WSTR behavioral genetics analyst who will approve the analysis plan. There is an hourly rate involved with this consultation.
- 1.6 Proposals must include all variables needed for the analysis as well as inclusion/exclusion requirements. Changes to the dataset will require an amendment to the manuscript proposal. **Only variables related to the outcome of interest will be included in datasets**; a proposer cannot request *all* the variables in the WSTR archive. A full list of available variables can be found in Attachment 1.

- 1.7 Geocoded addresses will not be provided unless IRB approval from the proposer's institution has been obtained. If geocoded addresses are required for the analysis, IRB approval must be sent to the WSTR before data will be released.
- 1.8 Proposals for consortia manuscripts where WSTR data is pooled with other cohorts will need to be approved, but the overview and analytic plan may be brief.
- 1.9 Proposals must include intended or potential journals to which the manuscript will be submitted. Journals will be reviewed for scientific integrity to avoid predatory journals.
- 1.10 If data is used for purposes other than what is included in the manuscript proposal, or findings are published without approval from the WSTR, the proposer will be barred from further access to WSTR data.

2.0 Authorship

- 2.1 The WSTR has established an authorship policy to facilitate collaborations and prevent authorship disputes to the extent possible. The WSTR has adopted authorship guidelines established by the International Committee of Medical Journal Editors, which stipulate the following conditions:
 - Making substantial contributions to the conception and design of the study, or the acquisition of study data, or the analysis and interpretation of study data.
 - Drafting the manuscript critically or revising it for important intellectual content.
 - Providing final approval of the version of the manuscript to be published.
- 2.2 All authors should meet all three conditions.
- 2.2 The lead author will determine the order of authorship. A major criterion for the order of authorship is the level of effort and contribution made by the members of the writing group.
- 2.3 It is the responsibility of the lead author to communicate with other writing group members, to identify data needed, and to establish a plan for writing the manuscript.
- 2.4 All members of the writing group should review and approve the final manuscript proposal and the final manuscript draft before submitting for WSTR review.
- 2.5 All authors must be willing to take public responsibility for their contribution to the work.
- 2.6 WSTR faculty and staff may meet the requirements for authorship and should be included as a co-author where appropriate. Examples of contributions include refining the design of the study, identifying a specific research question, providing substantial input on the analytic plan, and writing sections of the manuscript.
- 2.7 Contributions from WSTR faculty and staff that do not qualify for authorship include providing samples or data, offering technical advice, and providing general supervision of the research group. Contributions that do not qualify for authorship must be acknowledged in the resulting manuscript.

3.0 Data Availability

- 3.1 Data will be released to the proposer only after a completed data use agreement has been signed. A data use agreement must be signed by all individuals with access to the data. No WSTR data may be shared with individuals not listed in the data use agreement.
- 3.2 Core WSTR data: Survey data from the WSTR includes the enrollment survey and the follow-up Health and Wellbeing survey. All twins complete an enrollment survey and may have one or more follow-up surveys in 3-4-year intervals from enrollment. To ensure consistency in measurements, only enrollment surveys completed after January 2009 are included. The variable availability attachment (**Attachment A**) lists all available variables by survey and subject.
- 3.3 Completed ancillary study data: Data is available for studies that used the WSTR to collect new data; only those that have reached the end of their exclusivity period and have been integrated into the WSTR database are available. The completed ancillary study attachment (**Attachment B**) lists all studies that are available and provides a basic summary of the data available.

3.4 Ongoing ancillary study data: Investigators using data for a study that is still in the exclusivity period must provide which variables will be used in the analysis and indicate if any variables from the WSTR are needed for analysis.

4.0 Abstracts for Conferences

4.1 Abstracts must be based on an approved manuscript proposal and submitted **at least** 2 weeks prior to the conference submission deadline. Notification of abstract acceptance must be sent to the WSTR SOM upon receipt.

4.2 The final conference poster or presentation should be sent to the WSTR SOM after the conclusion of the conference.

5.0 Manuscript Updates and Review

5.1 On a quarterly basis, the WSTR SOM will send an email with a link to provide updates on all abstracts and manuscripts that are currently in process (**WSTR008.3**), including an intended submission date and intended journal. Intended journals will be reviewed for scientific integrity as noted previously.

5.2 Any changes to the proposal must be submitted to the WSTR and approved prior to analyses being conducted. All amendments will require a written explanation for why the changes are being made. A link to this form (**WSTR008.2**) will be provided in the manuscript approval. Significant changes such as changes to the specific aims or statistical analysis plan may require a new manuscript proposal.

5.3 If no substantial progress is made to the manuscript after a 12-month period, the WSTR will consider the proposal abandoned. Should an author wish to continue the project at a future date, a new proposal must be submitted and approved.

5.4 Final drafts of the manuscript along with the syntax used to conduct the analysis must be sent to the WSTR SOM prior to journal submission. The manuscript will be reviewed for accuracy of the data reported as well as the methods of analysis.

5.5 Manuscripts must be submitted at least 2 weeks before the submission deadline to ensure adequate time for review. The Director will review each manuscript and grant or deny approval within 2 weeks of receipt. If substantial changes are needed, manuscripts may need additional review before granting final approval.

6.0 Post-Submission Process

6.1 Once the manuscript has been submitted, the proposer or first author must inform the WSTR SOM within one week of the journal to which the manuscript was submitted as well as the submission date.

6.2 If the manuscript is accepted, the final published version must be sent once available.

6.3 If the manuscript receives a revise and resubmit with substantial changes to the analytic plan required, the proposer must submit an amendment that outlines the required changes. A tracked-changes version of the manuscript as well as a brief summary of the changes must be submitted to the WSTR before resubmitting to the journal (i.e., the point by point response to reviewers and the revised manuscript).

6.4 If the manuscript is rejected and the author decides to revise and submit to a new journal, the author must submit an amendment outlining the changes to the analytic plan, if appropriate, and the new proposed journal.

6.5 Proposers using a single dataset created from the WSTR database (i.e., the archive of data) must destroy the dataset once the final version of the manuscript has been published. If the manuscript is rejected and the author chooses not to submit to another journal, the dataset must be destroyed. Proposers will be sent a dataset removal certification form (**WSTR008.4**) once the WSTR SOM has been notified of manuscript status.

7.0 Acknowledgement

7.1 All manuscripts, presentations, and other publications must acknowledge the use and support of the WSTR. We recommend the following language for the acknowledgement statement: "This project was conducted, in part, with support from

the Washington State Twin Registry. We wish to thank the twins for taking part in the Registry.”

Forms

- WSTR008.1: Manuscript Proposal Form
- WSTR008.2: Manuscript Amendment Form
- WSTR008.3: Manuscript Status Form
- WSTR008.4: Dataset Removal Certification

Attachments

- Attachment A – Core WSTR Data Variable Availability
- Attachment B – Completed Ancillary Studies

Revision History:

Revision	Date	Description of Changes	Requested by
0.0	10/10/2019	Initial Release	
1.0	2/12/2020	Final Version	

Manuscript Proposal

Please allow 2 weeks for proposal review.

Full Title

Abbreviated title (max 40 characters)

Keywords

This proposal is for (choose all that apply)...

- Abstract for conference presentation
- Manuscript for publication
- Student thesis or dissertation

Proposer Information

Name

Affiliation

Address

Email

Phone

Writing Group

Will the proposer also be the first author?

Yes No

Is the first author a student?

Yes No

Students must have a mentor provide a letter of support which includes information about the purpose of the project and the student's role, a statement describing the mentor's support of and commitment to the proposed project, and the projected timeline for completion. Please upload the letter here.

First author name

First author affiliation

First author address

First author phone

First author email

Please list all co-authors, including name, affiliation, and email address.

Any changes to co-authors (adding, removing) will require an approved amendment.

Who will be analyzing the data for this manuscript?

- Proposer
 Writing group member
 WSTR

Please describe this individual's qualifications for conducting the data analysis.

Analysis Plan

What is the main hypothesis of your study?

Why are twins needed for this study? How will you use twins to answer your study question?

Please describe your analysis plan -- provide justification for inclusion/exclusion criteria, outcome, exposure, and co-variable definitions, other variables of interest (e.g. other potential confounders, mediating or moderating variables), statistical analysis, power considerations, and any anticipated challenges. How will missing data be handled? Will the outcome variables be treated as continuous/ordinal/dichotomous variables? If outcome variables are continuous variables, will you be making assumption for the normality distribution of the variables? How will your analysis be adjusted if the variables are not normally distributed? How will within-twin pair correlations be considered in your statistical analysis?

A list of available variables can be downloaded here.

[Attachment: "Variable Availability.xlsx"]

Please download the variable request table and fill in the variables that will be needed for your proposal.

[Attachment: "VariableRequest.docx"]

Please upload the completed variable request table.

Which journal(s) are you considering for this submission?

What is your proposed timeline for completion and submission?

The WSTR will send an email on a quarterly basis to obtain updates on the status of all manuscript proposals. If no update is provided within a 12 month period, a new proposal will need to be submitted and approved.

References (if applicable)

If none, please write 'none'

Application Acknowledgement

I have read the policies and procedures for publications. I understand that data will not be provided until the manuscript proposal has been approved and a data use agreement has been signed. I agree to conduct my research as described in this application. If any change in the research design is necessary, I will submit an amendment for approval. I understand that if data is used for purposes other than those included in the manuscript proposal, or if findings are published without approval from the WSTR, I will be barred from further access to WSTR data.

I agree

Signature

For Reference Only

Proposal Amendment

Please use this form to submit any changes to your proposal.

What change(s) need to be made to your current manuscript proposal? Choose all that apply.

- Writing group
- Main hypothesis/study questions
- Analysis plan
- Proposed journal(s)
- Proposed timeline

Are you adding or removing members from the writing group? Choose all that apply.

- Adding
- Removing

Who are you removing from the writing group and why?

Who are you adding to the writing group and why? Please include name, affiliation, and email address

What changes are being made to the main hypothesis/study questions?

What changes are being made to the analysis plan? Choose all that apply.

- Changes to inclusion/exclusion
- Changes to outcome variable(s)
- Changes to other variables
- Changes to the statistical method(s)
- Other changes

Please describe the changes being made to the analysis plan and the reason for the change.

Please list the journal(s) that you are considering for submission

Please summarize changes to the proposed timeline

1) Please provide an update on the status of your manuscript proposal, entitled [manu_title]

2) Do you need to make any changes to your currently approved proposal? Yes No

For Reference Only

Dataset Removal

The Washington State Twin Registry Publication Policies and Procedures document provided on [proposal_arm_1][pnp_date] stipulates that any data provided to [proposal_arm_1][proposer_name] must be destroyed at the end of the submission process.

Please certify that the following provided information has been removed or destroyed:

- 1) Survey data file "[proposal_arm_1][filename]" provided on [proposal_arm_1][datasetdate]
 Removed

 - 2) Any files derived from original survey dataset
 Removed
 Not created

 - 3) All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocode
 Removed
 Not provided

 - 4) Any other unique identifying number, characteristic, or code
 Removed
 Not provided

 - 5) By signing this certification, I confirm that the information specified above has been removed and permanently destroyed.
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