

AUGS PFD Registry
AUGS PFDR Data Use and Publication Policy

1. **PURPOSE:** The AUGS Research Registry Committee has implemented the following policy for both request and use of the Pelvic Floor Disorders Registry (PFDR) Data for research and publication. This policy applies to the request and use of PFDR Research (PFDR-R) data.

2. **SCOPE:** This policy applies to all individuals and entities requesting data from the PFDR-R and provides information on the specific and accepted professional use of this data and registry-derived information from AUGS.

3. **PARTICIPANT:** In this policy “Participant” is defined as either an individual surgeon participating in the PFDR or a PFDR site (group of practicing surgeons registered to participate in the PFDR).

4. **RESPONSIBILITY:** All Participants agree to comply with all aspects of the policy noted below regarding use and publication of PFDR data. Participants shall only use data in a way that is accurate and does not manipulate such information for perceived personal or organization benefit.

5. **AUGS DISCRETION:** At all times, AUGS retains the sole and exclusive discretion whether to release PFDR data or data analysis to any individual or entity, for any reason. Participation in the PFDR does not entitle a Participant to any PFDR data other than the Participant’s own data.

6. DATA USE POLICIES

6.1. Use of Data for Research and Publication

6.1.1. Participant use of its own data

A Participant may download and use its own data for research purposes, including publication, without permission from the AUGS Research Registry Committee.

Disclosure of data from any other PFDR Participant will require approval by the Registry Committee as described in section 7 below. In limited instances, two or three Participants with clear academic associations (e.g. Participants that are merged for accredited fellowship programs) may request approval to merge their data for use as by a single Participant. Such requests must be made by email to the Registry Committee. The Participants seeking such approval will be required to enter into a written agreement authorizing AUGS to share the data among the Participants.

After approval, the merged Participants may download, merge, and use their own data for research purposes, including publication, without additional permission from the AUGS Research Registry Committee.

6.1.2. Participant Use of PFDR Aggregate Data

- 6.1.2.1. PFDR data from all Participants that has been aggregated and de-identified as that term is defined under the Health Insurance Portability and Accountability Act of 1996 (“PFDR Aggregate Data”), may be used for clinical research by a Participant if reviewed and approved by the AUGS Registry Committee for scientific merit and ethical propriety.
- 6.1.2.2. PFDR Aggregate Data may be used to produce one or more of the following forms for reporting and dissemination of information: abstract, scientific meeting presentation, or manuscript for publication in the medical literature, under the following conditions:
 - 6.1.2.2.1. Participants can only publish PFDR Aggregate Data after permission is received by the AUGS Registry Committee;
 - 6.1.2.2.2. Any abstract, scientific meeting presentation or manuscript for publication in the literature must acknowledge the PFDR as the data source and include the PFDR name in the title, text or presentation materials;
 - 6.1.2.2.3. Any manuscript for publication in the literature must acknowledge the PFDR using the following language: “The authors are grateful to the PFDR and its members for their time and effort in contributing critical clinical information to the database. Without their contributions, this research would not have been possible”;
 - 6.1.2.2.4. The principal investigator (PI) of the project must be a PFDR participating surgeon or a member of one of the groups described in 7.1.1 below;
 - 6.1.2.2.5. All statistical analyses of PFDR Aggregate Data will be performed by the PFDR analytic staff and supervised by a PFDR biostatistician in collaboration with the research project investigative team. The raw PFDR Aggregate Data will not be disclosed to Participants;
 - 6.1.2.2.6. Participants are solely responsible for obtaining any necessary IRB approvals and compliance with all applicable state and federal laws and regulations;
 - 6.1.2.2.7. The analysis request results may not be copied or transmitted in any form to any individual who is not listed as an

approved investigator and who has not signed the required Data Use Agreement; and

6.1.2.2.8. Subsequent requests for data analysis must be submitted as new requests and are subject to the review and approval process described above.

6.2. Use/Disclosure of PFDR Benchmarking Report Data

6.2.1.1. Participant-specific PFDR Benchmarking Reports (available to each Participant through the PFDR Electronic Data Capture system) provide a summary of data and pre-defined outcomes for 1) the individual Participant accessing the report, and 2) aggregate data from all Participants within the PFDR-R. Benchmarking Reports provide summary information including, but not limited to, total enrollment, subject baseline characteristics, types of prolapse surgery or pessary treatment performed, treatment outcomes and complications.

6.2.1.2. Any information from the Benchmarking Report can be used internally within Participant organization for quality assurance and educational purposes. Such internal utilization may satisfy institution quality assurance requirements such as mortality and morbidity review and confidential service conference discussions. Process improvement within an institution may be monitored for continuous quality improvement impact, using the data and outcomes as reported for and by the PFDR.

6.2.1.3. Participant may use and publish the summary information derived from its own data (obtained from the Benchmarking Report or from download and analysis of the Participant's raw data). However, Benchmarking Report summary information from aggregate data (summarized from all other data) cannot be disclosed outside of the Participant for any reason, including but not limited to marketing purposes or to promote the Participant's program as compared to others. Participant is prohibited from publishing the Benchmarking Reports. Data contained within the Benchmarking Reports cannot be used for publication or research unless all requirements set forth as above in this document are met.

6.2.1.4. Participants are cautioned to consider the following when interpreting and using Benchmarking Report results: Results of PFDR Benchmarking Reports (in particular, rates of treatment outcomes and complications) do not account for differences in patient characteristics across Participants and may be unreliable at Participants with small numbers of patients.

7. PROCEDURES

7.1. Analysis Request Procedures – Request of analysis of PFDR Data for research

7.1.1. The following individuals or groups may request analysis of PFDR Aggregate Data:

- AUGS Board of Directors
- Registry Steering Committee
- Stakeholder Advisory Panel (and its individual members)
- Participants

7.1.2. Requests may be made for analysis results from PFDR Aggregate Data, including summary statistics and statistical output.

7.1.3. Analysis request applications will be considered during 3 review periods yearly. Applications must be submitted by the published due dates in order to be reviewed in a timely fashion (e.g. applications submitted in advance of a Sept 1 due date will be reviewed during September, etc...).

7.1.4. Complete the Application for PFDR Analysis Request available at <http://pfdregistry.augs.org>.

7.1.4.1. When completing a request, applicants must present a brief description of the planned research, including scientific rationale, research objectives and description of planned analyses, including all variables planned for inclusion in analyses. Applicants should request only analyses that are justified by the project (i.e. analyses using the minimum number of variables for the minimum number of years to adequately conduct the research)

7.1.4.2. Submit completed application to PFDRRegistry@aug.org.

7.1.5. Application review process

7.1.5.1. The AUGS PFDR-R Registry Committee will review the application. Application review results will be completed in 4-6 weeks.

7.1.5.1.1. A blinded review will be performed by at least 3 committee members using a standardized review form [need to develop].

7.1.5.1.2. The review process will consider scientific merit of the request and potential overlap with any previously approved project/analysis.

7.1.5.1.3. Scientific merit review criteria will include Significance, Potential Impact, Research Approach, Investigators, and Environment.

- 7.1.5.1.4. Reviewers may request any clarification or additional information from the applicant regarding the data request. This request can be made through the Registry Director to maintain the blinded review.
- 7.1.5.1.5. After initial reviews are complete and upon resolution of any additional requests, the application will be considered by the entire AUGS Registry Committee who will make a final decision.
- 7.1.5.2. Applications that are not approved will be sent a summary of the review along with notice that the request was not approved. In some cases, the Committee may recommend a revision of the request and allow resubmission at the next due date. All decisions are final.
- 7.1.5.3. The AUGS Registry Committee will respond to the applicant in cases of approved applications to include:
 - 7.1.5.3.1. Final decision and summary of review
 - 7.1.5.3.2. Assigned project number
 - 7.1.5.3.3. Assessment of costs of generating the analysis request
 - 7.1.5.3.4. Request the following from applicant:
 - 7.1.5.3.4.1. Approval letter from applicant's IRB
 - 7.1.5.3.4.2. Signed Data Use Agreement for each person involved with the project
- 7.1.6.** After review is complete, applicants with approved applications will send response and payment if analysis request is still desired.
 - 7.1.6.1. Upon AUGS receipt of payment, IRB documentation and signed Data Use Agreements, the analysis request will be placed into queue with high consideration given to the date when the final proposal and all documentation were received.
 - 7.1.6.2. Statistical analyses will be performed by the PFDR analytic staff and supervised by PFDR biostatistician(s) working in collaboration with the research project investigative team.
- 7.1.7.** Under exceptional circumstances, PFDR Aggregate Data (raw data) may be released to external collaborators with following restrictions:
 - 7.1.7.1. A Data Use Agreement will be required
 - 7.1.7.2. Individual Participants will not be identifiable in any released data
 - 7.1.7.3. Data will be released only for a particular project and must be destroyed after the specified project has been completed

- 7.1.7.4. Data may not be transferred to other researchers
- 7.1.7.5. Only the minimum amount of data necessary to accomplish the project will be released.
- 7.1.7.6. All analyses will be subjected to independent verification and usual publication request procedures must be followed.
- 7.1.7.7. Participant is solely responsible for obtaining any necessary IRB approvals and compliance with all applicable state and federal law and regulations.

7.2. Publication Request Procedures

7.2.1. Review of manuscripts describing analysis of PFDR Aggregate Data is required by the AUGS Registry Scientific Committee before submission to a journal for publication.

7.2.2. Manuscript Review Process

- 7.2.2.1. Manuscript publication in FPMRS is strongly encouraged. External journals will be considered on a case-by-case basis.
- 7.2.2.2. Submit a copy of the manuscript to AUGS PFDR-R Registry Committee at pfregistry@aug.org including PFDR approved project number (assigned when data request approved) and planned journal for submission. Manuscript must include title and list of authors.
- 7.2.2.3. The AUGS Registry Committee will forward the submitted items to the Publication sub-committee for review.
- 7.2.2.4. The manuscript must describe the data included as “aggregate Pelvic Floor Disorder Registry – Research (PFDR-R) data” and acknowledge AUGS PFDR and its members with the following statement: “The PFDR is grateful to its members for their time and effort in contributing critical clinical information to the database. Without the contributions by our members, this research would not have been possible.”
- 7.2.2.5. The review process will ensure the manuscript properly acknowledges AUGS PFDR and that the analyses described and performed are generally consistent with those previously approved in the PFDR Data Request application (not a scientific merit review).
- 7.2.2.6. Manuscript review will be completed within 2 weeks of submission.
- 7.2.2.7. The AUGS Registry Committee will respond to the applicant to include:

7.2.2.7.1. Final decision to approve manuscript or request for revision based on review.

7.2.2.8. The AUGS Registry Committee should be notified of final status of submitted manuscripts by sending an email to pfregistry@aug.org.

7.2.3. Abstract review process

7.2.3.1. Abstracts describing analysis results of PFDR Aggregate Data must also be reviewed. Abstracts which will be submitted to a national, regional or local scientific meeting for presentation should be submitted to the AUGS Registry Scientific Committee at least one week (including 5 business days) before the submission deadline for the meeting of interest. Due to the time-sensitive nature of abstract submissions, further lead time for the review is strongly encouraged, but a quick review and response will be completed by the 5th full business day AFTER submission.

7.2.3.2. Submit a copy of the abstract to AUGS Research Registry Committee to pfregistry@aug.org including PFDR approved project number (number assigned to Data Request Application when approved), planned meeting for presentation and date of abstract submission to meeting for review. Abstract must include title and list of authors.

7.2.3.3. Abstract must be submitted to the AUGS Research Registry Committee for review within 1 week (including 5 business days) of the submission date to the meeting for presentation.

7.2.3.4. Abstract must properly identify the data as “aggregate Pelvic Floor Disorder Registry - Research (PFDR-R) data”.

7.2.3.5. A blinded review will be performed. The review process will ensure the abstract properly acknowledges the data as originating from the PFDR. The review will also check that the analyses described and performed are generally consistent with those previously approved in the PFDR Data Request application.

7.2.3.6. Abstract review will be completed and a response sent to the authors by the 5th full business day after submission.

7.2.3.7. The AUGS Research Registry Committee will respond to the applicant to include:

7.2.3.7.1. Final decision to approve abstract or decision that abstract does not comply with PFDR requirements for publication of data/analyses results. If abstract is not approved, a brief explanation of the decision will be provided.

- 7.2.3.8. The AUGS Research Registry Committee should be notified of final status of submitted abstracts (whether accepted for presentation and presentation format) by sending an email to pfdregistry@aug.s.org.

7.3. Yearly Progress Reports

- 7.3.1.** A yearly progress report must be submitted for all projects that are not submitted for publication within a year of the PI receiving the data analysis. The report should include:
- 7.3.1.1. Title, updated list of the names of co-investigators, progress toward project goals and updated timeline for completion, and specific information about the security under which the data are held.
- 7.3.1.2. If insufficient progress is made (no abstract or manuscript submitted for publication) on an approved project within one year after statistical analyses are complete, an additional 3-6 months time may be requested by the PI to complete the project.
- 7.3.1.3. This report will be reviewed and must be approved by the AUGS Registry Scientific Committee.
- 7.3.2.** Failure to complete a project within the extended time approved by the AUGS Registry Committee may result in termination of the approved project.

7.4. Termination.

The AUGS Research Registry Committee reserves the right to terminate the activities of any project and require immediate return or destruction of analysis results and data for reasons including but not limited to: Suspected misuse of data; failure to report progress on a yearly basis; and lack of progress (no abstract or manuscript submission within 1 year of when the statistical analyses were completed and released for the project), particularly if another investigator has interest in pursuing a similar research question using the dataset.