

PERSONALIZED ENVIRONMENT AND GENES STUDY (PEGS) POLICY 1-1: PEGS SCIENTIFIC COLLABORATION GUIDELINES

The PEGS Executive Leadership Committee

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Collaborative research is an encouraged and welcomed aspect of the Personalized Environment and Genes Study (PEGS). When considering proposals for collaborative research, the Executive Leadership Committee (ELC) will deliberate on whether a proposed study promotes high-quality science, protects the privacy of cohort participants, and encourages the future growth of PEGS. Researchers seeking access to PEGS data will be compliant with the process and criteria outlined below.

PROCESS AND EVALUATION CRITERIA FOR PROPOSED COLLABORATIVE STUDIES

The PEGS ELC will review Research Concept Proposals and data/specimen requests using the process and criteria outlined below:

1. All proposed research will be collaborative and involve at least one PEGS investigator.
2. Before submitting an official Research Concept Proposal, researchers interested in initiating a collaborative investigation with PEGS will contact a member of the PEGS ELC and provide a brief description of the proposed project. Please contact the PEGS ELC member whose research expertise most closely aligns with the proposed research in your Research Concept Proposal, as listed above. The PEGS ELC member forwards this initial request to the PEGS ELC to ascertain whether it provides a novel contribution to the specific field of research and is distinct from already approved studies. A member of the PEGS ELC may contact the researcher for further discussion.
3. At least one PEGS investigator will serve as a co-investigator for all collaborative research, and the PEGS ELC members determine the appropriate PEGS investigator involvement at this time. The selected PEGS investigator will contact the researcher(s) and serve as the NIEHS point-of-contact and facilitator for this collaborative research.

4. The next step is the completion of a Research Concept Proposal using the [PEGS proposal form](#). A Research Concept Proposal will provide all relevant details for the proposed study including the research hypotheses, the planned study design and analyses, and the data and/or specimens requests. External researchers will request access to specific subsets of PEGS data and will be provided access only to the PEGS data required to conduct their study.
5. Research Concept Proposals will stipulate authorship of any publications produced as a result of proposed work. The proposal will identify the institutions and affiliations of the researcher and all potential collaborators.
6. Before submission, a PEGS investigator will review the initial proposal request to determine the feasibility of the proposed research and ensure that all required information is included in the proper format.
7. The PEGS ELC reviews and provides comments on submitted Research Concept Proposals within 90 days of submission. The PEGS ELC will determine the methodological soundness and scientific validity of the proposed research. The PEGS ELC issues one of the following decisions for each reviewed research proposal and data/specimen request: approve, approve pending minor revisions, defer approval until revised, or reject.
8. If revisions are requested by the PEGS ELC, the submitter may revise and resubmit their [PEGS proposal form](#), within 30 days of receiving the review decision from the PEGS ELC.
9. If the work outlined in a Research Concept Proposal would overlap with projects already being conducted by PEGS investigators, approval may still be possible. Researchers should discuss any potential overlaps with the PEGS ELC as early as possible to reach an informed decision on approval of the proposed research.
10. After the PEGS ELC approves a Research Concept Proposal, researchers must agree to and sign the Data User Code of Conduct, the Data Use Agreement, the Data Confidentiality Agreement and the No Publication Agreement before they are provided with/granted access to the requested PEGS data.
11. Substantial modifications or expansions to the originally submitted Research Concept Proposal (e.g., the research concept, hypotheses, etc.) require re-approval by the PEGS ELC.

DATA ACCESS AND PROPRIETY

1. Original PEGS data and data from collaborative projects should be available to both PEGS investigators and collaborators. Requests for data and/or specimens should include details on how the requested data will be made available to the required parties.
2. External researchers are provided data without personally identifiable information. External researchers will be provided access only to the PEGS data required to conduct their study.
3. Requests to collect new data or use limited resources (e.g., buccal samples) are subject to the following requirements:
 - Peer review
 - IRB approval
 - Justification of scientific need (i.e., why is the PEGS cohort the best option to address the research question)
 - Explanation of benefits to study participants
 - Minimization of the burden to participants
 - Maintenance of the confidentiality of participants and the security of collected data
 - Guarantee of voluntary participation for new data collection
 - Funding
4. For add-on studies, the PEGS study staff initiate the first contact with potential participants. Collaborators may be given personally identifiable information if a participant consents to its release for an add-on study. Collaborators will provide PEGS with copies of data collection instruments, forms, and informed consent materials developed for add-on studies and IRB approval letters.
5. For add-on studies, if biological samples are collected, collaborators will split the remaining samples after completion of the study, with a sufficient amount sent to the PEGS biorepository. The PEGS ELC may waive splitting the remaining biological samples at its discretion. The PEGS ELC must approve the laboratory used by collaborators for analysis.

6. New data collected as part of an add-on study are the property of both the principal investigator of the add-on study and NIEHS. These parties are jointly responsible for protecting the privacy of study participants.
7. Data are non-transferable unless the ELC grants written prior authorization for transfer to another party.
8. Collaborators can use and access PEGS data only for the purpose(s) outlined in the approved Research Concept Proposal. Access to the data is provided for **24 months** for secondary analysis and **five years** for add-on studies. Collaborators are expected to complete their analyses and draft a manuscript for review by the PEGS ELC within this period.
9. Unless the ELC approves other arrangements, collaborators will return newly created (e.g., computed or derived variables) and/or additional collected data (from add-on studies) along with appropriate documentation to NIEHS. For add-on studies, collaborators will provide NIEHS with copies of all data, including data generated from surveys, biological specimens, and environmental samples, in an approved format that can be linked to the PEGS datasets.
10. Collaborators will destroy all PEGS data in their possession after NIEHS/PEGS acknowledges receipt of their files.
11. Requests to extend the data access period will be submitted to the ELC a minimum of 60 days before the scheduled end date. NOTE: Researchers who require access to data after they have been returned can request that the PEGS ELC provide access to a copy of the original data for an agreed-upon period.

REPORTING

1. Collaborators will provide a timeline of planned research activities, including the period for which the PEGS data are needed. The standard period is 24 months for projects involving primary data analysis and five years for add-on studies.
2. Collaborators will submit annual research progress reports to the PEGS ELC. Reports will describe the project's current status, project milestones, risks or impediments to completing the project, plans to mitigate any risks or impediments, and any substantial modifications or expansions to the original submitted proposal (e.g., the research concept, hypotheses, etc.). The report will include abstracts submitted for presentation and manuscripts submitted for publication. If a researcher feels the expectation to complete analyses and produce a draft manuscript within 24 months for secondary analysis or five years for add-on studies is unreasonable, the report should address this. A member of the PEGS ELC may contact the researcher for further discussion.
3. When reporting results in a manuscript, investigators will specify the version of the PEGS dataset used for analysis. Refer to the PEGS website for additional details on the PEGS Data Freeze versioning system.
4. Before submission for publication, a copy of all manuscripts describing research conducted using PEGS data will be submitted for review to the PEGS ELC. Researchers will be notified of the outcome of the review within 30 days. It is the responsibility of the senior PEGS investigator serving as co-author to assist the researcher(s)/lead author(s) in meeting the requirements for conducting studies and publishing results using PEGS data.
5. Researchers must complete all required federal reviews before submitting an abstract or manuscript to the ELC for review before presentation or publication. The senior PEGS investigator can help facilitate the review process. If an ELC member has concerns about a paper submitted for review before submission for publication, the ELC will discuss and resolve the issues.
6. Collaborators are prohibited from using the PEGS data for publishing findings that are obtained from analyses other than those outlined in the Research Concept Proposal as per the Data Confidentiality Agreement and the No Publication Agreement.

FUNDING CONSIDERATIONS

1. Independent resources sufficient for executing the study are required from the external researcher(s).
2. External researchers may be required to reimburse PEGS for costs incurred from activities related to collaborative research activity. These funding decisions will be determined and coordinated by the PEGS ELC on a case-by-case basis.