Policies and procedures

ORGANIZATION AND GOVERNANCE

Steering Committee

Members of the PrePARED Consortium Steering Committee will consist of select members of participating cohorts, as well as others that can facilitate the activities of the consortium.

The functions of the PrePARED Consortium Steering Committee may include:

 Development and maintenance of the PrePARED Consortium Policies and Procedures Manual for data collection and management, data sharing and collaboration guidelines, and publication procedures

 Database development and maintenance

 Establishment of criteria for review, selection, and prioritization of research proposals using PrePARED Consortium cohort data or PrePARED Consortium resources

 Development of standard variables for analysis across cohorts

 Outreach to additional ongoing or proposed cohorts

 Coordination and approval of manuscript proposals

HUMAN SUBJECTS ISSUES

Ethical oversight will be provided by the appropriate ethical review committee from each participating institution. All efforts will be made to ensure subject confidentiality is in place at each participating site and within the consortium itself. Studies with prospectively collected data will include language within their informed consent forms that incorporates the principles of data sharing and biospecimen collection and storage to allow use of banked specimens for future laboratory assays. Individual consortium members will work with their respective ethical review boards to determine appropriate data sharing procedures for previously collected data.

DATA GUIDELINES

Mechanisms for data sharing will be needed initially to support collaborative analyses across different sites. Data for the pooled analysis will be located in final format at the data center. All individuals with access to data must sign a data use agreement ensuring confidentiality and compliance with procedures.

These data will comprise:

 Original cohort-specific variables

 New standardized variables (across cohorts)

 Coding regarding the compilation of variables

 (Eventually) New data generated from collaboration

These PrePARED consortium data must be accessible to collaborating members with the understanding that only analyses agreed to by the PrePARED consortium steering committee can be undertaken. Consortium members can apply to the PrePARED Consortium Steering Committee for approval of projects involving PrePARED Consortium data.

Upon PrePARED Consortium Steering Committee approval, access to various sections of the data can be granted to individuals with approved project / data analysis needs. Individual cohorts can choose whether or not to participate in each particular project. While the full PrePARED Consortium

database can only be accessed following PrePARED Consortium Steering Committee approval, individual cohorts are allowed full data access privileges to their own data at all times.

Access will be granted on a case-by-case basis based on the decision of the PrePARED Consortium Steering Committee as to the nature of the analysis and the information needed. These processes do not discourage collaboration with cohorts outside of the Consortium.

Initial data postings should be entirely de-identified. In the event of future proposals requiring identifiers such as date of birth, IRB clearance for accessing PrePARED Consortium data will be required, even for the original owners of parts of the collated data.

The Tulane Global Research Data Center will be responsible for the coordination of data management and pooling. This requires collection of the key variables from each cohort, transferring the variables to a common format, harmonizing the variable names, and organizing the data libraries of the individual cohorts to form a common data resource. A joint Redcap database will be created, with PIs of contributing studies having access (though not edit privileges) to the database, and data managers having access to their individual studies' data.

Data Sharing Policy

Consortium members wishing to use data should use the following procedure:

1. It is recognized that individual study data from each participating cohort is not equivalent to the pooled consortium data from the PrePARED Consortium. Participating cohorts remain in complete control of their own data at all times. However, all collated data from the Consortium will be shared with PrePARED Consortium members as determined by the PrePARED Consortium Steering Committee.
2. The PrePARED Consortium Concept Proposal with required preliminary information will be placed on in a shared folder or emailed to the steering committee. The Concept Proposal should be distributed at least one week prior to a Steering Committee meeting to be included in the meeting agenda.
3. The PrePARED Consortium Steering Committee will initially review the proposal and may seek clarification of issues in order to determine whether or not the data existing in PrePARED Consortium are likely to satisfy the request, or whether other data sources may be more appropriate.
4. Given that these conditions are met, approval is given contingent upon continuation of necessary support, and on sufficient progress as determined by the Steering Committee.
5. Data may be shared by direct transfer of data files. However, especially in circumstances in which there is risk of subject identification or when security or other legal restrictions apply to the data, a data enclave may be required as a physical location where the user may go to access shared data under controlled conditions (e.g., supervision by the PI or designated agent).
6. Data will be provided with necessary documentation, including explanations regarding complex shared data, assuming that costs are covered and that appropriate collaborative agreements are reached regarding, for example, the level of involvement of the appropriate PrePARED Consortium group in the proposed analyses.
7. To further enrich the PrePARED Consortium resource, researchers are required to supply their newly collated PrePARED Consortium research data to the PrePARED Consortium Data coordinating center after publication, and/or 12 months after completion of their project. Generally, all new knowledge, including new study measures, generated from PrePARED Consortium data collation should be returned to the Consortium. In addition, data sharing requests will be tracked over time by the Steering Committee and described in progress and final grant reports.

PUBLICATION AND AUTHORSHIP GUIDELINES

Publications Committee

At present, the steering committee also serves as the publications committee, but at some point a separate publications committee may need to be formed. The PrePARED Consortium Steering Committee is responsible for supervising manuscript preparation which includes assuring proper study design, methodology, including statistical analysis, appropriate authorship listings and acknowledgments to people and institutions.

Authorship

The general approach to authorship will be inclusive rather than exclusive, although the ICMJE criteria should be met. As a general rule, no more than two authors from an individual study should be included on a paper.

Each manuscript will be written by a group of participating researchers. The order in which other authors in the writing team will be listed will depend upon the extent of their contributions. One or two researchers in each team may take primary responsibility for data analysis and writing, and may sometimes be considered equal first authors. The last authors on the writing teams are generally considered senior researchers; their role is to supervise the draft development, edit the paper and accept full responsibility for its content. The PrePARED Consortium recognizes that the last author position will generally be the senior researcher from the group where the major part of the writing of the paper was undertaken unless the senior researcher of another group has a more substantial role in the development of the paper. The lead (first) author may pick a last author from a different institution than their location if the senior researcher has a special area of expertise and commits to a major supervisory role. The full authorship list of consortium papers must be accessible through Medline so that younger researchers can document their scientific accomplishments for professional advancement. In the event of internal writing team conflict, the issue will be submitted to the PrePARED Consortium Steering Committee for resolution. Final decisions about who should be considered as authors on collaborative papers will be made by members of the writing team, with input by the PrePARED Consortium Steering Committee as necessary, not by a journal or PubMed. This initial approach may be reconsidered in subsequent publications. If major imbalances appear between groups, and if these imbalances do not fairly reflect the level of contribution, the authorship lists will be negotiated within the PrePARED Consortium Steering Committee. Sites not submitting data can still self-nominate themselves to be on the working group and participate in paper preparation if they have expertise to offer. However, such individuals are still held to the above criteria for authorship. Other mechanisms for acknowledgment are discussed below.

Acknowledgment of Other Contributions

All papers will acknowledge funding support and relevant sponsorship for each individual cohort and where relevant, the consortium. Individuals that have contributed to a paper but not to the extent necessary to warrant authorship should be acknowledged. Where individuals are to be named, the lead author should request consent from the individual prior to publication.

Publication priority

In many cases, individual cohorts will wish to publish their own data on a topic prior to that topic being explored in the overall consortium. In that case, the steering committee may choose 1) to exclude the study's data from an analysis or 2) the steering committee/grant PI and individual cohort may come to an agreement about a timeline for data availability and inclusion. If the individual cohort does not conform to the agreed timeline, its data may be included in consortium publications without prior publication.

Manuscript Preparation, Review, and Approval

A major challenge in large collaborative undertakings is to ensure timeliness and effective coordination in developing manuscripts. Accordingly, the PrePARED Consortium Steering Committee will establish a priority list of manuscripts, mechanisms for writing and incorporating feedback, and expected dates for submission that respects competing demands on collaborating members but maintains a pace that is appropriate for the priority of the undertaking. The manuscript process begins with a study proposal submitted to the Steering Committee. When a person proposes a paper, if they have appropriate data from their cohort, it will be helpful to include pilot data analyses in the proposal. A list of all prior papers and proposals will be available in a shared folder to avoid overlap of analyses. The Steering Committee will review proposals (by e-mail, teleconference or conference discussion) and decide whether the proposal has merit within the consortium. For accepted proposals, the lead author will be responsible to set up a working group. The following checklist is proposed to encourage each writing team to designate responsibilities and to establish a timeline for manuscript development. A number of these steps can be addressed simultaneously rather than sequentially.

- Clearly delineate roles of each member of the writing team
- List papers already published using cohort-specific data that may have significant overlap
- Complete literature review and identify (bullet) key points for introduction and discussion
- Identify and coordinate with data pooling center(s) to complete basic analyses
- Develop outline of main analyses, table shells, and potential figures
- Identify and conduct secondary analyses
- First draft of results, tables, & figures
- First draft of methods
- First draft of title, abstract, introduction & discussion
- Incorporate secondary analyses
- Review and revision by authors
- Review by consortium (see below).

We propose the following guidelines for manuscript review by the overall consortium.

- Each of the contributing centers or group of cohorts will identify a contact for coordinating their input to any given manuscript. This contact is also responsible for obtaining any signatures or other paperwork necessary for final submission to the journal.
- Preliminary tables of results will be circulated along with the outline of the paper.
- When a draft manuscript is circulated, we require no less than a two-week and no more than a four-week turn around for any set of comments to be received by the writing team. Once this period has elapsed, the writing team should aim for a two-four week turn around.
    - Ideally comments will be ranked into two levels, (a) *major* (e.g., essential analytic and factual changes), and (b) *minor* (e.g., possible grammatical and other editorial changes).
    - The response from the writing team will only address any feedback to the co-author responses to the category (a) items noted above.
- Revised manuscripts will be circulated to all co-authors with the understanding that a fast turnaround is essential to the overall success of this research undertaking. The two-week turn around to final submission will be enforced. If this deadline is not met, the writing team will assume the co-author has no further comments and therefore accepts the work as-is.

 We recognize that substantive revisions can be incorporated during the peer review process.

For the overall process to work smoothly, the writing team and all co-authors must place high priority on the collaborative manuscripts. Clear communication and quick turn-around times will be essential for success.

The PrePARED Consortium shared folders will include a list of planned manuscripts, in general terms, and have a mechanism for tracking their development. In addition, studies may post information on manuscripts they plan with their own data or interest in future projects, to provide information on when data are likely to be available for group analyses and lay informal claim to topics of interest (although formal request may supersede such expressions of interest). Finally, a list of possible manuscript projects will be created, likely to be of particular use to students or fellows seeking research topics.

GRANT PROPOSAL GUIDELINES

Overview

This policy applies to new research proposals which use PrePARED data. In some cases, a new research proposal will involve acquisition of additional data (such as sample assays) which have not been previously collected as part of the PrePARED program. In other cases, a new proposal may involve analysis of already-collected data only. It is expected that the majority of new research proposals will be submitted for extramural funding. Examples include studies funded by investigator-initiated NIH research awards (R01s), grants from academic institutions, or from private sources (e.g. drug companies). However, it is recognized that some new research proposals may not be submitted for funding but may require preliminary studies conducted to demonstrate feasibility or to examine quality.

The Review Process

All new research proposals must be reviewed and approved before access to PrePARED data or specimens is permitted.

The review process is as follows:

1. New research proposals should be sent to the PrePARED Steering Committee. These can be sent to the project coordinator, Emily Harville (eharvill@tulane.edu). Specific aims and a one-page overview of the project idea are required to ensure that there is no scientific overlap and that resources are adequately allocated for the proposed work. The coordinator will ascertain that all elements are available for a satisfactory evaluation. The proposal will be logged into the PrePARED research proposals tracker and a record will be established. If all elements are not available, the initiator of the proposal will be contacted and requested to modify or add the required information.

2. The Steering Committee will review the proposal to determine if there is scientific overlap with current investigations or already-approved proposed investigations.

3. Initial approval/disapproval will be made by the Steering Committee. The Steering Committee will be allowed 4 weeks to make their decision. If concerns are major, Steering Committee comments will be sent back to the initial investigator for response and modification of the proposal if desired.

4. Once approval has been granted, letters documenting the approval will be sent on behalf of the Steering Committee to the investigator.

Deadline for new proposals: 12 weeks prior to grant deadline

Other Requirements for New Proposals
Support for the consortium: Grant proposals will normally be expected to include budget for administrative costs associated with maintenance of the consortium. If the proposed project requires additional data or other input from individual studies, administrative costs, data manager or investigator time, and/or consulting fees for those sites may be required as well.
Industry Involvement & Patents: Grant proposals with industry involvement must indicate whether intellectual property protection (i.e., patent or copyright, or to license any process, aspect or outcome of the study, including copyrightable software) will be sought.

IRB Review: The use of PrePARED data or biological materials is not necessarily exempt from review by an Institutional Review Board (IRB). If the new study proposal will be conducted by a non-local investigator, evidence of IRB review at the other institution must be provided to the Steering Committee before the study begins and must be included with any data distribution agreement (DDA). IRB approval and the informed consent must be provided to the Steering Committee before implementation of the proposed study begins.

Sponsorship: A PrePARED investigator or other approved collaborating investigator is expected to be a co-investigator or principal investigator on new study proposals in the role of PrePARED sponsor. The sponsor is responsible for presenting the study to the Steering Committee, monitoring the study to assure continuing compatibility with PrePARED Program policies and priorities and serving as a liaison to the PrePARED Program Steering Committee. In addition, manuscripts and abstracts are generally expected to include a PrePARED sponsor, except under circumstances that should be stated and justified as part of the original proposal.

Data Access and Integration: The data collected by the newly proposed study should be provided to the PrePARED Steering Committee for integration into the main database. The study PI will be given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of the new proposed study. After a reasonable time (in general, 36 months after data collection and cleaning are complete), the study data will be made available for additional uses by other investigators. Collaboration with the study investigators who collected the data is encouraged. It is the responsibility of the new study PI to state in writing to the Steering Committee any special circumstances that would mitigate these guidelines for data sharing. In the spirit of encouraging collaboration, reasonable and justified requests for limiting Steering Committee access to the data will be honored or some compromise will be worked out. A manuscript proposal must be reviewed and approved by the PrePARED Program Steering Committee before publication and for non-Tulane investigators, a DMDA must be in place before data or specimens will be provided.

Publications Resulting from New Proposals: All the publications from a new proposed/approved study must be reviewed and approved by the Steering Committee in accordance with PrePARED publications policy.

Modifications to New Proposals: Substantial changes to the science or scope of an approved new proposed study require review by the PrePARED Steering Committee. The PI must submit:

1. a revised study proposal with changes tracked, highlighted or bolded;

2. a brief modification request memo summarizing the changes and stating the rationale addressed to the PrePARED Steering Committee.

Substantial changes would include requests for additional biospecimens, significant additional data, or requests to add new outcomes or change the main analytical exposure. Formal modification requests are NOT needed for notification of a reduction in needed biospecimens or to add covariates, or to slightly modify the analytic approach. However, minor changes should still be communicated to the PrePARED Steering Committee.

FUTURE DIRECTIONS

The consortium is in its early days and procedures will need to be developed as the scope expands.

Initial items for development:

1. Manuscript proposal form
2. Grant proposal form
3. Shared folder for list of proposed manuscripts and grant proposals

Possible future needs:

1. Separate publications committee
2. Procedures for accessing specimens
3. Web-based request forms