Scope and Purpose

Large and complex multicenter HCSRN consortium projects may develop project-specific policies as part of their infrastructure and governance. Such guidance documents provide structure, clarification of responsibilities, and pre-defined practices for these projects.

This document is meant to provide general guidance for HCSRN consortium projects developing or updating such policies. Best practices from existing HCSRN project policies are synthesized and presented herein.

This document and its companion resources are intended to increase efficiency, avoid duplication of effort, encourage consistency and facilitate clarity while ensuring that HCSRN projects maintain control over their own policies. To be clear, these practices do NOT apply to independent new research projects proposed within the HCSRN in general, but are for new ancillary or affiliate projects that would draw upon a currently funded research network of the HCSRN (e.g., CRN, CVRN, MHRN, etc.).

Potential Policy Content Areas

Most existing new project policy and guidance documents for HCSRN consortium studies contain the elements below, though the degree of policy detail varies based on the nature, complexity and needs of the project.

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| Proposal idea submission, review and decision-making processes | - Relates to proposals that would be independently funded, yet draw upon the resources of a parent consortium (e.g., infrastructure, existing data sets, participation across multiple sites, etc.) in some way.  
- Newly proposed activities that are funded by the consortium itself (e.g., core project proposals for renewals, pilot and feasibility projects funded by core) may be included in a separate section or document, if applicable or desired.  
- May encompass training grants, proposals involving consortia and non-consortia sites (HCSRN or external), projects involving new data collection, projects analyzing existing data only, and so on. |
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| Guidance and considerations relating to site participation | Policies addressed whether or not proposal PIs and sites could be from outside the consortium (or HCSRN).  
* Practical considerations were often included as general guidance (e.g., budget caps, staff availability, etc.)  
* Though final decision making and budgetary authority resides with the PI of a new project, consortium leaders may be available to advise on the most appropriate sites to include on a specific proposal.                                                                                                                                 |
| Allowability and process for revising and resubmitting a proposal that was not approved | Most projects allowed for revisions. Decisions often were one of three categories, such as: Support without modification, Suggest modifications and reconsideration, or Decline to support.  
* Some policies explicitly indicated that except in rare cases where a major issue existed (e.g., inconsistent with consortium’s mission; in conflict with ongoing project), the goal was to approve or modify/approve all proposed projects.  
* Extant policies did not appear to address potential timeline constraints for re-review, should the PI be pursuing an open FOA. New policy writers may wish to address this proactively, though it may occur infrequently. |
| Resolution of competing or conflicting proposals, or other dispute resolution | May ask competing or conflicting proposal investigators to resolve independently, bringing in another body (e.g., Executive Committee, Proposal Committee) to assist, if needed.  
* May review competing proposals separately and vote on which will proceed.  
* May also include path for resolving general disputes relating to collaboration (e.g., site selection, review decisions, site performance post-funding, etc.) |
| Expectations and/or reporting requirements for approved studies | Depending upon the nature of the consortium and its needs, the proposal PI may be required to provide periodic updates to the consortium (e.g., Steering Committee). This may include funding status post-approval, and periodic progress updates post-funding. Newly developed methods may also require sharing.  
* Acknowledgement of support from the consortia in presentations and publications was often an explicit requirement. |
| Circumstances or changes to approved proposals that require re-review and approval | Significant changes to a proposed project often required resubmission and approval. It was helpful when specific examples of what would and would not be considered “significant” were included.  
* Approved proposals that were not submitted for funding within a predetermined time period sometimes also required resubmission. |

**Identified Best Practices - Policy Document**

1. Agree early on if proposal reviewers are to consider scientific quality, design or analytic plans of proposals or limit their review to other considerations (e.g., consistence with consortium’s mission, non-duplication, adequately resources for consortium infrastructure, tracking/ metrics, etc.)

2. Define roles and responsibilities of proposal reviewers, overall consortium PI, and proposal PI.
3. Decide who will review and approve proposed projects (e.g., new proposals committee, steering committee). Agree upon document composition and logistical issues (e.g., eligibility, site representation, term limits, meeting frequency, communications, processes, etc.) at the onset.

4. Provide a clear and single point of contact for new proposal submissions. Post your policy and process details to facilitate transparency.

5. Provide a new project proposal form, or a list of specific required elements along with page limits.

6. Track new and approved proposals to avoid conflicts or redundancy.

7. Agree upon what constitutes a conflict of interest within the review group. Determine if such conflicts exist for each new proposal reviewed. If members will be recused from a review due to conflicts, decide in advance if/how a substitute reviewer will be recruited.

8. Review proposals using pre-defined, documented criteria and review processes. Ensure the new proposal committee’s decision-making process is clear so proposal PIs understand how and when decisions are made, who makes them, and what considerations may affect decision outcomes.

9. Before disputes arise, agree upon and document a process for adjudicating disagreements, if needed. Ensure those tasked with resolving a given dispute have no conflicts of interest pertaining to the proposal or disputants involved.

10. Provide expected time for turnaround of proposals (submission-to-review outcome). If revision and resubmission of a proposal is invited by the committee, send any necessary details along with the original outcome decision.

11. Require that review and approval take place well before a formal proposal is submitted to a funding agency (e.g., 4 weeks in advance of the due date).

12. Proactively consider how your process could be made flexible for rapid turnaround funding opportunities.

13. Encourage and facilitate participation of PIs at research centers not currently part of the consortium. Agree in advance if PIs that are not from consortium (or HCSRN) sites are eligible to be the main PI of a new project.

14. Encourage junior level investigators to participate in proposal submission. If possible, provide mentors for them to lead new project proposals.

15. Encourage open discussion of site participation early in the process. Advise the proposal PI that his/her final site selection may depend not only on funding limitations, but data access, research capacity and staff availability across sites, and other factors.

16. Create a mechanism for tracking funding status of approved proposals. Hold PIs accountable for any reporting (or other) requirements set forth by the main consortium project.

17. Clearly communicate any reporting requirements of approved projects up front. Ensure the consortium has infrastructure in place to support tracking and receipt of required information or items.
18. Document and clearly communicate any process by which changes/revisions to the project will require re-review and approval by the committee (e.g., changes to aims, expansion of data elements required, submission to funder not occurring within specified timeframe). It can be helpful to include up front what will and what will not be considered “significant” by the consortium.

19. Develop and include a contingency plan describing what will occur should the volume of proposals exceed the committee’s capacity to review them. If scientific quality is a consideration, also describe how special expertise will be tapped should it not exist within the standing makeup of the review group.

**Identified Best Practices - New Proposal Submission Forms**

1. Include on or along with the submission form a brief explanation of the rationale for the review process. This will help investigators understand the goals of the review process and why it exists. This is especially desirable if your consortium accepts new proposals from researchers not associated with the parent project or the HCSRN.

2. Include on or provide with the submission form information about who will review their materials, the expected response timeframe, and possible outcomes (such as: approve, approve with modifications, do not approve).

3. Print clear instructions on the form itself, including how and to whom to return the completed form.

4. Include on the form itself who should be contacted with questions about the form or review process.

5. The amount of detail required for submission varies significantly from project to project. Requiring more information be submitted places a greater burden on both the submitting PI and the review committee. Consider the pros and cons of requiring more or less detail about proposed studies, within the context of the specific consortium, the number and variety of new proposals expected, the relationship of submitting PIs to the consortium, and so on.

6. Don’t reinvent the wheel. Refer to the example provided below.

**Other New Project Proposals Policy Resources**

Check HCSRN Member Resources for these additional resources to assist project teams in developing new project proposal policies.

- HCSRN Project Policy Template
- Existing Policies & Content Comparison: New Project Proposals Policies
- Example: Cancer Research Network New Proposal Submission

**Other HCSRN Project Policy Topics**

Similar best practices guidance, examples, and content comparisons of publication and authorship policies are also available through the [HCSRN website](http://www.hcsrn.org).
Additional best practices policies resources are also continuing to be developed for other topics, including data sharing and for-profit collaborations. These will be added to Member Resources on www.HCSRN.org as they become available.

**Submitting Updates & Feedback**

This is a dynamic, living document. Additional best practices and resources can be added over time.

To provide an updated project policy, submit a new policy for the repository, share a best practice, ask questions or provide feedback, please contact:

Ella Thompson, HCSRN Manager  
email: thompson.e@ghc.org  
phone: 206.442.5211