RECOVER
Researching COVID to Enhance Recovery

An Initiative Funded by the National Institutes of Health

RECOVER Ancillary Studies Oversight Committee (ASOC)

Review Process and Guidance

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The RECOVER Ancillary Studies Oversight Committee (ASOC) is committed to the ethical conduct of research and the appropriate prioritization of ancillary studies conducted within RECOVER. This policy outlines the RECOVER ASOC procedure for reviewing ancillary study proposals that enter RECOVER.

1.0 RECOVER Ancillary Study Activity Management

The RECOVER Ancillary Studies Oversight Committee (ASOC or "the Committee") shall manage all ancillary study activity for RECOVER. Ancillary study proposals that include a request for RECOVER biospecimens or a Letter of Support must be submitted for review by the ASOC. Submission of ancillary study proposals that do not include a request for RECOVER biospecimens or a Letter of Support is optional.

2.0 Application Process for Ancillary Study Proposals

2.1 Submission Timeline

Investigators applying for research permission must complete an application for the Committee's review (see "Application Requirements" below). The Committee reviews proposals on a monthly basis. **All applications (regardless of funding status) must be submitted to the Committee by the first Thursday of the month to be included in the Committee's next review that month.**

Investigators planning to apply for funding from the NIH or other external funding sources must receive the Committee's approval prior to including a support letter in their research application to the NIH or other external funding sources. **The Committee recommends that research proposals for studies requiring external funding be submitted at least eight (8) weeks prior to a funding application deadline to allow enough time for an appropriate review.** If the Committee approves the application and provides a letter of support to the investigator, then the investigator will notify the Committee of the funding decision.

2.2 Application Requirements

The Committee requires submission of the following documents before review will begin:

- *Application Form for RECOVER Ancillary Studies Proposals:* Investigators must complete an application form for approval. The application form is only available electronically.
    I. *Common data elements:* The NIH is committed to common data elements (CDEs), and investigators are strongly encouraged to ensure their data collection is compatible with them. Please refer to the NIH CDE Repository for more information.
    II. For proposals requesting the use of biospecimens, the following must be included:
        - Type of biospecimen (plasma, serum, urine, etc.)
        - Quantity of biospecimen, with justification
        - A description of how any excess biospecimen material will be handled or disposed of

- *IRB Approval:* IRB approval (of the research proposal) is **not** required for Committee review. Please note that a Letter of Support from the Committee does **not** substitute for or

replace any federal or institutional policies related to IRB procedures—such as those stipulated in a grant, by a funding agency, by the investigator's institution and local IRB, by the NYU single IRB, by a RECOVER site IRB, by the NIH, and so on. Ancillary study applications that receive a Letter of Support from the Committee and are proposing research that is **not** exempt under the Common Rule (i.e., human subjects research) will be required to have IRB approval in order to receive RECOVER biospecimens and/or data.

- *Industry participation:* Proposals for industry sponsorship or collaboration will be evaluated in accordance with the procedures described above.

Research proposals should not include, contain or disclose any confidential, proprietary, or sensitive information.

3.0 Committee Review

3.1 Confidentiality and Conflicts of Interest

Research proposals submitted to the Committee and all Committee deliberations regarding the research proposals are confidential. Committee members will contact the Committee Chair if they need to recuse themselves from a proposal or to discuss whether a possible conflict of interest may require recusal. Conflict of interest is defined per the NIH and Other Transaction Authority (OTA) policies.

3.2 Review Process

The Committee may contact the applicant to request clarifications or additional documents to ensure that the application is ready for full Committee review. Applicants will be notified of the scheduled full Committee review date. The Committee will collectively discuss and review each proposal to confirm its scientific merit, using the agreed upon review criteria outlined in the ASOC Checklist for Reviewing Ancillary Studies (see **Appendix B**) to guide the review. Following this review, the Committee will vote on whether to approve and/or provide a letter of support for the research proposal.

3.3 Priority of Access

Review of protocols that require access to inventory data linked to the RECOVER Biorepository will be performed in parallel with the PASC Biorepository Core (PBC) and Data Resource Core (DRC).

Priority of access is determined during the review process. Priority will be given to studies that:

1. Do not conflict with the main RECOVER objectives
2. Are judged to have scientific merit by extending knowledge beyond the original scope of RECOVER
3. Are judged to be feasible

4. Are consistent with and can further the overall goals of RECOVER
5. Do not overlap with existing RECOVER hypothesis/studies or with funded RECOVER pathobiology studies.

Applicants are encouraged to review the RECOVER literature. A list of consortium publications will be found here, and research summaries on a subset of these RECOVER publications here. Additional perspectives from expert presenters are available via recordings of presentations from the RECOVER Research Review Seminar Series.

The determination of whether specimens are available in sufficient quantity will be made by the Biospecimen Access Committee (BAC) based on the inventory of samples at the time of review. Biospecimen samples will be distributed to approved and funded studies on a first-come, first-served basis. A Letter of Support from the Committee is not a guarantee that sufficient quantities of specimens will remain at the time of funding.

Please note: Applicants are responsible for biospecimen shipping and handling costs and should budget accordingly.

4.0 Revision and Resubmission of Proposals

The Committee may request a revision of the proposal prior to consideration of acceptance. In this case, the Committee will provide comments from at least two (2) reviewers and the PI must respond to the reviewer comments within ninety (90) days. Resubmissions should include a "Response to Reviewers" document addressing each comment point-by-point, a tracked version of changes, and a clean version of the revised proposal.

Ancillary studies that are not approved or not funded become inactive. If the PI wishes to resubmit the proposal for funding, they must communicate this to the Committee. A summary of the main points of the critique, plus a summary of the PI's response to the critique should be provided. A statement about changes to participant burden must be included. If either the science, scope, or burden has changed, the revised proposal must be approved by the Committee and RECOVER leadership committees.

5.0 Post-Approval Processes and Responsibilities of the Ancillary Study Investigators

Upon receiving approval from the Committee and the necessary external funding to carry out the approved proposal, investigators should notify the ASOC and make arrangements for retrieval and shipping of biospecimens, if applicable.

1. *Final application or proposal:* A copy of the final proposal as submitted for funding should be submitted to the Committee.
2. *Timeline of the ancillary study:* The Committee approval is valid for a two-year period. The ancillary study PI is required to provide an update on the progress of the study as

outlined under “Status reports.” If the ancillary study has not been funded two years from the date of approval, the ancillary study PI will need to resubmit the proposal to the Committee.