Note: This paper version of the Submission Form is for REFERENCE ONLY. Investigators who are interested in submitting a RECOVER ancillary study proposal and/or requesting a letter of support from the ASOC must email RECOVER_AncillaryStudies@rti.org to request access to complete the submission form electronically.

A. Lead Principal Investigator (PI) and Associated PIs

Lead PI *(one individual only, responsible for the proposal)*:

1. First Name:

2. Last Name:

3. Middle Initial:

4. Lead PI Biosketch *(please attach the biosketch as a separate Word Document or PDF)*.

5. Will this proposal use a Multiple Principal Investigator (mPI) system?
   - ☐ Yes
   - ☐ No

6. If this proposal uses an mPI system, then please list the full names of each mPI and provide Biosketches for each:

mPI 1	
mPI 2	
mPI 3	

7. Please indicate if the proposed ancillary study includes a collaboration with a current NIH RECOVER Investigator serving as a co-investigator or mPI in the ancillary study.
   - ☐ Yes
   - ☐ No

If the proposed ancillary study includes a collaboration with a current NIH RECOVER Investigator serving as a co-investigator or mPI in the ancillary study, then please provide the name of the NIH RECOVER Investigator, the investigator's affiliation (name of Hub or core) and e-mail address, and their role in the ancillary study. If there are multiple collaborations with existing NIH RECOVER Investigators, please complete for all such collaborations.

	Name	Affiliation	Email	Role
1				
2				
3				
4				

B. Lead PI Contact Information

Note: E-mail address will be listed publicly with other research proposals that are approved

1.	E-mail Address:	
2.	Affiliated Institution:	
3.	Telephone Number:	
4.	Address Line 1 (if applicable):	
5.	Address Line 2:	
6.	Address Line 3:	

Address Line 1: Building, Company, or Institution Name (e.g., NYU Langone Tisch Hospital)

Address Line 2: Building Number (if applicable) and Street Name/Number (e.g., 123 4th Ave.)

Address Line 3: City, State and Zip Code (e.g., New York, NY 12345)

C. Areas of Research Expertise Needed for Review of Proposal

Please select the areas of research expertise that are needed for the review of your proposal *(select all that apply)*:

- ☐ Cardiopulmonary
- ☐ Immunology and Hematology
- ☐ Mechanistic Pathways
- ☐ Metabolic Disorders
- ☐ Microbiology
- ☐ Neuropsychiatric
- ☐ Omics
- ☐ Other (please describe): _____

D. Plans for Funding

1. Funding mechanism:

2. Deadline for Submission Date (if applicable):

E. Title

1. Provide the title of the proposal:

2. *(Optional)* Please attach the mother grant specific aims and research strategy. *Note: not including this could lead to a delay in the final determination.*

F. Hypothesis and/or Specific Aims of the study.

Provide a brief statement ***(maximum 1–2 sentences)*** describing the proposal's main hypothesis. If the proposal has multiple aims, please provide a brief statement for each aim:

G. Background, Significance, and Feasibility

Provide a brief statement summarizing the background, significance, feasibility and innovation ***(maximum 250 words for each)*** of the proposed research.

1. **Background:**

2. **Significance:**

3. **Feasibility**:

H. Study Design, Including Primary Outcomes and Covariates

Please use a **CONSORT** (Consolidated Standards of Reporting Trials) flow diagram to delineate study design (including groups for comparison), list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis. *You may attach this as a separate Word Document or PDF file, or include it as plain text in this document.*

I. Need for RECOVER Resources & Justification of Use

Please select the type of RECOVER resources the proposal is requesting to use (*select all that apply*):

- ☐ Retrospective collection of samples and data
  - ☐ Stored samples and data
    - ☐ Adult
    - ☐ Pediatric
    - ☐ Autopsy
  - ☐ Stored data only
    - ☐ Adult
    - ☐ Pediatric
    - ☐ Autopsy
- ☐ Prospective recruiting/interaction/collection *(please specify the types of groups being requested):* _____

J. Phenotype Requirements

(Complete this section only if your request is for stored samples and/or data)

1. Please specify the phenotypes for which you would like samples and/or data by completing the chart below. You can build up to 8 distinct cohorts with distinct characteristics. For each cohort, specify the infection status (either "Infected" OR "Uninfected"), the PASC status (if infected), the number of subjects, and the time points (you can request any or all of the following: baseline,

3months, 6-mo, 12-mo, 24-mo, 36-mo, 48-mo), and please provide a description of the symptoms.

Group	Infection Status	PASC Status	# Subjects	Timepoints	Symptom Description
Example	Infected	PASC+	20	3-mo 12-mo 36-mo	(describe the symptoms)
1					
2					
3					
4					
5					
6					
7					
8					

2. Please describe your phenotype of interest:

3. Provide brief justification of the proposed cohort size (number of subjects):

K. Biospecimen Requirements - Adult

(Complete this section only if applicable)

1. Please specify the biospecimen type *(select all that apply)*:

☐ Plasma **Specify aliquot volume in microliters**: _____ **Specify the treatment type for the Plasma samples by selecting one of the following:** ☐ EDTA ☐ Sodium Citrate ☐ Sodium Citrate-CPT ☐ Doesn't matter
☐ Serum **Specify aliquot volume in microliters:** _____
☐ PBMC
☐ PAXGene RNA Whole Blood
☐ Oragene OGR-600 Saliva
☐ Urine **Specify the required volume in microliters:** _____
☐ Stool

☐ White Blood Cells
☐ Nasal Cells
☐ Nasopharyngeal Cells

2. Provide brief justification of the proposed quantity of biospecimen needed:

L. Biospecimen Requirements - Autopsy

(Complete this section only if applicable)

1. Please specify the biospecimen type *(select all that apply)*:

☐ Serum **Specify aliquot volume in microliters: _____**
☐ Blood Spot
☐ Stool
☐ CSF Fluid
☐ Bronchial Cells
☐ Frozen Tissue
☐ FFPE Section

2. Provide brief justification of the proposed quantity of biospecimen needed:

M. Biospecimen Requirements – Pediatric

(Complete this section only if applicable)

1. Please specify the biospecimen type *(select all that apply)*:

☐ Plasma **Specify aliquot volume in microliters: _____**
☐ Serum **Specify aliquot volume in microliters: _____**
☐ Blood Spot
☐ PBMC
☐ Oragene OGR-600 Saliva
☐ White Blood Cells
☐ Red Blood Cells

2. Provide brief justification of the proposed quantity of biospecimen needed:

N. Data Requirements

(Complete this section only if applicable)

1. Please describe the data that you need for your study:

2. Provide brief justification of the request for data:

O. Patient Recruitment/Interaction Requirements (Allowed only for RECOVER Investigators.)

(Complete this section only if applicable)

1. Will you be recruiting existing RECOVER participants or participants not currently enrolled in RECOVER? *(Select all that apply)*
   - ☐ RECOVER participants
   - ☐ Participants not currently enrolled in RECOVER

2. What will you ask the existing RECOVER participants to do? *(Select all that apply)* ☐ Collect additional samples *(Please **describe**):*

   ☐ Collect additional data *(Please **describe**):*

   ☐ Other *(Please **describe**):*

3. Please state the proposed cohort size (number of subjects) for RECOVER participants:

4. Please provide brief justification of the proposed cohort size (number of subjects) for RECOVER participants:

5. Please state the proposed cohort size (number of subjects) for participants not currently enrolled in RECOVER:

6. Please provide brief justification of the proposed cohort size (number of subjects) for participants not currently enrolled in RECOVER:

P. Inclusion & Exclusion Criteria

(Complete this section only if applicable)

1. Briefly describe the proposal's cohort inclusion and exclusion criteria. Refer to the protocol as needed to describe criteria.

2. Depict the RECOVER site(s) of inclusion:

   ☐ I want to recruit from a single RECOVER site *(please **provide the name of the site** you want to recruit from):*

   ☐ I want to recruit from multiple RECOVER sites *(please **provide the names of all the sites** you want to recruit from):*

Q. Protection of Human Subjects Plan

(Complete this section only if applicable)

Provide a brief description of the risks, benefits, consent process, and protection against risk, making particular note of approaches for vulnerable subjects. If applicable, please describe the safeguards that will be put in place to reduce or prevent participant burden.

R. Patient or Community Engagement

1. Please indicate whether you conferred with patient communities, such as a community advisory board or a group of patients, on your proposal.

   ☐ Yes

   ☐ No

2. *(Optional)* If you did confer with patient communities on your proposal, then please provide more details regarding (1) at what point during the study development period did you choose to consult with patient communities, (2) the composition of the patient community you conferred with, and (3) examples of how you assessed and implemented patient feedback into your proposal:

3. *(Optional)* If you did **not** confer with patient communities on your proposal, then please provide more details, such as justification for why patient/community consultation was not obtained, or a brief description of plans to include patient/community consultation in the future:

S. Additional Study Impact

Please indicate whether this study will require new/additional testing or new/additional data collection. If so, then what are the measures being proposed to minimize site/staff burden?

T. Study Overlap

1. RECOVER maintains a list of consortium publications and research summaries on a subset of these publications. Additional perspectives from expert presenters are available via recordings of

presentations from the RECOVER Research Review Seminar Series. Are you aware of any significant overlap between your proposed study and the current RECOVER studies?

☐ Yes *(**Please provide details** to justify this overlap, such as how your proposal is complementary to the studies or promotes necessary replication):*

☐ No

2. Please refer to the list of funded RECOVER pathobiology awards available at https://recovercovid.org/pathobiology. Are you aware of any significant overlap between your proposal and any of the funded RECOVER pathobiology awards?

☐ Yes *(**Please identify** the funded RECOVER pathobiology awards that your proposal overlaps with, and please provide details to justify this overlap):*

☐ No

U. References

List relevant literature citations; maximum of 10

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

9 _____

10 _____