IDCRC Secondary Research Proposal

Title of Proposed Study:	
IDCRC Parent Protocol Number(s):	
Date of Proposal Submission (dd mmm yyyy):	

Lead Investigator:			
Lead Investigator's Institution:			
Lab mailing address (for receipt of samples):			
Phone:		Email	
Affiliated with IDCRC and/or VTEU?		◯ Yes	◯ No
If yes, please indicate IDCRC investigator and unit of affiliation (e.g., COU, LOU, SDSU):			

Project Team

Provide contact information for any additional project team members. If more than four, please use an additional page:

Investigator name:	Institution:	Email:

Other Support Personnel

Provide contact information for any additional personnel necessary to complete this request, such as those performing MTA or IRB review:

Name and role:	Email:

Funding

Are funds available to support the proposed study?	◯ Yes ◯ No
If yes, please describe the funding source:	
If no, please describe plans for securing funds to support proposed studies:	

Trainee Opportunities

Are opportunities proposed for early-stage investigators?	◯ Yes ◯ No
If yes, please describe briefly:	

Information requested

Requests must be for existing data and/or specimens as described in the parent protocol(s):

Participant data	◯ Yes ◯ No
Participant specimens*	◯ Yes ◯ No
Genomic data	◯ Yes ◯ No
Will study involve any human or non-human genomic analysis?	◯ Yes ◯ No
If study involves genomic analysis, please describe:	
If human, will analysis include more than 1000 persons' samples?	◯ Yes ◯ No

If requesting specimens, please note the following:

1. Documentation of IRB/EC approval or determination that the work is not human subjects research is required from each institution at which the proposed work with IDCRC specimens will be conducted. Specimens cannot be provided/used until after this documentation is sent to the IDCRC Secondary Research Project Manager via IDCRC.sec.research@fredhutch.org. We will contact proposal investigators to request this and any other required information after the proposal completes the scientific approval process.
2. Study proposals requesting specimens from outside of the US may require additional approvals before specimens can be provided/used. The IDCRC Secondary Research Project Manager will work with proposal investigators and relevant sites to obtain these approvals.

Proposal Narrative

In a separate document using Arial 11 or equivalent, with at least 0.5" margins on all sides, standard letter paper size (8 ½" x 11") size, and in a maximum of 3 pages (not counting references), please write your proposal in the following structure:

I. Background and rationale

Please describe study rationale, relevant background information, implications of prior research, opportunities for trainees, and anticipated contribution of proposed study to the IDCRC research agenda including potential expansion of VTEU lab capabilities and/or capacity.

II. Proposed study

A. Study hypotheses and objectives

1. The primary hypotheses
2. The major study objectives and endpoints needed to achieve those objectives

B. Study design/methods, including, as appropriate, details regarding:

1. Type of study (e.g., analysis of existing data; cross-sectional data analysis; new laboratory assays with existing stored specimens)
2. Outcomes to be measured
3. Sample size
4. Brief assay and analysis plan
    i.) Specify any laboratory work or statistical analyses that will be done in a Core IDCRC Laboratory or at the SDMC (e.g., SDSU, Emmes).

C. Study Deliverables: Please describe plan for publication and/or presentation. Describe any reports that will be provided to the IDCRC. *Please note, if the proposal is approved, the proposal investigator must agree to provide an interim report (twice yearly) and a final written report to the Secondary Research Project Manager before the specimen request can be fulfilled.

III. Requested specimens, data and/or analysis

(Please contact IDCRC.sec.research@fredhutch.org if you require assistance in completing this section.)

A. Provide a detailed description of specimens/data required and assays/analyses to be conducted. Please specify the following:

1. Protocol(s)
2. Time point(s) or visit(s)
3. Study cohort(s)/group(s)
4. For specimens, provide an overview of assays to be conducted:
    i.) Specimen type and minimum volume/number of cells requested
    ii.) Provide a detailed description of assay(s) to be conducted (e.g., drug assays, immunologic and virologic tests)
    iii.) Provide inclusion or exclusion criterion for sample selection (e.g., participants with positive responses, females only)

iv.) Indicate what sample metadata will be required (e.g., treatment assignment, demographics, HLA type)

5. For study data, provide a detailed analysis plan, including the data being requested, as specifically as possible. Include the following when describing the request:

i.) Type of data (e.g., assay, clinical, survey)

ii.) Sample size and variables needed

iii.) Power calculations for primary objectives (if appropriate)

iv.) If a specific format for the data is required (e.g., SAS transfer file)

IV. Resources requested

Please describe the level of IDCRC/VTEU involvement or support needed for this project. Items may include specimen lists, laboratory assays, dataset preparation analysis, plan development and/or statistical analysis assistance.

End of document.

When completed, please return this form, and your Proposal Narrative in PDF format, to IDCRC.sec.research@fredhutch.org.