Infectious Diseases Clinical Research Consortium

18. SECONDARY RESEARCH USE OF SPECIMENS AND/OR DATA

This section describes the steps for soliciting, reviewing, approving, and implementing proposals for secondary research use of IDCRC specimens and/or data.

18.1 Scope

This section covers the process for requesting specimens and/or data for secondary research and comprises the following key steps: (1) solicitation of proposals; (2) submission of proposals (solicited or unsolicited); (3) review of proposals for feasibility and scientific merit; (4) approval of proposals; (5) study implementation, which includes transfer of IDCRC specimens and/or data; and (6) interim and final written study reports, as well as study outcomes, such as publication or public presentation. Studies proposing the secondary research use of specimens and/or data are defined as those studies requesting the use of stored specimens (with or without accompanying data) and/or data collected under the parent protocol for purposes that are not covered by the parent protocol and study informed consent form (referred to under the "Secondary Use of Stored Specimens and Data" section of the protocol). This process does not cover proposals for use of stored specimens and/or data collected under the parent protocol for purposes that are covered by the parent protocol for studies specific to primary, secondary, and exploratory objectives/endpoints.

The transfer of data and/or specimens will typically occur after completion of the parent protocol (i.e., transfer of retrospective data and/or residual study specimens). In certain cases (e.g., when testing of samples may provide important insights pertaining to the study), and with approval of the protocol team, data and/or specimens may be transferred while the protocol is still ongoing; in this scenario, specimens and/or data will not be transferred until all primary data analysis has been completed. In rare instances (e.g., for assay development during a pandemic where relevant specimens are not available), specimens may be transferred prior to analysis of primary and secondary endpoint specimens only if there are sufficient numbers of specimen aliquots available for per protocol endpoint assays (i.e., minimum aliquots required for each per protocol assay and back-up aliquots), and with approval of the protocol leadership. This IDCRC MOP section does not include a request for funding for secondary research studies; as part of the application process, investigators will be required to identify the source(s) of funding for their proposed studies including cost of specimen shipment from the repository. While biological specimens are owned by the institution at which they were collected, IDCRC policy governs the custody, management and access to all specimens collected as part of IDCRC clinical research studies, including specimens for secondary research (refer to MOP Section 17 Specimen Management for detailed IDCRC policy on sample custody and management).

Secondary Research Committee (SRC) Membership

The committee will be comprised of members of the protocol team including the protocol chair(s) and protocol specialist, and a representative from DMID, the Laboratory Operations Unit (LOU), the Statistical and Data Sciences Unit (SDSU), the Clinical Operations Unit (COU), a relevant Expert Working

Group (EWG) member, and the data center (if not the SDSU). If the protocol will evaluate a product, a representative from the developer will be invited to join the committee.

Secondary Research Project Manager (PM)

This position is key to the proper execution and completion of the procedures described herein. This position will reside within the IDCRC LOU and work closely with the SRC.

18.2 Procedure

Solicitation: The IDCRC Leadership Group will list protocols and a general description of the samples and data available for secondary research use on the public facing website, https://idcrc.org and solicit internal and external investigators to submit proposals for the secondary research use of data and/or specimens collected from each IDCRC protocol where residual specimens are available. The LOU will provide the LG with the updated sample and data list to be updated on the IDCRC website once quarterly. Investigators will be encouraged to include training opportunities, and there will be targeted outreach to early-stage investigators to submit proposals. Investigators may contact the IDCRC with general inquiries regarding opportunities for collaboration at the email alias IDCRC.sec_research@fredhutch.org. Unsolicited requests for data and/or specimens will also be considered.

Submission: Proposals are submitted to IDCRC.sec_research@fredhutch.org using the IDCRC Secondary Research Proposal Template (exhibit 18.3.1). The template will be available on the IDCRC website https://idcrc.org. Upon receipt of a secondary research proposal, the PM reviews the proposal for overall completeness. If needed, the PM will contact the proposal lead investigator for additional information to facilitate internal assessment and review.

Scientific and Feasibility Review: The PM will determine the study type(s) by reviewing relevant protocol language that specifies the allowed secondary research uses of specimens and/or data.

For each proposal, the PM will perform an initial assessment of data and/or specimen availability. Study subjects that have NOT given informed consent to allow for specimens to be used for secondary research will not be included. The PM will also account for specimens that are reserved for secondary outcomes analysis that are pending from the protocol and remove them from any calculation of available specimens. If applicable, the DMID representative will review the clinical trials agreement (CTA) and confirm alignment with the specimen and/or data request. A summary of the inventory (for feasibility assessment) and the completed proposal will be provided to the SRC for review. Using the Secondary Research Study Review Form (Exhibit 18.3.2), each member of the SRC reviews the proposal with a focus on scientific merit and feasibility. Considerations include track record of lead investigators, impact of the proposed studies, training opportunities for early-stage investigators, potential to increase lab capabilities and/or capacity within the IDCRC/VTEU, potential conflicts or overlap with planned or ongoing IDCRC work, specimen and data availability and associated timelines, and regulatory requirements. For those instances where an application requests data and/or specimens from more than one IDCRC protocol, all applicable protocol chairs will be consulted to review and approve the application. If required, subject matter experts will be asked to review the proposal and provide feedback on scientific merit and the potential impact by completing the Review Form. The completed review forms will be submitted in a timely manner to the PM who will compile the forms, email the forms to the SRC, and schedule a meeting to discuss the final outcome of each application.

One of three outcomes may occur:

1. Proposal is not approved: Specific messaging approved by the SRC will be communicated to the investigator by the PM.

2. Proposal requires revision: The PM will inform the investigator of the requested changes, and an updated proposal may be submitted to the PM for follow-up review by the SRC.

3. Proposal is approved. See below for next steps.

Proposal Approval Notification: Upon feasibility and scientific review, the PM sends a letter notifying the investigator(s) of study approval. The letter states that interim (if applicable, studies less than 6 months duration do not require interim reports) and final written reports are a requirement for receipt of specimens/data, and the requirement to comply with the IDCRC Agreement on Confidentiality and Use of Data/Specimens. If the investigator(s) agrees to these terms, they sign and date the letter and submit to the PM. The IDCRC Publication Policy and the publication terms of any applicable CTA will also be provided to the investigator. The IDCRC Leadership Group will start the process to execute an MTA with the proposal lead investigator. Specimens and/or data will not be released until the MTA has been fully executed and is on file at the IDCRC Leadership Group. It is the responsibility of each site investigator to obtain local institutional ethics approval to use samples for secondary research studies. Proof of local ethics approval, such as an Institutional Review Board (IRB) letter, will be submitted by each site investigator to the PM, who will verify that the approval is in place.

Study Implementation. Upon receipt of the signed approval letter, the PM sends a formal email to the IDCRC Specimen Coordinator to coordinate specimen selection and shipment, or to the data center representative for data transfer, as applicable. The PM oversees the study implementation process serving as a liaison and directing communication/resources among proposal investigators and representatives in the LOU and data center as applicable. All shared samples/data will be coded (preferably double coded).

Transfer of Secondary Research Data: For secondary research proposals requesting data, the PM works closely with the data center designee to confirm that requested data have been successfully transferred and are accessible to the proposal investigator. It may be specified in the study proposal document whether a designated statistician in the SDSU is a collaborator on the proposal who would then facilitate data transfer.

Transfer of Secondary Research Specimens: For secondary research proposals requesting specimens, the PM works closely with the data center designee, and the respective specimen coordinator to establish specimen selection based on the proposal selection criteria and specimen availability. Upon selection of an available and appropriate sample set to fulfill study research objectives, the IDCRC Specimen Coordinator communicates with the lead investigator to obtain any required documentation (e.g., import or export permits) and coordinates shipment of samples with the biospecimen repository and the investigator's institution at a mutually agreeable date. The receiving investigator will be responsible for paying the shipping costs of the specimens. The PM tracks and documents that study specimens were received.

Study Completion: Interim (twice yearly) and final study reports will be submitted to the PM who will distribute to the SRC for review. Abstracts and manuscripts from the approved studies will be approved by the IDCRC Publications Committee. Publications resulting from the use of these specimens or data should cite the IDCRC parent grant, protocol, and sites from which the specimens were collected and/or

data generated.

The secondary research study investigators will destroy any residual samples at the end of the study unless otherwise designated by the SRC.

Exhibit 18.3.1 – IDCRC Secondary Research Proposal – Application Instructions

Exhibit 18.3.2 – IDCRC Secondary Research Proposal – Review Form