18. SECONDARY RESEARCH USE OF SPECIMENS AND/OR DATA

18.1 Scope

This section outlines the process for submitting and processing requests for specimens and/or data from IDCRC protocols for secondary research.

Studies proposing the secondary research use of specimens and/or data are defined as those studies requesting the use of stored specimens and/or data collected under IDCRC parent protocol(s) for purposes that are not covered by the parent protocol and study informed consent form.

The transfer of data and/or specimens must align with the 'Secondary Use of Stored Specimens and Data' section of an IDCRC protocol, if available, and will typically occur after both clinical and non-clinical database lock (i.e., lock of per protocol assay data) for the parent protocol. In certain cases, secondary research requests for data and/or specimens may be considered while the protocol is still ongoing (e.g., when specimens are collected for the purpose of secondary research and in alignment with DMID policy). The IDCRC does not support funding requests as part of this process and requestors are expected to have identified the source(s) of funding to support their projects prior to submission, which may include the cost of transferring specimens and/or data.

Specimens and data resulting from IDCRC protocols are typically owned by the institution at which they were collected. However, IDCRC policy governs the custody, management and access to all specimens and data collected as part of IDCRC clinical research studies, including specimens for secondary research, as outlined in the Specimen Management MOP.

18.2 Procedure

Submission:

Secondary research requests should be assembled using the IDCRC Secondary Research Proposal Form available on the IDCRC website. Secondary research requests may be submitted at any time and should be submitted by the proposing investigator(s) to the Leadership Operations Center (LOC) by e-mail at idcrc@emory.edu. Once received, a secondary research proposal is assigned a unique identification number (parent protocol number followed by sequential request number e.g., ##-####-SR##) for tracking purposes, maintained in a pipeline tracking sheet, and

administratively reviewed by a LOC administrator. If needed, the LOC administrator will contact the investigator(s) for additional information to facilitate internal assessment and review.

Scientific and Feasibility Review:

Once a request has cleared the initial administrative review, the LOC administrator will be responsible for overseeing the review and approval process. The request form and any relevant supplemental documents will be forwarded to the LOU and/or SDSU depending on the nature of the request, as outlined in the table below.

Secondary Research Request Type	LG Unit to Conduct Feasibility Review
Specimens	LOU
Data stored at Emmes	LOU
Data stored at SCHARP	SDSU

The applicable LG unit will have ten (10) business days to review the request and conduct an initial assessment of data and/or specimen availability and the feasibility of transferring the specimens and/or data being requested. If any outreach to Emmes is required to complete the feasibility review, the CPM will be included on communications. If applicable, the appropriate DMID study representative will review the clinical trials agreement (CTA) and confirm alignment with the specimen and/or data request. Once this assessment is complete, the proposal will be reviewed by a protocol-specific *Secondary Research Committee (SRC)*. The committee will be comprised of members of the relevant protocol team(s), including the IDCRC protocol representative, the protocol chair(s), the DMID Medical Officer, the Laboratory Operations Unit (LOU), and the Statistical and Data Sciences Unit (SDSU). Depending on the nature of the request, additional subject matter experts, including a representative from the developer if a product is being evaluated, may be invited to join the committee. If a member of the SRC is also the proposing investigator, they will be recused from providing a review and scores.

Each member of the SRC reviews the proposal with a focus on scientific merit, study design and feasibility. The reviewer will have 10 calendar days to respond with their vote and provide comments, after which point a non-response will be considered an abstention. The LOC administrator will compile the votes and summarize reviewer comments, email the IDCRC protocol representative of SRC to review and share their recommendation with the SRC by email, and request their concurrence. If needed, the LOC administrator will schedule a meeting to discuss the final outcome of each application. The outcome of the review is shared with the IDCRC Executive Management Team and the FHI Protocol Specialist for awareness.

One of three outcomes may occur:

1. Proposal is not approved: Notification of decision and specific feedback will be communicated to the investigator by the LOC administrator.

2. Proposal requires revision: Notification of decision and specific feedback will be communicated to the investigator by the LOC administrator with an invitation to submit an updated proposal for re-review.

3. Proposal is approved. Notification of decision will be communicated to the investigator by the LOC administrator, outlining the terms of approval.

Typical terms of approval for a secondary research request include:

1. The proposing investigator is responsible for covering shipping of specimens and the effort to prepare specimen picklists and data, if applicable. The Proposing Investigator will work directly with the unit performing these activities to develop a budget and funding mechanism to support these activities.
2. Acknowledgement and agreement that only the secondary research described in the approved proposal will be conducted. Any additional analysis outside of the approved scope would require a separate request, even if specimens and/or data are already transferred.
3. Execution of a Materials Transfer Agreement or Data Use Agreement, depending on the type of request, prior to the transfer of any specimens and/or data. IDCRC agreements will be executed by Emory University as applicable.
4. Submission of local ethics approval or waiver (e.g., an Institutional Review Board letter) prior to transfer of specimens and/or data.
5. Agreement to comply with the IDCRC Publication Policy and any publication terms from the parent study if applicable.
6. Submission of a final written report to the LOC administrator for IDCRC review of progress.
7. Agreement on the residual specimen plan at the end of the study (typically, residual specimens will be destroyed).

Study Implementation. Upon receipt of the signed approval letter from the investigator acknowledging receipt and agreement of terms, the LOU and/or SDSU will coordinate specimen selection and shipment and/or data transfer.

Transfer of Secondary Research Specimens: For secondary research proposals requesting specimens, the LOU protocol coordinator works closely with the data center designee to establish specimen selection based on the proposal selection criteria and specimen availability, including the CPM in communications for studies that include data from Emmes. Upon selection of an available and appropriate specimen set to fulfill study research

objectives, the LOU protocol coordinator communicates with the lead investigator to obtain any required documentation (e.g., import or export permits) and coordinates shipment of specimens 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 and if applicable, the costs for the data center to prepare the specimen picklists and transfer of any specimen-associated data via a data transfer plan (DTP). The LOU protocol coordinator tracks and documents that study specimens were received.

Transfer of Secondary Research Data from Emmes: For secondary research proposals requesting clinical and/or lab data from Emmes, the LOU protocol coordinator works closely with Emmes and DMID to coordinate the transfer and to confirm that requested data have been successfully transferred and are accessible to the proposal investigator in alignment with DMID policy.

Transfer of Secondary Research Data from SCHARP: For secondary research proposals requesting clinical data from SCHARP, the LOC administrator will work closely with the SDSU/SCHARP team. SCHARP will facilitate a DTP with the lead investigator that details the logistics of the data transfer. The investigator will be responsible for funding the effort to prepare the data for transferring. The SCHARP representative will copy the LOC Administrator on communication pertaining to the transfer of the data for status tracking purposes.

REVISION HISTORY:

Version number	Approval Date DD MMM YYYY	Summary of Changes
2.0	02 APR 2025	Requests will be coordinated by the LOC. Modified SRC committee membership and streamlined review workflow. Clarified terms of approval.