Infectious Diseases Clinical Research Consortium

2.0 IDCRC ADMINISTRATIVE PROCESSES

2.1 Annual Conflict of Interest Process

The IDCRC requires that an annual financial disclosure form be on file for any Consortium member who may be responsible for having substantial independent decision making in respect to the design, conduct or reporting of IDCRC research. At a minimum, this IDCRC annual disclosure must be provided for:

- Principal Investigators, and/or members of the research team identified as Key Personnel on the IDCRC grant award or supplemental award.
- Individuals participating in Expert Working Group (EWG) decisions related to the research, voting on/rating proposed research concepts/protocols.
- Individuals serving on the Clinical Site Selection Committee (CSSC) or otherwise providing input regarding study site selection.
- Members of IDCRC leadership who are key personnel and/or vote on concept proposals as part of the Executive Management Team (EMT).

IDCRC members who fall into one of the above defined groups must report Significant Financial Interests for himself /herself and for his/her spouse, domestic partner and dependent children that are related to the Investigator's participation in the IDCRC. Although institutions require similar disclosures, the IDCRC must monitor for Conflicts of Interest (COIs) that are specific to its mission and operations.

The annual disclosure process is administered by the Leadership Operations Center Administrative Core (LOC AC), through an electronic survey, normally near the end of each grant year (November 30). Those required to complete the survey will be notified via e-mail. Annual disclosures will be good for one year from the date of completion. Should a new member join the IDCRC in one of the roles outlined above, they will be required to complete this process within 60 days and will then complete a new form at the next cycle. Federal employees serving on EWGs or in other roles as outlined above are exempt from this process as they are covered under federal conflict disclosure policies.

2.2 Non-Disclosure Agreements (NDA)

The confidentiality of IDCRC activities is protected through NDAs. At the creation of the IDCRC, an NDA was executed between Emory University and DMID to establish the terms and conditions for all network NDAs. Emory subsequently executed a multi-party Master NDA agreement with all IDCRC unit and VTEUs institutions, flowing down the requirements from the agreement with DMID to units of the Consortium. Official VTEU sub-sites, listed in their applications, should also be signatories to the Master NDA.

Should a non-IDCRC, third-party need to share information with the network, the master NDA allows for the execution of a Task Order, that would then hold each party to the terms and conditions listed in the Master NDA.

2.3 Material Transfer Agreements (MTA)

In recognition that there will be multiple research projects requiring the transfer of research materials within the network, an umbrella MTA agreement has been executed across the IDCRC to facilitate this process. For protocols that plan on transferring materials among institutions covered under the umbrella MTA, a Task Order form must be executed between each of the applicable Parties, that lists the Statement of Work (SoW), the performance period, and the Original Material to be transferred. Studies that are transferring materials outside of the network, this may include sub-sites, will require execution of a separate, stand-alone agreement. The Laboratory Operations Unit (LOU) is responsible for working with the LOC AC to identify the need for an agreement for each study and oversee the execution of all relevant agreements, through Emory university.

2.4 Other IDCRC Study Agreements

For IDCRC trials requiring IND/IDE, NIAID will lead the negotiation of Clinical Trial Agreements (CTAs) with pharmaceutical companies (or other providers of investigational agents). For trials not under IND/IDE, or when the need for additional study agreements is identified, the IDCRC LOC, in close consultation with Emory University's Office of Sponsored Programs, will be responsible for determining the most appropriate agreement execution pathway with the applicable parties. Inquiries related to IDCRC agreements may be directed to idcrc@emory.edu.

2.5 IDCRC Recommended process for coordination and documentation of Meeting Minutes

Formal minutes should be taken for meetings held by the IDCRC Leadership Group, Executive Management Team (EMT), Clinical Operations Unit (COU), Laboratory Operations Unit (LOU), Statistical and Data Science Unit (SDSU) and Leadership Operations Core (LOC). The process outlined below should be followed for regular IDCRC calls. Expert Working Groups (EWGs) and protocol teams have a separate process for minutes.

1) The unit responsible for the call will designate a minute-taker for the meeting.
2) Minutes will be drafted immediately following the meeting.
3) The draft will be provided to the leadership of the unit for their review within 72 hours of the meeting.
4) Comments will be returned to the minute-taker within 72 hours of sending out the draft.
5) Minutes will then be finalized for distribution as a draft in Microsoft Word form prior to the next regular meeting of the unit. The unit will circulate these Draft Minutes to attendees with the agenda and other materials for the upcoming call.
6) Minutes will be approved as the first agenda item of the next meeting of the unit.
7) Minutes are then converted to PDF, disseminated, and filed in the appropriate file on SharePoint.

2.6 Genomic Data Sharing Plan

As required under the NIH Genomic Data Sharing Policy, the IDCRC complies with regulations relating to large genomic data submission to the database of Genotypes and Phenotypes (dbGaP) of NCBI or other approved databases as appropriate to the study and the data. Where appropriate and required by NIH policy, study PIs are responsible for and will be required to submit large-scale human genomic data as well as relevant associated data (e.g., phenotype and exposure data) to an NIH-designated data repository in a timely manner, including any information necessary to interpret the submitted genomic data, such as study protocols, data instruments, and survey tools.

The need for genomic data sharing will be discussed during the protocol development phase of an IDCRC study. If it is determined that genomic data generated from a study is to be shared, the COU/FHI 360 will ensure that the appropriate language to allow for this data sharing is included in the protocol and approved Informed Consent Form (ICF).

Prior to receiving implementation funding, the LOC AC will ensure that details of the data sharing plan for the study are included in the project proposal that is submitted to the IDCRC Program Officer, prior to the release of protocol implementation funds.

Additionally, the LOC AC will create and maintain a tracker of studies and their approved genomic data sharing plan and submit this tracker as part of the LG's annual RPPR process. The LOC AC, through Emory University, will also be responsible for providing institutional certification that the data was submitted in compliance of the GDS Policy.