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7 IMPAACT General Policies and Procedures: Funding, Conflict of Interest, Certificate of Confidentiality, and ClinicalTrials.gov

7.1 IMPAACT Funding Procedures

The IMPAACT Network leadership and central resources (Operations Center, Statistical and Data Management Center [SDMC], and Laboratory Center [LC]) are funded through cooperative agreements (UM1 awards) with the National Institute of Allergy and Infectious Diseases (NIAID). Each clinical research site (CRS) is funded by NIAID or the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). NIAID sites receive funding directly from NIAID (through the Clinical Trials Unit [CTU]) and through the IMPAACT Finance and Contracts Office at Johns Hopkins University (JHU); NICHD sites receive funding from NICHD through a contracted coordinating center.

7.1.1 IMPAACT Funding Process for Pharmaceutical Company-Supported Studies

The IMPAACT Network may receive funding from pharmaceutical companies to support the conduct of a study. The funding level can vary depending on the study; a study may be fully funded by the pharmaceutical company or only partially funded, in which case costs are shared with the Network. In either case, the pharmaceutical company provides funding directly to the IMPAACT Finance and Contracts Office, which then funds the CRSs through a task order. For studies supported by pharmaceutical companies, the IMPAACT Finance and Contracts Office provides funding to the CRSs for both personnel and non-personnel study costs. The development of study budgets for these studies follows the same process as the Network-supported studies, and Management Oversight Group (MOG) approval is required (see Section 11). Once the MOG has approved the study budget, the Operations Center works with the IMPAACT Finance and Contracts Office to enter the budget into the pharmaceutical company's template and submit it to the pharmaceutical company for review and approval. Once approved, the IMPAACT Finance and Contracts Office receives funding based on milestones or a payment schedule defined in the funding agreement. Pharmaceutical funding is not included in the annual funding plan submission request to NIAID; however, enrollment projections and spending estimates are compiled during the annual budgeting and mid-course correction processes.

7.1.2 IMPAACT Funding Process and Timeline for NIAID-Funded Sites

NIAID funds CRSs as part of CTUs through UM1 awards. CTUs receive core (infrastructure) funding from NIAID for their administrative center and their CRSs. CTUs also receive study-specific (protocol) funding for the CRSs through their UM1 award to support site personnel effort specific to protocols; non-personnel study-specific (protocol) funding is provided to the CRSs through the IMPAACT Finance and Contracts Office in the form of a task order. Protocol funding for both personnel and non-personnel costs is provided by the IMPAACT Finance and Contracts Office directly to protocol-specific sites. Sites submit invoices to the IMPAACT Finance and Contracts Office for payment based on schedules presented in task orders executed between the IMPAACT Finance and Contracts Office and the sites.

- **Core funds** are provided to maintain scientific and administrative expertise and infrastructure at the CTU and at each affiliated CRS. Continued core support is based on satisfactory evaluation by the Network and NIAID. Costs in this category include:
  - CTU Principal Investigators (PIs) to maintain CTU administration and scientific contribution
  - CTU Coordinators and other CTU administrative, financial, and oversight staff
  - Regulatory, pharmacy, data management, and laboratory oversight staff
  - Quality management staff and activities
  - Community education and engagement staff and activities
  - Maintenance and replacement of equipment
  - Travel to Network meetings
  - Mentoring and training of staff

- **Study-specific (protocol) funds** are provided in addition to core funds to support study-specific preparatory activities (as "start-up funding"), implementation, and close-out for each IMPAACT protocol. Study-specific budgets are developed by the IMPAACT Operations Center in collaboration with the SDMC, LC, protocol chairs, other team members, site representatives, and JHU and are reviewed and approved by the MOG. Protocol funding needs are projected for the Network annually based on these budgets, together with study-specific timelines and participant accrual plans; resulting protocol funding plans are submitted to NIAID by the IMPAACT Finance and Contracts Office. Mid-course correction updates to the annual budget are also developed based on the criteria above and submitted to NIAID by the IMPAACT Finance and Contracts Office. The mid-course correction is normally requested mid-point in the award funding period. Costs in the protocol funding category include:
  - Study-specific regulatory, clinical, laboratory, pharmacy, statistical, and data management activities not otherwise supported by core funds
  - Study-specific community education and engagement activities
  - Study-specific participant recruitment and retention activities
  - Study-specific participant reimbursement
  - Study-specific evaluations (including but not limited to laboratory assays performed at site laboratories)
  - Study-specific equipment and supplies
  - Clinical trials insurance (if legally required; see Section 11 for further details)
  - Additional Community Advisory Board (CAB) support/activities, as needed

The Division of AIDS Office of Clinical Site Oversight (OCSO) representative and Grants Management Specialist send a letter to the CTU PIs to provide guidance on budget development for the coming year.

IMPAACT leadership develops an annual protocol funding plan based on study-specific budgets, anticipated study initiation dates, number of studies planned to be implemented by each CTU, number of participants, and other factors that have cost implications. The recommendations are submitted to NIH

Grants Management Branch (GMB) and NIAID (OCSO and the Prevention Sciences Program Chief). The IMPAACT Finance and Contracts Office works closely with NIH partners to ensure adequate review and compliance. DAIDS informs IMPAACT leadership of the protocol funding level it intends to provide and requests a plan to allocate the funding to NIAID-funded sites. Given the role of DAIDS in the funding of the IMPAACT scientific portfolio, IMPAACT and DAIDS leadership engage in an ongoing dialogue to ensure adequate funding levels to support the Network's scientific agenda.

Each year, CTUs complete a non-competing grant progress report (PHS 2590 package), including a budget and budget justification for the coming year. Unless otherwise instructed, this package is due 60 days prior to the annual anniversary date (i.e., 1 October for a 1 December award date). The format and forms for this package are available at: https://grants.nih.gov/grants/forms/report_on_grant/progress_reports.htm.

In addition to submitting the renewal package, CTUs must also account for expenditures by funding source(s) through their annual Federal Financial Report (FFR). The FFR also includes information on unliquidated balances (funds obligated to the CTU, but not expended). The CTU is required to file the FFR within 90 days of the calendar quarter in which the funding cycle ends. This report is submitted directly to NIH's Office of Financial Management (OFM).

The Network may request a carryover of unspent funds in its annual Research Performance Progress Report (RPPR) submission. GMB staff cannot act on any carryover requests received until OFM notifies them that the FFR has been accepted.

If a CRS identifies a need for additional funds, CTU and CRS leadership should first review the CTU award to determine if there are funds that can be re-budgeted to cover the proposed costs, which they can manage given their expanded authority. If re-budgeting is not possible, the CTU/CRS should submit a request including the amount needed, along with a detailed justification, to the IMPAACT Finance and Contracts Office. The IMPAACT Finance and Contracts Office will determine if there is sufficient funding within the award to fund the additional request. Depending on the amount requested, approval by the IMPAACT MOG may be needed.

7.2 Conflict of Interest and Financial Disclosure Policies

The IMPAACT Network seeks to maintain objectivity in all of its research by ensuring that the selection of products for testing, as well as the design, conduct, and reporting of Network studies is not biased by financial interests. In accordance with the provisions of the US Code of Federal Regulations (CFR), the Network adheres to the following policies:

- *NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedure*: This policy is in compliance with 42 CFR 50/F and 45 CFR 94; see Section 7.2.1.
- *United States Food and Drug Administration (FDA) Financial Disclosure by Clinical Investigators*: This policy is in compliance with 21 CFR 54 and applies to studies conducted under an Investigational New Drug (IND) application; see Section 7.2.2.

Figure 7-1 summarizes these policies as they relate to IMPAACT Network members. Depending on their Network roles and responsibilities, members may be subject to the requirements of one or both policies.

Figure 7-1. Financial Disclosure Requirements and Responsibilities for IMPAACT Network Members

<table>
<tr><th>HIV/AIDS Clinical Trials Networks
Financial Disclosure Policy and Procedure</th><th>FDA Financial Disclosure by Clinical Investigators</th></tr>
<tr><td>• All members of IMPAACT leadership and oversight committees (MOG, Scientific Leadership Group (SLG), Scientific Committees, Multidisciplinary Protocol Review Group (MPRG), Study Monitoring Committee (SMC)</td><td rowspan="2">For each IND study conducted at a CRS, all study site personnel listed on Form FDA 1572</td></tr>
<tr><td>• Protocol chairs and other protocol team members who make direct and significant contributions to or decisions about a study and/or study data, as determined by Network leadership</td></tr>
<tr><td colspan="2">Note: Pharmaceutical company representatives and US Federal government employees who are protocol team members are required to report under other Federal guidelines.</td></tr>
</table>

7.2.1 NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy

All Network members who are required to disclose financial information under the HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedures (see Figure 7-1) must complete the "Statement of Financial, Equity, and Intellectual Property Interests" at least annually or when joining a protocol team or committee. The office of HIV/AIDS Network Coordination (HANC) coordinates collection of these disclosures. Further guidance is provided in the NIH HIV/AIDS Clinical Trials Network Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure which is available at: https://www.hanc.info/resources/sops-guidelines-resources/site-management.html#fdcoi.

Members of a protocol team who do not have key decision-making roles are not required to disclose under this policy.

7.2.2 FDA Financial Disclosure by Clinical Investigators

Separately from the NIH disclosure policy described in Section 7.2.1, sponsors of IND studies are required to disclose to the FDA certain financial arrangements between sponsors and clinical investigators, as well as certain interests of clinical investigators in the study product or in the sponsor of the study. To fulfill this requirement, CRSs are required to maintain documentation of certain financial arrangements and interests for IND studies.

DAIDS policy on *Collection of Financial Disclosure by Clinical Investigators Conducting DAIDS-Sponsored IND Trials* applies to all investigators and sub-investigators (individuals listed on Section 6 of Form FDA 1572) participating in any DAIDS sponsored and/or supported study where DAIDS is the IND holder. Financial disclosure forms must be completed for each IND study at the timepoints noted in Figure 7-2.

Disclosures should be indicated on behalf of the staff member as well as the staff member's spouse and dependent children. Financial disclosure documentation must be maintained and updated, as applicable, throughout the period of study implementation. The original forms, any updated forms, and the new forms should be available on site for review. Further guidance on the requirements for collection and monitoring of financial disclosure forms is available in the Collection of Financial Disclosure by Clinical Investigators Conducting DAIDS-Sponsored IND Trials policy, available at: https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

IMPAACT has developed a financial disclosure form template that may be used to meet FDA requirements (available on the IMPAACT website or through the Operations Center). Alternatively, an equivalent form provided by a pharmaceutical company co-sponsoring an IMPAACT study may be used, or a study-specific financial disclosure form may be developed. The DAIDS Sponsor's Authorized Representative (SAR), in consultation with the pharmaceutical company (if applicable) and protocol team, will make the final decision regarding which financial disclosure form will be used. The IMPAACT Operations Center clinical research manager (CRM) will inform participating sites of which type of form will be used for a given study.

Figure 7-2. Financial Disclosure Requirements and Responsibilities for IMPAACT Network Members

Timepoint to Complete Financial Disclosures	Staff Required to Complete
Prior to site-specific study activation (at the time a site completes the Form FDA 1572, as described in Section 11)	Site IoR and all site staff listed on the Form FDA 1572
At any time when a new study staff member is added to the Form FDA 1572 (also applies to name changes)	New site staff member who is added to the Form FDA 1572
At any time when the financial interests of a site staff member listed on the Form FDA 1572 change	Applicable site staff member
At any time when a site staff member is removed from the Form FDA 1572	Site staff member who is removed from the Form FDA 1572
At any additional time, as required by the sponsor, i.e., as part of study close-out procedures	Site IoR and all site staff listed on the Form FDA 1572

If required, DAIDS, through the Operations Center, will collect the completed forms.

7.2.3 Subrecipient Financial Conflict of Interest

Under 42 CFR 50/F, institutions carrying out Public Health Service (PHS)-funded research must maintain an up-to-date, written, enforced policy on financial conflict of interest (FCOI). In addition, if an institution carries out such research through a subrecipient (e.g., subcontractor or consortium member), the institution must take reasonable steps to ensure that any subrecipient investigator complies with the regulation. The institution must either require that subrecipient investigators comply with the institutional policy or the subrecipient must certify that its policy complies with the regulation.

IMPAACT Finance and Contracts Office staff are required to verify that the subrecipient institution has the required institutional FCOI policy in place prior to issuance of a subaward. The IMPAACT Finance and Contracts Office maintains a list of IMPAACT Member Institutions (IMIs) that are currently listed in the Federal Demonstration Partnership (FDP) Clearinghouse. Any IMPAACT subrecipient that is not listed in the FDP Clearinghouse must complete "The Johns Hopkins University School of Medicine Significant Financial Interest Statement for JHU SOM Subrecipients Conducting PHS-Funded Research" form. Forms must be updated on a yearly basis. Subaward agreements will not be issued without FCOI verification.

7.3 NIH Certificate of Confidentiality

A Certificate of Confidentiality (CoC) is deemed issued under the IMPAACT Network NIH award. Documentation of NIH funding or support, the NIH CoC Policy (NOT-OD-17-109), the NIH Grants Policy Statement (See 4.1.4.1), and subsection 301(d) of the Public Health Service Act, serve as documentation of the issuance of a Certificate for a specific study. The certificate protects the privacy of

IMPAACT study participants at US sites whose personal information has been or will be collected. Effective 1 October 2017, in compliance with *Section 2012 of the 21st Century Cures Act* and updated NIH policy, all NIH-funded studies are automatically included in the certificate.

All participating US investigators are required to protect the privacy of all study participants and shall not:

- Disclose or provide, in any US federal, state or local civil, criminal, administrative, legislative or other proceeding, the name of such individual or any such information, document or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document or biospecimen pertains; or

- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research, unless the disclosure is intended for the purposes of other scientific research that is in compliance with applicable US federal regulations governing the protection of human subjects in research.

The CoC does not cover voluntary disclosures made by study participants, the reporting of suspected harm to others or self, or requests by authorized US Department of Health and Human Services (HHS) personnel. IMPAACT protocols incorporate sample informed consent forms that contain language describing the CoC and its limitations for study participants at US sites; US site staff inform participants of the limitations of coverage of the CoC during the informed consent process.

For more information on the CoC, refer to the law pertaining to the Certificate of Confidentiality [Public Health Service Act 301(d)] and the NIH Certificates of Confidentiality Kiosk, including information on 42 U.S.C. 241(d), as amended by Public Law No. 100-607, Section 163 (4 November 1988).

7.4 Processes for Registration and Results Entry for IMPAACT Studies in ClinicalTrials.gov

ClinicalTrials.gov is a US government-funded clinical trials registry.

In September 2007, the US Food and Drug Administration and Amendments Act (FDAAA) mandated that certain types of clinical trials be registered in ClinicalTrials.gov and that results be entered for all trials except for Phase I and observational studies. This mandate applied to all trials initiated or ongoing as of 26 December 2007. In September 2016, the US Department of HHS issued a Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) that clarifies and expands the regulatory requirements and procedures for submitting registration and summary results information of clinical trials on ClinicalTrials.gov, in accordance with FDAAA 801. Also in September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted within one year after the Primary Completion Date (PCD), whether the clinical trial is subject to FDAAA 801 or NIH policy (see Section 7.4.3 for the PCD definition). This policy is effective for applications for funding, including grants, other transactions, and contracts submitted on or after 18 January 2017. For the NIH intramural program, the policy applies to clinical trials initiated on or after 18 January 2017. In addition, some journals require that studies (including Phase I) be registered on ClinicalTrials.gov.

7.4.1 Division of AIDS ClinicalTrials.gov Protocol Checklist

For all IMPAACT studies (IND and non-IND), study CRMs and the Statistical and Data Analysis Center (SDAC) work to complete and submit the DAIDS ClinicalTrials.gov Protocol Checklist during protocol development. Generally, around the time of Clinical Sciences Review Committee (CSRC) review, the CRM drafts the checklist and emails it along with the draft protocol to SDAC (ct.gov@sdac.harvard.edu). SDAC colleagues confirm the details of the draft checklist, including whether results will be required and the anticipated PCD as provided by the study statistician, and finalize the checklist. The final checklist is sent back to the CRM. If mandatory informed consent language is required as indicated on the checklist, the CRM ensures that appropriate language is included in the protocol. As noted in Section 9, the completed checklist must be included with each protocol submitted for DAIDS Regulatory Review. During regulatory review, the Regulatory Support Center (RSC) verifies the content of the form aligns with protocol language and communicates any discrepancies to the protocol team. Any issues with the checklists are forwarded to SDAC (ct.gov@sdac.harvard.edu). The anticipated PCD is also shared with the DAIDS RSC Clinical Study Information Office (CSIO) for entry into the NIAID Clinical Research Management System (CRMS).

7.4.2 ClinicalTrials.gov Registration for IMPAACT Studies

All IMPAACT studies are registered.

- For IND studies, where the IND is held by DAIDS, the sponsor is DAIDS, and the study is registered and maintained by DAIDS.
- For non-IND studies, the sponsor is the Network (ACTG or IMPAACT), and the study is registered and maintained by the Network.

For non-IND studies, the Operations Center is responsible for drafting the initial registration record. For IND studies, the Operations Center sends the final protocol, along with the ClinicalTrials.gov checklist to DAIDS and their regulatory contractor, who is responsible for drafting the initial record and sending the draft to the study CRMs, copying IMPAACT.CTGOV@fstrf.org. Once the initial registration record is drafted, the study CRM sends the document for review by the protocol chairs and protocol statisticians. Review comments are requested within five business days. The study CRM coordinates integration and resolution of comments with the Operations Center staff responsible for the registration (non-IND studies) or with the DAIDS contractor (IND studies).

Per FDAAA, protocols must be registered no later than 21 days after the first participant is enrolled. To meet International Committee of Medical Journal Editors (ICMJE) requirements to publish with one of their journals, protocols must be registered prior to the first participant enrollment. In general, sub-studies and observational studies do not need to be registered, although protocol teams may register them if desired. See Section 11 for timing of study registration in ClinicalTrials.gov in relation to other open to accrual requirements.

For non-IND studies, once the record has been made public, the Operations Center forwards the National Clinical Trial (NCT) number, affiliated protocol number, and any updates to the anticipated PCD to the RSC CSIO. Studies will appear on the DAIDS automated email six months before the PCD is met. This email is sent to the SDAC ClinicalTrials.gov representative and each Network ClinicalTrials.gov email listserv. Once a study appears on the automated email list from DAIDS, the SDAC ClinicalTrials.gov representative contacts the study statistician to check the accuracy of the PCD. In addition, if studies are terminated prematurely or if actual PCDs occur more than six months before the anticipated PCD, study

statisticians notify the SDAC ClinicalTrials.gov email alias (sdac.ct.gov@sdac.harvard.edu). Notification of any changes are sent to the RSC CSIO (CSIO@niaid.nih.gov) to update the NIAID CRMS.

7.4.3 Results Entry for ClinicalTrials.gov

Results for IMPAACT clinical trials must be submitted within one year of the PCD, defined by ClinicalTrials.gov as the "date on which the last participant was examined or received an intervention to collect data for the primary outcome measure. Whether the clinical study concluded according to the protocol or was terminated does not affect this date." This date may coincide with the "closed to follow-up" date or may occur earlier than the "closed to follow-up" date, depending on the study. For studies which have multiple primary outcome measures, the PCD is the latest date meeting the definition above; there is only a single PCD for a study.

The NIH definition of a clinical trial is "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Further information is available at: https://grants.nih.gov/policy/clinical-trials/definition.htm.

When the PCD has been met for a study, the activities shown in Table 7-1 are initiated.

Table 7-1. Activities and Responsibilities to Ensure Compliance with ClinicalTrials.gov Requirements following PCD

Timeframe	Activity	Responsible Group
Within two months after PCD	• Finalize the list of sites that enrolled participants in the study on ClinicalTrials.gov • Submit protocol documents and Letters of Amendment	• Network contacts or DAIDS contractor
Six months after PCD	• Take ownership of the protocol record and initiate results entry (documented by email between IMPAACT.CTGOV@fstrf.org and CT.GOV@sdac.harvard.edu); note that only one owner is allowed to be in the record at the same time	• SDAC
Before starting results entry	• Review and update the entire protocol record	• SDAC
Within one year after PCD	• Submit study results • Notify RSC CSIO of the ClinicalTrials.gov study results submission date to update in NIAID CRMS	• SDAC
Once results have been made public	• Notify IMPAACT.CTGOV@fstrf.org that ownership of the study has been transferred back to the Network	• SDAC

SDAC is responsible for responding to all queries from ClinicalTrials.gov as the activities shown in Table 7-1 are completed. To help with this process, SDAC enters the designated Network contact information in the Results Point of Contact fields of the ClinicalTrials.gov protocol record. The Network contacts will communicate with the appropriate parties and respond to the query.

For studies where a second round of results entry will be required, e.g., when participant follow-up continues after the PCD and/or when results for secondary outcomes are delayed, SDAC will retain ownership of the record until all results have been made public.

7.5 Letters of Support

To respond to funding or other support requests relating to an ancillary study, proposing investigators may request a letter of support from the Network. Letters of support are generally developed in support of ancillary study requests, as described in Section 15; however, any grant application related to IMPAACT requiring a letter of support should follow the procedures described in this section. These procedures will facilitate the timely submission of requests for letters of support for IMPAACT-related grant applications, track proposals to which the Network has committed, and preclude the Network from obligating itself to participate in studies that do not have adequate budgetary support.

Investigators are responsible for submitting requests for letters of support to the Network by emailing IMPAACT.capsubmssions@fstrf.org at least six weeks ahead of the grant application deadline. Submitted materials should include a cover letter or message, draft letter of support, copy of the specific aims of the grant, budget justification, and draft budget. Investigators should also indicate the mechanism through which they plan to submit the proposal for IMPAACT review (e.g., proposal included in approved protocol as an exploratory objective, a New Work Concept Sheet [NWCS], Data Analysis Concept Sheet [DACS], or a Data Request [DR]); see Section 15 for more details regarding proposal mechanisms.

For letters of support involving an IMPAACT protocol that is not yet concluded, the Operations Center shares the submitted materials with the relevant protocol chairs for review and comment. The relevant protocol chairs or designees review the submitted materials and send comments to the Operations Center within seven days of receipt. If they do not comment within the seven-day period, they forfeit the right to comment on the proposal. Chairs should review the submitted materials to determine whether:

- The proposed research is already being addressed
- If there may be potential negative impacts on ongoing protocol data analyses or specimen use priorities
- If specimens are requested, the proposed research falls within the general research usage of stored specimens under which participants have consented

The MOG, or Network chair and SDMC PI on behalf of the MOG, reviews the submitted materials. If specimens are requested, the LC PI may also review. The Network chair reviews for alignment with IMPAACT Network priorities and the SDMC PI reviews for resource needs, e.g., time estimate for preparation of data and/or specimen requests. If substantial resources are requested, support for the SDMC will be required in the grant application. If approved, the Operations Center will finalize the letter of support for the grant applicant. If not approved, the Operations Center will inform the investigator(s).