15 ANCILLARY STUDIES, INVESTIGATIONS, AND ACCESS TO STUDY DATA

15.1 Scope and Definitions

This section describes the requirements for the development, submission, review, approval, and conduct of Data Requests (DRs), Data Analysis Concept Sheets (DACSs), and New Works Concept Sheets (NWCSs). The requirements for completion of Specimen and Data Usage Agreements (SDUAs) are also included.

The procedures apply to IMPAACT and non-IMPAACT investigators.

Information on available biological specimens for concluded IMPAACT and Pediatric AIDS Clinical Trials Group (PACTG) studies can be accessed on the interactive Specimen Repository website at http://www.specimenrepository.org. IMPAACT protocol documents and study completion statuses may be found on the IMPAACT website (http://impaactnetwork.org) or requested from the Operations Center at IMPAACT.OperationsCenter@fstrf.org. Operations Center support for the development of DRs, DACSs, or NWCSs is not provided unless otherwise directed by the IMPAACT Management Oversight Group (MOG). The procedures outlined below may vary on a case-by-case basis.

For some ancillary studies, investigators may submit requests for funding or support to external groups; if letters of support are required from the Network to support these applications and requests, processes for letters are outlined in Section 7.

Table 15-1. Definitions

Data Analysis Concept Sheet (DACS)	A proposed investigation involving analysis of existing data from an IMPAACT (or PACTG) study to be undertaken by the Statistical and Data Analysis Center (SDAC) with IMPAACT funding. If the IMPAACT Network has not designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed.
Data Request (DR)	A proposed investigation for which existing data from an IMPAACT (or PACTG) study are being requested for analyses to be performed without IMPAACT funding. (Note that an SDAC statistician may be among the proposing investigators but would not be seeking IMPAACT support for the work.) If the IMPAACT Network has not designated the IMPAACT study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed. The statistical design of the research project and associated data analyses must be undertaken by the proposing investigators without IMPAACT funding.
New Works Concept Sheet (NWCS)	A proposed investigation involving use of existing biological specimens and data from an IMPAACT (or PACTG) study that may or may not require IMPAACT funding and may or may not involve analysis work by SDAC. If the IMPAACT Network has not designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT NWCS that is not yet completed.
Specimen and Data Use Agreement (SDUA)	A formal agreement describing the receipt and specific use of IMPAACT (or PACTG) study specimens and/or IMPAACT (or PACTG) study data to be exported to external investigators. Parties to the agreement are the IMPAACT Network and the recipient(s) of the specimens and/or the data.
Public Use Dataset	Data from an IMPAACT (or PACTG) study that are in a format that does not require an SDUA for receipt of the file.
Relevant studies	IMPAACT (or PACTG) protocols, DACSs, or NWCSs that provide data or specimens to be analyzed in a proposed DR, DACS, or NWCS.

15.2 Responsibilities and Procedures for Development and Review of Ancillary Studies

Development and Submission

Proposing investigators should review their proposal in the context of the overall IMPAACT research agenda; this agenda is shared on the IMPAACT Network website: https://impaactnetwork.org. Investigators should also consult with the protocol chair and relevant Scientific Committee (SC) for input regarding potential overlap of a proposed research project with approved IMPAACT research prior to developing a proposal; this early consultation is particularly important for DACSs and NWCSs which need significant Statistical and Data Management Center (SDMC) resources.

Prior to submitting a proposal, proposing investigators should consider the following:

- **For DRs:** Confirm that the data required are not available in public use datasets, if available, for the IMPAACT study of interest. Guidance on available public use datasets may be obtained by contacting the SDAC at sdac.data@sdac.harvard.edu.

- **For NWCSs:** Consider using the interactive Specimen Repository website (http://www.specimenrepository.org) to determine availability of specimens for concluded studies.

Following this background research and preparation, investigators should develop and submit the proposal using the appropriate form available on the IMPAACT website adhering to the specified page limit. Completed proposals should be submitted by the proposing investigator(s) to the Operations Center via the following email address: impaact.capsubmissions@fstrf.org. The proposal is then assigned an identification number for tracking purposes, and the tracking number is communicated to SDAC at cbar.qb@sdac.harvard.edu.

Upon receipt of a proposal, the Operations Center proposal coordinator reviews the proposed ancillary study to ensure that all required elements are included. If the document is missing information, the proposal is returned to the investigators for completion; the Operations Center proposal coordinator may also provide initial questions for the proposing investigators' response to help facilitate the review process. Following this initial review, the Operations Center will forward the proposal as described in Sections 15.2.2 – 15.2.4.

For NWCSs: The Operations Center proposal coordinator also reviews the language in the relevant protocol(s) and sample informed consent forms (ICFs). The proposing investigator should work with the relevant study sites to confirm if the site-specific ICFs and Institutional Review Board/Ethics Committee (IRB/EC)-approval documents require that the site IRBs/ECs approve the shipment or use of samples for other research investigations. Prior to requesting specimens for new laboratory testing, investigators must also ensure compliance with relevant sites' Material Transfer Agreements (MTAs). This review will also identify any restrictions on use of specimens for a particular research area that would need to match the scope of the NWCS. The proposing investigator may contact the Operations Center for site contact information, as needed.

Note: There is no IMPAACT-funded SDAC statistical support for the design and development of DRs, other than guidance on availability of public use datasets noted above.

15.2.2 Protocol Chairs and/or Potentially Overlapping DACS or NWCS Lead Investigators Review

For proposals requesting data from an IMPAACT study that is not yet concluded, the Operations Center shares the proposed ancillary study to the relevant protocol chairs or designee for review and comments. If the objectives of the proposal may overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed, the Operations Center shares the proposed ancillary study with the lead investigators of the approved DACS or NWCS.

The relevant protocol chairs or designees and/or relevant approved DACS or NWCS lead investigators review the proposed ancillary study with respect to potential overlap with study objectives or approved analyses 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. If the relevant protocol chair is listed as an investigator on the DACS or NWCS, their review may not be requested, and the proposal will proceed directly to SC review (see Section 15.2.3).

The relevant protocol chairs or designees should ensure the following in their review of the proposed ancillary study:

- The proposed ancillary study will not jeopardize the completion of the relevant protocol(s) or the publication of the primary results.
- The proposed ancillary study does not compete or overlap with objectives of the protocol(s) or with other ancillary studies.

The relevant approved DACS or NWCS lead investigators should comment on whether the objectives of the proposed ancillary study compete or overlap with the objectives of their approved DACS or NWCS.

A proposed ancillary study may be deferred if further information is required from the investigators to address potential issues concerning overlap or appropriateness of using data from IMPAACT studies to address the proposed study objectives. In this scenario, the Operations Center will inform the proposing investigators and request the specific information needed.

If a proposal is deferred, unless otherwise directed, investigators may submit a revised proposal that addresses the overlap or concerns raised by the protocol chairs, SC, or Network leadership for re-review.

If the proposal is disapproved, the Operations Center notifies the proposing investigators and informs SDAC (cbar.qb@sdac.harvard.edu) and the Data Management Center (DMC) (fstrf.nwcs@fstrf.org).

If the proposal is approved, the proposal is shared for relevant SC review, as below.

15.2.3 Scientific Committee (SC) Review

Following protocol chair or designee review (and/or review by potentially overlapping approved DACS or NWCS lead investigators, if applicable), the relevant Operations Center SC representative shares the proposed ancillary study with the relevant SC chair, vice chair, and SDAC SC representatives.

As part of their review, the SC chair, vice chair, and SDAC SC representatives determine if there is a need for review by the full SC or if they will review and approve the proposed ancillary study on behalf of the SC. They may also determine that additional information is needed from the proposing investigators before any decisions can be made.

The relevant SC reviews the scientific merit and feasibility of the proposed ancillary study and decides whether to approve it for submission to the Network Leadership (MOG/Scientific Leadership Group [SLG]) for review, approval, disapproval, or deferral. The SC should account for the following in their review of the proposal:

- The proposal uses data from the IMPAACT studies appropriately to address the proposed objectives (taking into account any comments from the protocol chairs and/or relevant DACS/NWCS lead investigators about competing or overlapping objectives).
- The proposal aligns with IMPAACT Network research goals and objectives.
- The SC may provide feedback on the scientific merit of the research project, including any significant limitations that might arise in addressing the proposed objectives in using data from IMPAACT studies.
- **For DRs:** As part of the SC review, the SDAC SC representatives (after consulting with the protocol statisticians and data managers, as needed) should comment on availability of the requested data items and overlap with ongoing or planned analyses. If the DR requires data customization, the SDAC SC representatives should provide an estimate of approximate SDMC staff time needed.
- **For DACSs and NWCSs**: SDAC SC representatives should also coordinate internal review of the proposal for SDMC estimated time and resources required for completion of work; these estimates should be added if none are included.
- **For NWCSs:** If specimens from an IMPAACT study that has other ongoing NWCSs are being requested, the SC may request that the DMC review the proposal for specimen availability.

A proposed ancillary study may be deferred if further information is required from the investigators to address potential issues concerning overlap or appropriateness of using data from IMPAACT studies to address the proposed study objectives. In this scenario, the Operations Center SC representative will inform the proposing investigators and request the specific information needed.

If the proposal is disapproved, the Operations Center proposal coordinator notifies the proposing investigators and informs SDAC (cbar.qb@sdac.harvard.edu) and the DMC (fstrf.nwcs@fstrf.org). At the discretion of the SC chair and vice chair, the notification may specify the reasons for disapproval and include comments.

If the proposal is approved, the proposal is shared for Network leadership review, as below.

15.2.4 IMPAACT Network Leadership Review

Following SC review, the relevant Operations Center SC representative shares the proposed ancillary study with the Operations Center proposal coordinator to share with relevant Network leadership representatives:

For DRs and DACSs: Applicable proposals are shared with the Network chair and SDAC principal investigator (PI) for discussion of resources required and determination of the need for review by the full MOG or SLG. As part of their review, the Network chair and SDAC PI determine if there is a need for review by the full MOG or SLG or if they will review and approve the proposed ancillary study on behalf of the Network. Generally, the Network chair and SDAC PI review and approve ancillary studies on behalf of the Network.

For NWCSs: Applicable proposals are shared with the Laboratory Center (LC) PI and SDAC PI for discussion of resources required and determination of the need for review by the full MOG or SLG. In some cases, the Network chair may review on behalf of the LC, e.g., if there is a conflict of

interest. As part of their review, the LC PI and SDAC PI determine if there is a need for review by the full MOG or SLG or if they will review and approve the proposed ancillary study on behalf of the Network. Generally, the LC PI and SDAC PI review and approve ancillary studies on behalf of the Network.

Network leadership representatives may determine that additional information is needed from the proposing investigators before any decisions can be made.

Full MOG or SLG review may be required for some ancillary studies if significant SDMC or other Network resources are required for data preparation or as otherwise determined by the Network chair, LC PI, and SDAC PI. If additional leadership review is required, the Operations Center proposal coordinator will notify the MOG or SLG to review the proposed ancillary study and render a decision (approve, disapprove, or defer).

A proposed ancillary study may be deferred if further information is required from the investigators to address potential issues concerning overlap or appropriateness of using data from IMPAACT studies to address the proposed study objectives. In this scenario, the Operations Center proposal coordinator will inform the proposing investigators and request the specific information needed.

If the proposal is disapproved, the Operations Center proposal coordinator notifies the proposing investigators and informs SDAC (cbar.qb@sdac.harvard.edu) and the DMC (fstrf.nwcs@fstrf.org). At the discretion of the Network chair, LC PI, and/or SDAC PI, the notification may specify the reasons for disapproval and include comments.

If the proposal is approved, the Operations Center proposal coordinator notifies the proposing investigators and informs SDAC (cbar.qb@sdac.harvard.edu). For DRs and NWCSs, the DMC is also notified (fstrf.nwcs@fstrf.org). This communication includes a copy of the approved proposal along with instructions to the proposing investigators regarding the need for completion of an SDUA (see Section 15.4), if applicable. For NWCSs, this communication also indicates that the proposing investigator must work with sites to determine if specimen shipment and testing is permitted per IRB or other regulatory requirements.

15.3 Special Considerations for Proposals Requiring Genetic Analyses

An ancillary study proposal that involves use of existing IMPAACT human genetic data must be clearly linked to the protocol and/or NWCS(s) under which the human genetic data were created and should also specify:

(A) the frequency and expected range of individual polymorphisms
(B) the rationale for studying the polymorphisms, including evidence of association with outcome

Investigators who will be performing human genetic testing on IMPAACT specimens must clearly specify this in their NWCS proposal. Only specimens from participants who have consented to non-protocol human genetic testing of their specimens will be available for NWCS human genetic testing.

Investigators who receive IMPAACT genome-wide association studies (GWAS) data under a proposed IMPAACT ancillary study should not submit these data to a National Institutes of Health (NIH) GWAS data repository. In compliance with the NIH Genomic Data Sharing Policy (NOT-OD-07-088), for sharing of data obtained in NIH-supported or -conducted GWAS, the SDMC will have already submitted to the NIH GWAS data repository (named the “database of Genotypes and Phenotypes”, or “dbGaP”)

GWAS data that were generated with IMPAACT funding, and only from participants who have consented to dbGaP submission.

Investigators who produce new GWAS data under a NWCS using IMPAACT specimens may submit these datasets to an NIH GWAS data repository (such as dbGaP). This requirement must be clearly stated in the NWCS proposal and, if approved by IMPAACT leadership, must only be done for those participants who have consented to dbGaP submission.

15.4 Specimen and Data Usage Agreements

SDUAs are required for ancillary studies when data are to be exported from SDAC or the DMC for analysis, and for ancillary studies requiring use of biological specimens. The SDUA forms are issued by the Operations Center proposal coordinator to proposing investigators and, in accordance with the ancillary study review process, following approval from the Network. The following sections provide additional information on the projects that require an SDUA and the procedures for completing and submitting an SDUA.

The completed SDUA must be submitted to the Operations Center by the proposing investigator(s) and any other collaborating investigators who will receive and be responsible for the data (and specimens, for NWCSs) before the data (and specimens, for NWCSs) are released. SDAC and the DMC will be notified upon receipt of the completed SDUA via the specified email aliases (fstrf.nwcs@fstrf.org, cbar.qb@sdac.harvard.edu, sdac.sdua@sdac.harvard.edu).

Data and/or specimens for projects requiring an SDUA will not be released or shipped until the SDMC has confirmation that the Operations Center has received a signed SDUA.

15.4.1 Projects that Require an SDUA

In general, an SDUA is required for any ancillary study for which data are to be exported from the SDAC or the DMC and/or for which biological specimens are to be used. An SDUA is typically required for all NWCSs.

More specifically, an SDUA is typically required for the following:

- All NWCSs
- Any DR or DACS for which data are to be exported
- Any export of human genomic data
- Shipment of specimens and/or datasets for an approved IMPAACT protocol if the activity has not been described in the protocol or Division of Acquired Immunodeficiency Syndrome (DAIDS) Clinical Trials Agreement (CTA)
- Export of data from multiple studies for a meta-analysis or other grouped analysis, even if not developed as a formal DR or DACS

15.4.2 Projects that do not Require an SDUA

Under the following conditions, an SDUA may not be required:

- The use of data that have been moved to a public repository or de-identified per requirements for public use datasets.

- Shipment of specimens and/or data if the send-out has been described in an approved IMPAACT protocol and, therefore, did not require a DR, DACS, or NWCS.
- Shipment of specimens and/or data to pharmaceutical companies when covered by DAIDS CTAs.
- Shipment of specimens and/or data for the purposes of quality assurance.
- Shipment of specimens to an IMPAACT funded site, laboratory, or repository for the purpose of long-term storage.
- Any DR or DACS for which SDAC statisticians will perform the analyses and no data will be exported to other investigators.

15.5 Responsibilities and Procedures for Completion of Ancillary Studies

To support approved ancillary studies, representatives from the SDMC will be assigned as noted below:

- **For DRs:** An SDAC statistician or epidemiologist is assigned to work with proposing investigators and the DMC to facilitate the transfer of data. This coordinator also serves as the contact person for any data-related questions. The SDMC will inform the proposing investigators of any costs associated with providing data in formats other than those in which they already exist (these costs will need to be covered by the proposing investigators).

- **For DACSs:** An SDAC statistician or epidemiologist is assigned (or confirmed) to work with the proposing investigators to complete and publish the proposed analyses.

- **For NWCSs:**
  - If SDAC is performing associated data analyses, an SDAC statistician is assigned (or confirmed) to work with the proposing investigators to complete and publish the proposed analyses.
  - If the proposing investigators are performing associated data analyses, an SDAC statistician or epidemiologist is assigned to work with the proposing investigators and the DMC to facilitate the transfer of specimens and, if applicable, associated clinical data. This coordinator also serves as the contact person for any data-related questions.
  - A laboratory data manager (LDM) from the DMC is assigned to each approved NWCS. The LDM assists the proposing investigators (and SDAC coordinator, if assigned) by coordinating the shipment of specimens to the testing laboratories. The following should be considered:
    - Specimens from participants who did not consent to non-protocol testing of their specimens will not be shipped for NWCS testing.
    - The Operations Center reviews the language in the relevant protocol(s) and sample ICFs and the proposing investigator also checks the site-specific ICFs (approved by the IRBs and submitted to DAIDS PRO) and IRB/EC approval materials for participating sites to identify any relevant differences/information to help determine if site IRB approval is required prior to shipping or using samples. This review will also identify any restrictions on use of specimens for a particular research area that would need to match the scope of the NWCS.
    - If the last aliquot (defined below) is potentially going to be used for a NWCS, the assigned LDM or DMC designee will request the following additional approvals:
      - If the study is not yet concluded (i.e., still has ongoing analyses), the protocol chair must approve the use.
      - If the study is concluded, Network leadership must approve the use. Network leadership includes the Network chair, LC PI, SDAC PI, SDAC Associate Director, Operations Center Director, and the DMC Laboratory Data Division Chief. In some cases, it will also be sent to the IMPAACT SLG for review and approval.
    - The last aliquot is defined as the last aliquot available from a specific participant, visit, or specimen type if the specimen is from a baseline (Week 0) time point OR the specimen is

from a perinatal study and is the last specimen at any visit for a parental participant or their infant with HIV.

- Data or specimens will not be shared until the SDMC has received confirmation from the Operations Center that the SDUA process is complete and the proposing investigator has obtained IRB approval (or waiver) for the NWCS.
- Proposing investigators must submit to the DMC any data generated from assays performed on IMPAACT specimens. The LDM works with the testing laboratory to transfer assay results back to the DMC regardless of whether an SDAC statistician is performing the data analysis.

15.6 Publications Resulting from Data Requests

It is the responsibility of the investigator/author to ensure that development of manuscript results from the proposed ancillary study follow the procedures specified in Section 19 , including timelines, authorship, Network review, and citations. Any publications associated with the proposal should include acknowledgement of IMPAACT.

15.7 Procedures for Access to Study Data During Trial Conduct and After Trial Completion

The central database for the majority of IMPAACT studies resides at the SDMC. This includes case report form (CRF) data, results of protocol-specified laboratory analyses, and ancillary study data. This section describes the policy for site, Network investigator, and non-Network investigator access to study data during conduct of a trial and after study closure and database lock.

IMPAACT is a rich source of data that should, in many instances, be accessible to members and others outside of IMPAACT. Special reports and analyses beyond routine approved activities are often required or desired for specific applications by IMPAACT members outside of a protocol, DACS, or NWCS team. The Network must balance the importance of making appropriate data available as quickly as possible with the need to conserve resources and, most importantly, preserve the integrity of ongoing studies.

The simple request method outlined below will ensure that protocol chairs are aware and approve of the requests for access to data from their studies. In addition, by using this procedure, the SDAC PI, in consultation with the SLG, ensures that the requests are appropriate (i.e., do not release confidential information to unauthorized persons), clearly specified, prioritized, and fulfilled on a timely basis. Finally, this centralized procedure allows IMPAACT to have a record of what data were requested from which studies, and for what purpose.

There are several types of data access requests that are not covered by this set of procedures, as follows:

1. Requests to access data for which any kind of proposal (protocol, DACS, NWCS, or DR) would be appropriate. IMPAACT investigators, including SDAC or DAIDS staff, or external investigators who wish to publish or present results involving IMPAACT data, must submit a proposal for Network leadership approval; refer to Section 15.2.
2. Requests from sites for summary data that have previously been made available in some form to the IMPAACT membership at large. The SDMC will provide that data in a reasonable amount of time without requiring approval through the formal request process.
3. Requests by SDAC staff: SDAC staff frequently require access to data for purposes of conducting internal IMPAACT business. Results of these analyses are not intended for publication or presentation and are kept confidential. Examples of such needs are: (1) analyses which are necessary to plan successor studies and (2) analysis of virology calibration data. Only the approval of the senior statistician is necessary for within-SDAC access for sample size calculations, etc. If a protocol will reference information from ongoing study(ies), the standard data request procedure outlined below

must be followed, wherein the study chair(s) of the ongoing study(ies) would be consulted.

4. Data and Safety Monitoring Board (DSMB) Requests: Requests for special analyses made by the DSMB are considered confidential. Generally, the DSMB would contact the SDAC statistician assigned to the study in question or to the SDAC liaison to the DSMB.

15.7.1 General Guidelines Regarding Data Access

The fundamental principles guiding the approval process for requests for data or analysis are as follows:

- The fulfillment of requests must not jeopardize the completion of the study(ies) or the publication of the primary manuscript(s) and must be compatible with the sample ICFs in the protocol(s).
- The right to access or receive IMPAACT data does not imply the right to disseminate them: these are two clearly distinct concepts. IMPAACT as a group determines who is authorized to disseminate its data in any form.
- Patient confidentiality must be respected and protected. The minimum amount of data necessary to achieve a stated purpose should be distributed, particularly data which could conceivably be used to identify a patient through cross-linking of other information. For example, patient birth dates should not be released unless there is compelling reason to do so.
- Site confidentiality must be respected and protected. Data should not be associated with a given site unless there is compelling reason to do so.
- In general, SDAC (and the study pharmacologist, if applicable) will conduct all team-initiated analyses.
- Sites have access to data from their site.

15.7.2 Procedures for Data Access Requests

The requestor must send the request by electronic mail to SDAC.DATA@fstrf.org, either directly or routed through the statistician, data manager, or other members of the DMC. Requests to SDAC.DATA must be highly specific, including at a minimum the following information: who is asking for the data, the specific data they need and when they need it, the purpose of the request, how the data will be used, and who else will be given access to it. SDAC.DATA will log the request and forward it to the appropriate individuals, including the statistician(s), the protocol chair, and the SDAC PI, asking for approval/disapproval or comment.

The SDAC PI acts for the SLG and thus will seek guidance from the SLG if the appropriateness of the request is unclear.

The final decision will be communicated by email back to the initiator of the request. If the data request is approved, the SDMC will fulfill it after the requestor agrees in writing to the following stipulations:

- The data will only be used for the purpose described in the original data request;
- Any other use of the data would require prior IMPAACT approval (by sending a follow-up request to SDAC.DATA or by submission of a DACS, NWCS, or DR, as appropriate); and
- The data will not be provided to anyone or disseminated in any way other than as specified in the original data request, unless prior IMPAACT approval is granted.

Appeals Procedure: Decisions to deny data access may be appealed in writing to the SLG.

15.7.3 Specific Examples of Data Access Requests

The following are examples of required requests for data access using this process.

1. Requests by DAIDS Staff, Protocol Chairs, IMPAACT Scientific Committee Chairs, the SLG Chair, or the Operations Center

   DAIDS staff may require information for reports to the National Institute of Allergy and Infectious Diseases (NIAID), Congress, constituency groups, or the media. All DAIDS staff requests should only come through the DAIDS Program Officer for SDMC or their designee. Requests from study chairs, SC chairs, or the SLG chair often involve information needed to monitor study/IMPAACT progress (such as data completeness by a clinical site or reasons for dropout). These requests are normally made through the study statistician or SDAC SC representative, who would consult with the SDAC PI if the issues were unclear. The Operations Center will occasionally need to initiate the fulfillment of a supplemental contract with a pharmaceutical company by requesting information or data access per the contract. This request will come from the Operations Center to SDAC.DATA. SDAC must have copies of the appropriate sections of these contracts on file.

2. Requests from the Regulatory Affairs Section of DAIDS

   Requests from the Regulatory Affairs Section of the Pharmaceutical and Regulatory Affairs Branch of DAIDS may originate when an adverse event report (AER) indicates a severe toxicity in a study participant and further investigation of the case history is required to resolve safety concerns. The US Food and Drug Administration (FDA) requires a 10-day turnaround for this information, beginning at the time the adverse event is reported to DAIDS. Such requests should be channeled to the SDAC PI through the DAIDS Program Officer.

3. Pharmaceutical Protocol Team Member Requests

   Pharmaceutical companies participate in CTAs with DAIDS and in supplementary contracts with IMPAACT. They also often require data access or analysis beyond what is in the CTA for FDA review of a New Drug Application (NDA) or to determine future drug development. All requests for fulfillment of CTAs, supplementary contracts, or additional information should come through SDAC.DATA, who will review the requests for appropriateness.

4. Investigator/Site Requests

   An investigator requests clinical data from a particular study or studies for purposes other than publication or presentation (which would require a Concept Sheet or DR).

5. External (non-IMPAACT members) Data Requests

   Requests for IMPAACT data may originate from various parties outside of IMPAACT. These may include researchers, government agencies, pharmaceutical companies, and representatives of the media. The individual receiving the request should obtain the name of the requestor and the organization they represent, if any, and direct the requestor to follow the procedures described in Section 15.2. Information about the encounter should be sent to SDAC.DATA to give advance warning of the impending request.