15 ANCILLARY STUDIES AND INVESTIGATIONS

15.1 Scope and Definitions

This section describes the requirements for the development, submission, review, and approval of Data Requests (DR), Data Analysis Concept Sheets (DACS), and New Works Concept Sheets (NWCS). The requirements for completion of Specimen and Data Usage Agreements (SDUA) are also included.

The procedures apply to IMPAACT and non-IMPAACT investigators.

Information on available biological specimens for concluded studies can be accessed on the interactive AIDS Clinical Trials Group (ACTG)/IMPAACT specimen repository website at http://www.specimenrepository.org/home.html. IMPAACT protocol documents and study completion status 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).

Table 15-1. Definitions

Data requests (DR)	A proposed investigation for which existing data from an IMPAACT (or Pediatric AIDS Clinical Trials Group [PACTG]) study are being requested for analyses to be performed without IMPAACT funding. (Note that a Statistical and Data Analysis Center [SDAC] statistician may be among the proposing investigators, but would not be seeking IMPAACT support for the work.) Unless the IMPAACT Network has 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.
Data Analysis Concept Sheet (DACS)	A proposed investigation involving analysis of existing data from an IMPAACT (or PACTG) study to be undertaken by SDAC with IMPAACT funding. Unless the IMPAACT Network has 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.
New Work Concept Sheet (NWCS)	A proposed investigation involving use of existing biological specimens from an IMPAACT (or PACTG) study that may or may not require IMPAACT funding and may or may not involve analysis work by SDAC. Unless the IMPAACT Network has 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, DACS or NWCS that provide data or specimens to be analyzed in a proposed DR, DACS, or NWCS

15.2 Data Requests

15.2.1 Responsibilities for Data Requests

Proposing Investigators

- Confirm that the data they require 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.
- 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 DR.
- Develop and submit a proposal using the DR form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm. Completed forms are to be submitted to impaact.capsubmissions@fstrf.org.

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

Operations Center Proposals Coordinator

- Receives and processes the proposed DR (assigns ID number and primary SC, notifies Statistical and Data Management Center (SDMC) of receipt at specified email addresses); initiates IMPAACT review.
- Communicates with proposing investigators, SDMC, and relevant SC coordinators regarding next steps, review status, and outcomes.

Relevant Protocol, DACS, and NWCS Chairs

- For proposals involving existing data from an IMPAACT study that is not yet concluded, review the proposed DR with respect to potential overlap with protocol objectives or approved secondary analyses and send comments to the Operations Center proposals coordinator.
- For proposals involving existing data from an approved DACS that is not yet completed, review the proposed DR with respect to potential overlap with the DACS objectives and send comments to the Operations Center proposals coordinator.
- For proposals involving existing data generated under a NWCS, review the proposed DR with respect to potential overlap with the NWCS objectives and consistency with approval for use of samples and send comments to the Operations Center proposals coordinator.

Scientific Committee

- The relevant SC reviews and renders a decision on the proposed DR (approve, disapprove, or defer).
- A DR may be disapproved because it:
  - Might jeopardize the completion of the relevant protocol(s) or the publication of the primary results.
  - Overlaps with objectives of the protocol(s) or with approved secondary analyses, DACSs, or NWCSs.
  - Raises significant concerns about the appropriateness of using data from the IMPAACT protocol(s) to address the proposed study objectives.
- A DR may be deferred if further information is required from the investigators to address potential issues concerning overlap or appropriateness of using data from IMPAACT protocol(s) to address the proposed study objectives.
- The SC chair and vice chair may determine that full committee review is not necessary and approve the DR for network leadership review on the SC's behalf.

Management Oversight Group (MOG)

- If the network chair and SDMC principal investigator (PI) determine that full MOG review is required, the MOG reviews DRs approved by the relevant SC and renders a decision (approve, disapprove, or defer). DRs may require full MOG review if more than minimal SDMC or other network resources are being required to prepare the datasets or as otherwise determined by the network chair and SDMC PI.

15.2.2 Procedures for Data Requests

15.2.2.1 Submission of Data Requests

Proposing Investigators

- Develop a proposal using the DR form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm, adhering to the specified page limit.
- Electronically submit the completed DR form to the Operations Center at impaact.capsubmissions@fstrf.org.

Operations Center Proposals Coordinator

- Reviews the proposed DR to ensure that all required elements are included. If the document is missing information, returns the proposed DR to the investigators for completion.
- Assigns the DR an ID number
- Assigns the DR to the relevant SC(s) – in consultation with the network chair, if needed – and distributes it to the SC coordinator
- Notifies the SDMC of receipt of the DR via the specified email aliases
- For DRs requesting data from an IMPAACT protocol, DACS, or NWCS that is not complete, distributes the proposed DR to the relevant protocol, DACS, or NWCS chair for review and comments
- Distributes relevant protocol, DACS, or NWCS chair comments to the SC coordinator prior to their reviews, if available

15.2.2.2 Review of Data Requests

Relevant Protocol Chairs

- The relevant protocol chair or designee reviews the proposed DR and provides comments to the Operations Center proposals coordinator within 7 days of receipt. If the protocol chairs do not comment within the 7-day period, they forfeit the right to comment on the proposed DR. Protocol chairs do not have authority to approve or disapprove unless the study is ongoing, the primary analyses are not complete, or the secondary analyses have not been defined.

SC Review

- The relevant SC reviews the DR to ensure that
  - It will not jeopardize the completion of the relevant protocol(s) or the publication of the primary results.
  - It does not compete with objectives of the protocol(s) or with approved secondary analyses, DACSs or NWCSs.
  - It is an appropriate use of IMPAACT study data.
- 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 protocol(s).

- The SC chair and vice chair may determine that full committee review is not necessary and approve the DR for network leadership review on the SC's behalf (or they may determine that additional information is needed from the proposing investigators before full committee review).
- If the DR is deferred pending receipt of additional information, the SC coordinator will inform the proposing investigators and request the specific information needed.
- If the DR is disapproved by the SC, the SC coordinator communicates the outcome to the proposing investigators, specifying the reasons and including the SC's comments, as confirmed by the SC chair and vice chair.
- The SC coordinator notifies the Operations Center proposals coordinator of the final SC review outcome of the SC review and, if approved, provides the SC-approved version of the DR for network leadership review.

IMPAACT Network Leadership Review

- DRs approved by SCs are forwarded by the Operations Center proposal coordinator to the network chair and SDMC PI for discussion of SDMC resources required and determination of the need for review by the full MOG; if the network chair and SDMC PI agree that review by the full MOG is not indicated, the network chair can approve the DR on behalf of the MOG. Full MOG review may be required for DRs if more than minimal SDMC or other network resources are required for data preparation or as otherwise determined by the network chair and SDMC PI.
- If the network chair or SDMC PI determines that additional information is needed before the review process can be considered complete and approval granted, the DR will be returned to the proposing investigators with the specific request.
- The final review outcome is communicated to the proposing investigators and the SDMC by the Operations Center proposal coordinator, along with instructions to the proposing investigators regarding the need for completion of an SDUA.

15.2.2.3 After IMPAACT SC and Leadership Review of Data Requests

Proposing Investigators

- If a DR is deferred by the SC or by the MOG, unless otherwise directed, investigators may submit a revised DR that addresses the overlap or concerns raised by the SC or network leadership within 4 months following the deferral notice for re-review. If this is not done within 4 months, the Operations Center proposals coordinator will send a notice to the investigators indicating the DR will be withdrawn.

SDMC

- If the DR is approved by the MOG, an SDAC coordinator will be named by SDAC. The SDAC Coordinator will work with the DMC to facilitate transfer of data upon confirmation by the Operations Center that the Specimen and Data Usage Agreement (SDUA) process is complete and will serve as the contact person for any 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).

15.2.2.4 Special Considerations for Data Requests Requiring Genetic Analyses

A DR 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 receive IMPAACT genome-wide association studies (GWAS) data under a DR should not submit these sequences to an NIH GWAS data repository. In compliance with the NIH policy, NOT-OD-07-088, for sharing of data obtained in NIH-supported or -conducted GWAS, 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.

15.2.2.5 Specimen and Data Usage Agreements for Data Requests

For data to be exported under a DR by the SDMC, a SDUA is typically required in accordance with Section 15.6 below. The Operations Center proposal coordinator will notify the DR investigators of this requirement with the final approval notification. The completed SDUA must be submitted to the Operations Center by the proposing investigator(s) who will receive and be responsible for the data, before the data are released. The SDMC will be notified upon receipt of the completed SDUA via the specified email aliases.

15.2.2.6 Publications Resulting from Data Requests

Any publications associated with the DR should include acknowledgement of provision of data by IMPAACT.

15.3 Data Analysis Concept Sheet

15.3.1 Responsibilities for DACS

Proposing Investigators

- Review the IMPAACT research agenda on the network website
- Encouraged, but not required: Consult with the protocol chair or relevant SC regarding research ideas and potential overlap of a proposed research project with approved IMPAACT research prior to developing a DACS, particularly if significant SDMC resources will be needed
- Develop and submit a proposal using the DACS form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm. Completed forms are to be submitted to impaact.capsubmissions@fstrf.org

Operations Center Proposals Coordinator

- Receives and processes the proposed DACS (assigns ID number, notifies SDMC of receipt at specified email aliases); initiates IMPAACT review
- Communicates with proposing investigators, SDMC, and relevant SC coordinators

Relevant Protocol Chair (or designee)

- Review the proposed DACS and send comments to the Operations Center proposals coordinator

Scientific Committee (SC)

- Conducts scientific review and renders a decision on the proposed DACS (approve, disapprove, or defer). Ensures that the proposed data analyses do not:
  - Jeopardize the completion of the relevant protocol(s) or the publication of the primary results
  - Compete with already approved DACSs or secondary analyses
- With the SDMC representatives on the SC, verifies the estimated SDMC resources requested for completion of work in the DACS
- Assesses the appropriateness of using data from the IMPAACT protocol(s) to address the proposed study objectives

Network Leadership (MOG or SLG)

- Reviews DACSs approved by the relevant SC, evaluates the requested SDMC and other resources, and renders a decision on the proposed DACS (approve, disapprove, or defer). Full MOG (or SLG) review may be required if more than minimal SDMC or other network resources or other network resources are being requested or as otherwise determined by the network chair and SDMC PI.

15.3.2 Procedures for DACS

15.3.2.1 Submission of DACS

Proposing Investigators

- Develop a proposal using the DACS form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm, adhering to the specified page limit.
- Collaborate with the SDAC statistician performing the analysis.
- Electronically submit the completed DACS to the Operations Center at impaact.capsubmissions@fstrf.org.

Operations Center Proposals Coordinator

- Reviews the proposed DACS to ensure that all required elements are included. If the document is missing information, returns the proposed DACS to the investigators for completion.
- Assigns the DACS an ID number
- Assigns the DACS to the relevant SC(s) – in consultation with the network chair, if needed – and distributes it to the SC coordinator
- Notifies the SDMC of receipt of the DACS via the specified email aliases
- For DACS requesting use of data from an IMPAACT protocol that is not complete, distributes the proposed DACS to the relevant protocol chair for review and comments
- Distributes relevant protocol chair's comments to the SC coordinator(s) prior to their reviews, if available

15.3.2.2 Review of DACS

Relevant Protocol Chairs

- The relevant protocol chair (or designee) reviews the proposed DACS and provides comments to the Operations Center proposals coordinator within 7 days of receipt. If the protocol chairs do not comment within the 7-day period, they forfeit the right to comment on the proposed DACS. Protocol chairs do not have authority to approve or disapprove unless the study is ongoing, the primary analyses are not complete, or the secondary analyses have not been defined.

SC Review

- The relevant SC reviews the science and feasibility of the DACS and decides whether to approve it for submission for network leadership (MOG) review, disapprove it or defer. Also reviews the DACS for SDMC time and verifies or provides an updated estimate.
- The SC chair and vice chair may determine that full committee review is not necessary and approve the DACS for network leadership review on the SC's behalf (or they may determine that additional information is needed from the proposing investigators before full committee review).
- If the DACS is deferred pending receipt of additional information, the SC coordinator will inform the proposing investigators and request the specific information needed.
- If the DACS is disapproved by the SC, the SC coordinator communicates the outcome to the proposing investigators, specifying the reasons and including the SC's comments, as confirmed by the SC chair and vice chair.
- The SC coordinator notifies the Operations Center proposals coordinator of the final SC review outcome of the SC review and, if approved, provides the SC-approved version of the DACS for network leadership (MOG) review.

IMPAACT Network Leadership Review

- DACSs approved by SCs are forwarded by the Operations Center proposal coordinator to the network chair and SDMC PI for discussion of SDMC resources and determination of the need for review by the full MOG (or SLG); if network chair and SDMC PI agree that full group review is not indicated, the network chair can approve the DACS on behalf of the leadership. Full MOG or SLG review may be required for a DACS if more than minimal SDMC or other network resources are being requested or as otherwise determined by the network chair and SDMC PI.
- If the network chair or SDMC PI determines that additional information is needed before the review process can be considered complete and approval granted, the DACS will be returned to the proposing investigators with the specific request.
- The final review outcome is communicated to the proposing investigators and to the SDMC by the Operations Center proposal coordinator, with instructions to the investigator regarding the need for completion of an SDUA.

15.3.2.3 After IMPAACT SC and Leadership Review of DACS

Proposing Investigators

- If a DACS is deferred by the SC or by the MOG/SLG, unless otherwise directed, investigators may submit a revised DACS that addresses the concerns raised by the SC or network leadership within 4 months following the deferral notice for re-review. If this is not done within 4 months, the Operations Center proposals coordinator will send a notice to the investigators indicating the DACS will be withdrawn.
- Must comply with the timelines for analyses and manuscript preparation procedures specified in Section 19 of the IMPAACT MOP.

SDMC

- If the DACS is approved by the MOG (or SLG), an SDAC statistician will be named by SDAC (or confirmed if already identified). This statistician will work with the other investigators to complete and publish the proposed analyses.

15.3.2.4 Special Considerations for DACSs requiring Genetic Analyses

A DACS 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. See Section 15.2.2.4 for additional details.

15.3.2.5 Specimen and Data Usage Agreements for DACSs

In the event that data used in a DACS need to be exported from SDAC or the Data Management Center (DMC) to the investigators, an SDUA may be required in accordance with Section 15.5 below. The Operations Center Proposal Coordinator will notify the DACS investigators of this requirement, with the final approval notification. The completed SDUA must be submitted to the Operations Center by the proposing investigator(s) who will receive and be responsible for the data, before the data are released. The SDMC will be notified upon receipt of the completed SDUA via the specified email aliases.

15.3.2.6 Publications resulting from DACSs

It is the responsibility of the investigator/author to ensure that development of manuscripts results from DACS follow the procedures specified in Section 19 of the IMPAACT MOP, including timelines, authorship, network review, and citations.

Any publications associated with a DACS should include acknowledgement IMPAACT.

15.4 New Work Concept Sheets

15.4.1 Responsibilities for NWCS

Proposing Investigators

- Review the IMPAACT research agenda on the network website.
- Use the interactive ACTG/IMPAACT specimen repository website (http://www.specimenrepository.org/home.html) to determine availability of specimens.
- Consult with the protocol chair or relevant SC regarding research ideas and potential overlap of a proposed research project with approved IMPAACT research prior to developing a NWCS, particularly if significant SDMC, assay support, or other resources will be needed.
- Develop and submit a proposal using the NWCS form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm. Completed forms are to be submitted to impaact.capsubmissions@fstrf.org.

Operations Center Proposals Coordinator

- Receives and processes the proposed NWCS (assigns ID number, notifies SDMC of receipt at specified email addresses); initiates IMPAACT review
- Communicates with proposing investigators (e.g., confirms receipt and provides ID number), SDMC and relevant SC coordinators

Relevant Protocol, DACS and NWCS Chairs

- Review the proposed NWCS and send comments to the Operations Center proposals coordinator

Scientific Committee (SC)

- Conducts scientific review and renders a decision on the proposed NWCS (approve, disapprove, or defer). Ensures that the proposed data analyses do not:

    - Jeopardize the completion of the relevant protocol(s) or the publication of the primary results
    - Compete with already approved DACS, NWCSs or secondary analyses
- With the SDMC representatives on the SC, verifies the estimated SDMC resources requested for completion of work in the NWCS
- Assesses the appropriateness of using data from the IMPAACT protocol(s) to address the proposed study objectives

Network Leadership Group (MOG or SLG)

- Reviews NWCSs approved by the relevant SC, evaluates the requested resources, and renders a decision on the proposed NWCS (approve, disapprove, or defer)

15.4.2 Procedures for NWCS

15.4.2.1 Submission of NWCS

Proposing Investigators

- Develop a proposal using the NWCS form available on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm, adhering to the specified page limit
- Use the interactive ACTG/IMPAACT specimen repository website (http://www.specimenrepository.org/home.html) to determine availability of specimens
- Collaborate with the SDAC statistician performing the analysis, if applicable
- Electronically submit the completed NWCS form to the Operations Center at impaact.capsubmissions@fstrf.org

Operations Center Proposals Coordinator

- Reviews the proposed NWCS to ensure that all required elements are included. If the document is missing information, returns the proposed NWCS to the investigators for completion.
- Assigns the NWCS an ID number
- Assigns the NWCS to the relevant SC(s) – in consultation with the network chair, if needed – and distributes it to the SC coordinator
- Notifies the SDMC of receipt of the NWCS by sending it to the specified email aliases
- For NWCS requesting use of specimens or data from an IMPAACT protocol that is not concluded, distributes the proposed NWCS to the relevant protocol chair for review and comments.
- For NWCS requesting the use of specimens from an IMPAACT protocol that has other ongoing NWCSs, contacts the DMC for their review and comments
- Distributes relevant protocol chair and DMC comments to the SC coordinator(s) prior to their reviews, if available.

15.4.2.2 Review of NWCS

Relevant Protocol Chairs

- The relevant protocol chair (or designee) reviews the proposed NWCS and provides comments to the Operations Center proposals coordinator within 7 days of receipt. If the protocol chairs do not comment within the 7-day period, they forfeit the right to comment on the proposed NWCS. Protocol chairs do not have authority to approve or disapprove unless the study is ongoing, the primary analyses are not complete or the secondary analyses have not been defined.

SC Review

- The relevant SC reviews the science and feasibility of the NWCS and decides whether to approve it for submission for network leadership (MOG) review, disapprove it or defer. Also reviews the NWCS for SDMC time and verifies or provides an updated estimate, if applicable, and evaluates other requested resources.
- The SC chair and vice chair may determine that full committee review is not necessary and approve the NWCS for network leadership review on the SC's behalf (or they may determine that additional information is needed from the proposing investigators before full committee review).
- If specimens from an IMPAACT study that has other ongoing NWCSs are being requested, the SC coordinator may contact the DMC for input on specimen availability.
- If the NWCS is deferred pending receipt of additional information, the SC coordinator will inform the proposing investigators and request the specific information needed.
- If the NWCS is disapproved by the SC, the SC coordinator communicates the outcome to the proposing investigators, specifying the reasons and including the SC's comments, as confirmed by the SC chair and vice chair
- The SC coordinator notifies the Operations Center proposals coordinator of the final SC review outcome of the SC review and, if approved, provides the SC-approved version of the NWCS for network leadership (MOG or SLG) review.

IMPAACT Network Leadership Review

- A NWCS approved by the SC is forwarded by the Operations Center Proposal Coordinator to the Laboratory Center PI and SDMC PI for discussion of resources and determination of the need for review by the full MOG or SLG; if the Laboratory Center PI and SDMC PI agree that full group review is not indicated, the Laboratory Center PI (or network chair) can approve the NWCS on behalf of the MOG/SLG. Full MOG or SLG review is required for a NWCS for which significant resources are being requested or as otherwise determined by the LC PI and SDMC PI.
- If the LC PI or SDMC PI determines that additional information is needed before the review process can be considered complete and approval granted, the NWCS will be returned to the proposing investigators with the specific request.
- The final review outcome is communicated by the Operations Center proposal coordinator to the proposing investigators and to the SDMC via the specified email aliases, with instructions to the investigators regarding the need for completion of an SDUA.

15.4.2.3 After IMPAACT SC and Network Leadership Review of NWCS

Proposing Investigators

- If a NWCS is deferred by the SC or by the MOG/SLG, unless otherwise directed, investigators may submit a revised NWCS that addresses the concerns raised by the SC or network leadership within 4 months following the deferral notice for re-review. If this is not done within 4 months, the Operations Center proposals coordinator will send a notice to the investigators indicating the NWCS will be withdrawn.
- The investigators must comply with the timelines and procedures for analyses and manuscript preparation and review specified in Section 19 of the IMPAACT MOP.
- The investigators must submit to the DMC any data generated from assays performed on IMPAACT specimens.

SDMC

- If the NWCS is approved by the MOG or SLG and SDAC will be performing associated analyses, an SDAC statistician will be named by SDAC (or confirmed if already identified). This statistician will work with the other investigators to complete and publish the proposed analyses.

- If the NWCS is approved by the MOG or SLG and the data are to be exported to the investigators for analysis, an SDAC Coordinator will be named by SDAC. The SDAC Coordinator will work with the DMC to facilitate transfer of specimens and, if applicable, associated clinical data upon confirmation by the Operations Center that the Specimen and Data Usage Agreement (SDUA) process is complete and will serve as the contact person for any questions.
- A Laboratory Data Manager (LDM) from the DMC is assigned to each approved NWCS. The LDM will assist the proposing investigators (and SDAC Coordinator, if assigned) by coordinating the shipment of specimens to the testing laboratories.
    - Specimens from participants who did not consent to non-protocol testing of their specimens will not be shipped for NWCS testing.
    - Specimens collected at CRSs located outside the United States whose IRB, ethics committees, or equivalent have not approved the NWCS will not be shipped.
    - Specimens will not be shipped until the DMC has received confirmation from the Operations Center that the Specimen and Data Usage Agreement (SDUA) process is complete and that the Proposing Investigator has IRB approval (or waiver) for the NWCS research project.
- The LDM will work with the testing laboratory to transfer assay results back to the DMC regardless of whether an SDAC statistician will be performing analysis or not.

15.4.2.4 Special Considerations for NWCSs requiring Genetic Analyses

A NWCS that involves use of existing IMPAACT human genetic data must be clearly linked to the protocol and/or the NWCS(s) under which the human genetic data were created. See Section 15.2.2.4 for additional details.

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 produce new GWAS data under a NWCS using IMPAACT specimens may submit these data sets 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.

15.4.2.5 Specimen and Data Usage Agreements for NWCS

An SDUA is required for all approved NWCSs. The Operations Center Proposal Coordinator will remind the NWCS investigators of this requirement, with the final approval notification. The completed SDUA must be submitted to the Operations Center by the proposing investigator(s) who will receive and be responsible for the data, before associated data and specimens are released. The SDMC will be notified upon receipt of the completed SDUA via the specified email aliases.

15.4.2.6 Publications resulting from NWCS

It is the responsibility of the investigator/author to ensure that development of manuscripts results from NWCS follow the procedures specified in Section 19 of the IMPAACT MOP, including timelines, authorship, network review, and citations.

Any publications associated with a NWCS should include acknowledgement IMPAACT.

15.5 Specimen and Data Usage Agreements (SDUA)

SDUAs are defined in Section 15.2 above and the form can be accessed on the IMPAACT website at http://impaactnetwork.org/resources/study-proposals.htm.

15.5.1 Projects that require an SDUA

An SDUA is required for the following:

- Any export of human genomic data
- Any NWCS
- Export of data under a DR or DACS
- Shipment of specimens and/or data sets for an approved IMPAACT protocol if the activity has not been described in the protocol or DAIDS Clinical Trials Agreement
- Export of data from multiple studies for a meta-analysis or other grouped analysis, even if not developed as a formal DR or DACS

15.5.2 Projects that do not require an SDUA

- The use of data that have been moved to the public repository at the National Technical Information Service 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 Clinical Trials Agreements
- 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

15.5.3 Procedures for Completion and Submission of SDUAs

Operations Center will notify investigators for projects that require an SDUA with the final approval notification. However, timelines for projects that must have an SDUA (as indicated in section 15.5.1 above) will be facilitated if a completed SDUA is submitted with the initial proposal.

When the SDUA for a DR, DACS, or NWCS is complete, the IMPAACT Operations Center will notify the SDMC at the specified email aliases and copy the relevant statistician(s); the completed SDUA will be attached to the notification.

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