IMPAACT Network Ancillary Studies & Investigations

Manual of Procedures (MOP) Section 15, Version 3.0
20 January 2021

IMPAACT
International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Ancillary Studies

Data Request (DR)	Data Analysis Concept Sheet (DACS)	New Works Concept Sheet (NWCS)
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**.	A proposed investigation involving analysis of **existing data** from an IMPAACT (or PACTG) study to be **undertaken by Statistical and Data Analysis Center (SDAC) with IMPAACT funding**.	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**.

Additional information and definitions can be found in MOP Section 15

Ancillary Studies

- If the IMPAACT Network has not designated a 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.
- For DACSs and DRs: The objectives should also not overlap with objectives specified in an approved IMPAACT DACS or NWCS that is not yet completed.
- For NWCSs: The objectives should also not overlap with objectives in an approved IMPAACT NWCS that is not yet completed.

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Proposal Development, Submission, & Review Process

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Prior to Submission of a Proposal

Data Request (DR)	New Works Concept Sheet (NWCS)
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.	Consider using the interactive Specimen Repository website: http://www.specimenrepository.org to determine availability of specimens for concluded studies.

- Review proposal in context of overall IMPAACT research agenda
- Consult with Protocol Chair/Vice Chair and Scientific Committee (SC) for overlap with approved IMPAACT research

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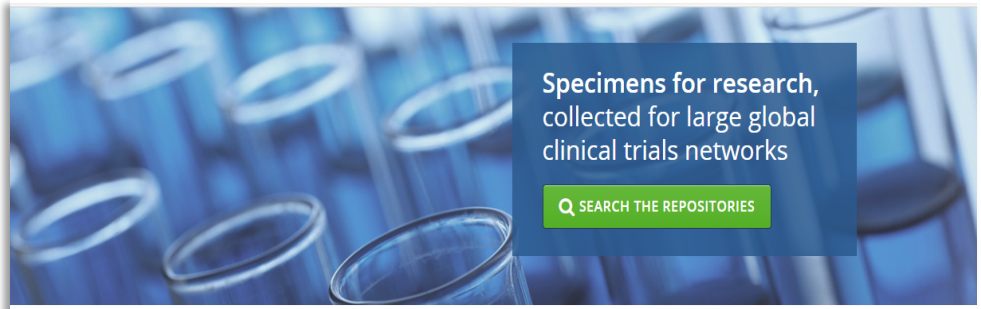

The specimen repositories are a collaboration between several clinical trial networks to make the larger body of specimens collected for HIV research available to investigators.

The specimens stored at the repositories were initially collected for specific studies that have concluded, have been approved for use by network leadership and are now available to investigators conducting new research.

Using this website

You can use the interactive search tool on this website to learn about the types of specimens available at the repositories. After completing a search, you can see the number of specimens and unique participants available, information about the studies for which they were collected, and what research was published for those studies. The search tool will also provide you with a report that lists your specimens of interest. You can then use this report to help write your research proposal to the network.

What's in the repositories?

Network	ACTG	IMPAACT	HVTN
Specimens	3056379	426251	3833704
Protocols	243	21	44
Types of specimens	24	10	13
Cryopreserved PBMCs	743495	151153	807233
Plasma	1743864	263322	960361
Serum	514589	10517	1987527

ACTG AIDS CLINICAL TRIALS GROUP IMPAACT HIV VACCINE TRIALS NETWORK

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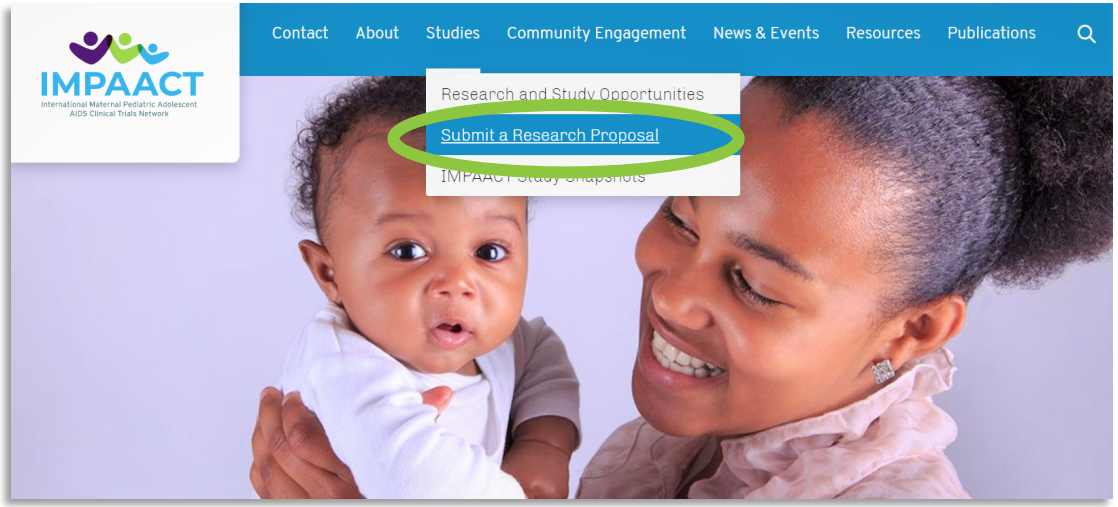
IMPAACT Study Proposals



- Concept Sheet (CS), DACS, NWCS, and DR templates are available at: https://www.impaactnetwork.org/studies/submit-research-proposal.
- All completed submissions should be sent to the IMPAACT Operations Center for consideration by the IMPAACT network using this email address: impaact.capsubmissions@fstrf.org. Upon receipt, the Operations Center will confirm receipt of your submission.

IMPAACT CONCEPT SHEET

Please submit the completed concept sheet to the IMPAACT Operations Center for consideration by the IMPAACT Network using this email address: impaact.capsubmissions@fstrf.org. Upon receipt, the IMPAACT Operations Center will contact you to provide information concerning the next steps. As further described in the Network Manual of Procedures, Section 9, concept sheets should be approximately 5-10 pages in length, exclusive of cost and references.

Please provide the following information:

Concept Submitted by: [Name and email address]

Date Submitted: [DD MMM YYYY]

Scientific Area: [Check one]
Complications and Coinfections ( ) HIV Treatment ( )
Tuberculosis ( ) ART-Free Remission ( )

Title of Concept Sheet:

Proposing Investigator(s): [Include name, address, phone number, email; also include proposal for leadership of the protocol, including the proposed protocol chair and vice chair.]

Lay Summary: [The lay summary should be as concise as possible (ideally limited in length to 1-3 paragraphs), written in a 6th to 8th grade language level.]

Rationale:

Background:

Primary Objectives:

Secondary Objectives:

Hypotheses:

Design:

Population: [Include major inclusion/exclusion criteria and whether co-enrollment in other studies is allowed.]

Study Intervention/Product Regimens: [Outline the regimens, including doses and duration; indicate status of pharmaceutical support and if there are any product availability issues.]

Sample Size and Accrual: [Include the approximate sample size to address the primary objective(s).]

Primary and Secondary Outcome Measures:

Study Duration: [Include timeline for both enrollment and follow-up.]

Concept Sheet Number: [Assigned following submission to IMPAACT]

Laboratory Assays:

Potential Study Sites:

External Support, Collaboration, and/or Funding: [If external support, collaboration, and/or funding are anticipated, please describe.]

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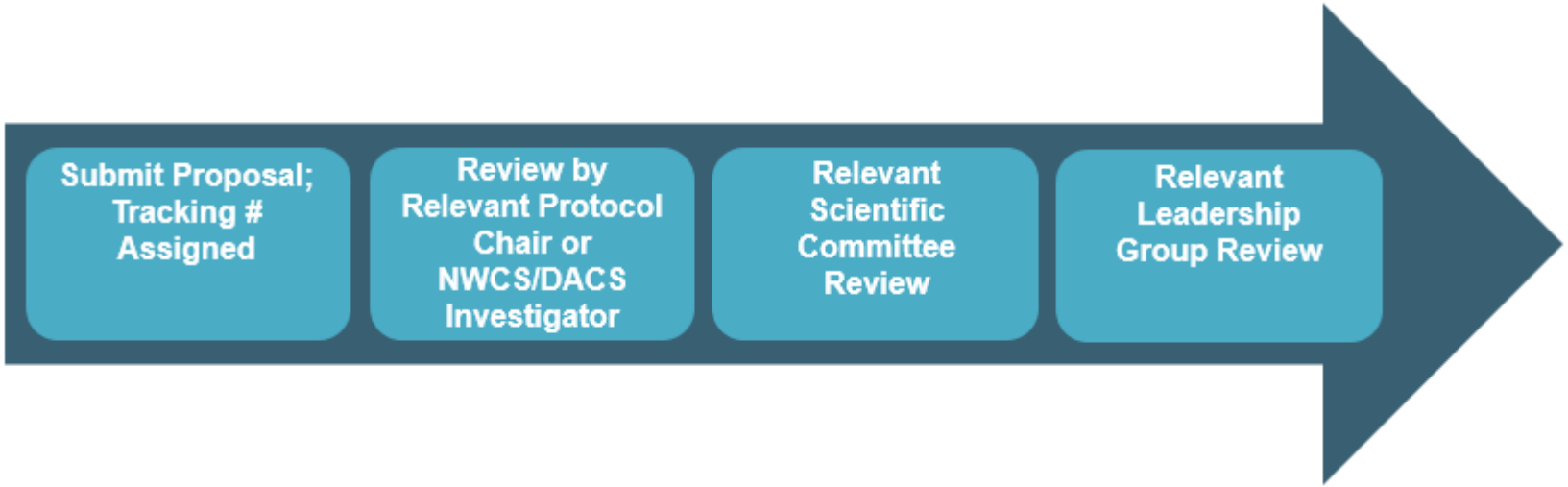
Ancillary Studies Review Process

- Study proposals using the appropriate template form should be submitted to: impaact.capsubmissions@fstrf.org
- The Operations Center will then assign a number to the proposal and initiate the IMPAACT review process



Initial Review of DACS, NWCS by relevant Protocol Chair

- The relevant Protocol Chairs or designees and/or relevant 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.

Additional information can be found in MOP Section 15.2.2

Overview of Proposal Review Outcomes

- 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, Scientific Committee (SC), or Network leadership for re-review.
- If the proposal is **disapproved**, the Operations Center notifies the proposing investigators and informs SDAC.
- If the proposal is **approved**, the proposal is shared for relevant SC review.

Additional information on the above outcomes can be found in MOP Sections 15.2.2 - 15.2.4

Scientific Committee (SC) Review

- If approved the proposal goes to SC 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.
- The relevant SC reviews the science 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.

Additional information on this review can be found in MOP Section 15.2.3

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 DR and DACS**: the Network chair and SDMC principal investigator (PI) determine the need for review by the full MOG or SLG; or if the Network Chair and Statistical and Data Management Center PI will review and approve the proposed ancillary study on behalf of the Network. Generally, the Network chair and SDMC PI review and approve ancillary studies on behalf of the Network.

- **For NWCS**: the Laboratory Center (LC) PI and SDMC PI determine the need for review by the full MOG or SLG. In some cases, the Network Chair may review on behalf of the LC PI. As part of their review, the LC PI and SDMC PI determine if there is a need for review by the full MOG or SLG or if the LC PI and SDMC PI will review and approve the proposed ancillary study on behalf of the Network. Generally, the LC PI and SDMC PI review and approve ancillary studies on behalf of the Network.

Final Proposal Review Outcomes

A proposed ancillary study may be:

- **Deferred,** if further information is required, the Operations Center proposal coordinator will inform the proposing investigators and request the specific information needed.
- **Disapproved**, the Operations Center proposal coordinator notifies the proposing investigators and informs SDAC: cbar.attask@harvard.edu.
- **Approved**, the Operations Center proposal coordinator notifies the proposing investigators and informs SDAC: cbar.attask@harvard.edu. For NWCSs, the Data Management Center (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 a Specimen and Data Usage Agreement (SDUA; see MOP Section 15.4). For NWCSs, this communication also includes information about whether specimens collected at certain sites cannot be used due to lack of site IRB approval or other regulatory requirements.

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Specimen and Data Use Agreement (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 datasets 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

Responsibilities and Procedures for Completion of Ancillary Studies

Data Request (DR)	Data Analysis Concept Sheet (DACS)	New Works Concept Sheet (NWCS)
An SDAC coordinator is assigned to work with proposing investigators and the DMC to facilitate transfer of data and to inform investigators of any costs.	An SDAC statistician or epidemiologist is assigned (or confirmed) to work with the proposing investigators to complete and publish the proposed analyses.	A DMC Laboratory Data Manager is assigned to each approved NWCS. Either an SDAC coordinator or a statistician is assigned.

Additional information and definitions can be found in MOP Section 15.5

Publication Requirements and Procedures

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** of the IMPAACT MOP, including timelines, authorship, Network review, and citations.
- Any publications associated with the proposal should include acknowledgement of IMPAACT.

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.
- The requestor must send the request by email 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 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.
- Additional information on procedures for accessing data can be found in MOP Section 15.7. For specific examples of data access requests, refer to section 15.7.3.

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Resources

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IMPAACT Network MOP

Further details on DACS, DR, NWCS, and concept sheet development and review processes are available in the IMPAACT Network MOP

https://www.impaactnetwork.org/resources/manual-procedures

- Section 9: Protocol Development and Modification
  - *Section 9.1: Concept Development and Review*
- Section 15: Ancillary Studies, Investigations, and Access to Study Data
- Section 19: Publications Requirements and Procedures

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Thank you for viewing!

Please e-mail:
impaact.capsubmissions@fstrf.org
with questions

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