IMPAACT Protocol Chair Roles and Responsibilities: Overview and Activities during Protocol Development

Sharon Nachman, IMPAACT Network Chair, and
Patricia Flynn, IMPAACT Network Domestic Vice Chair

13 September 2022

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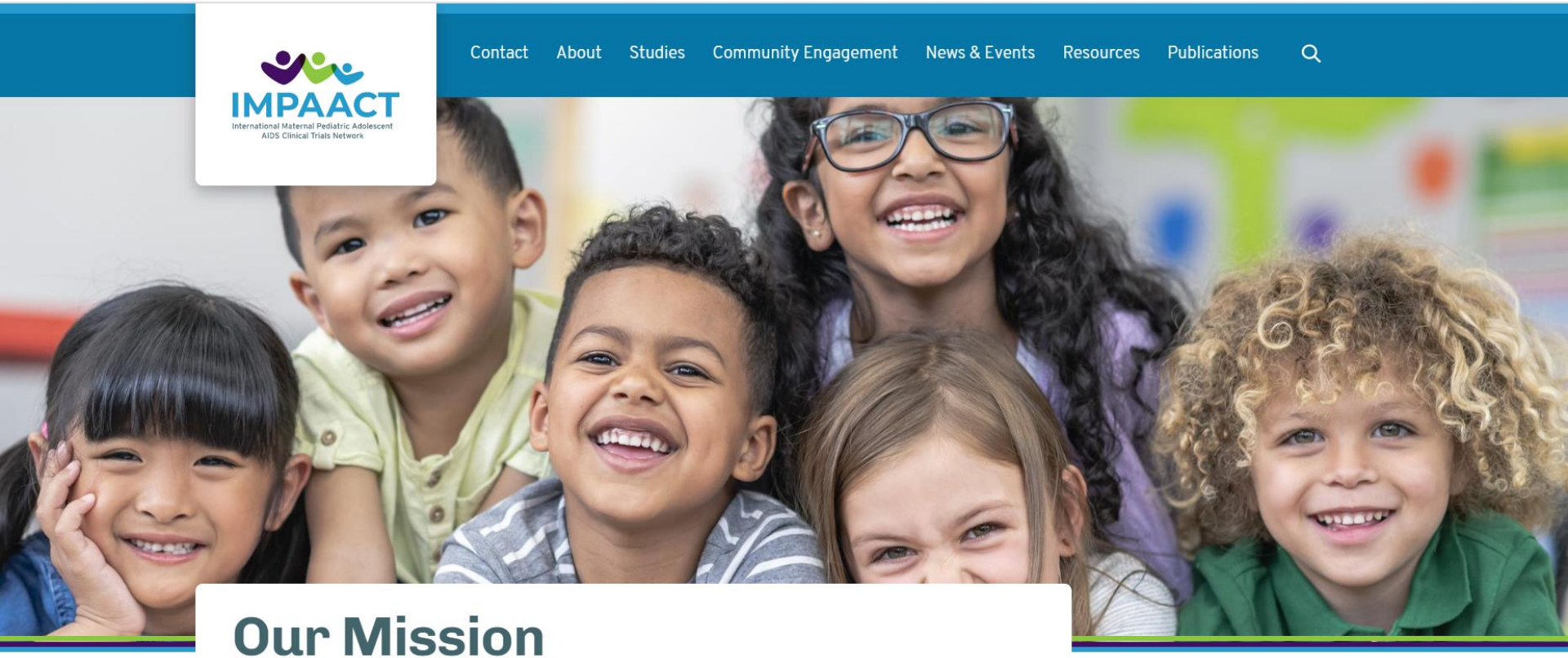
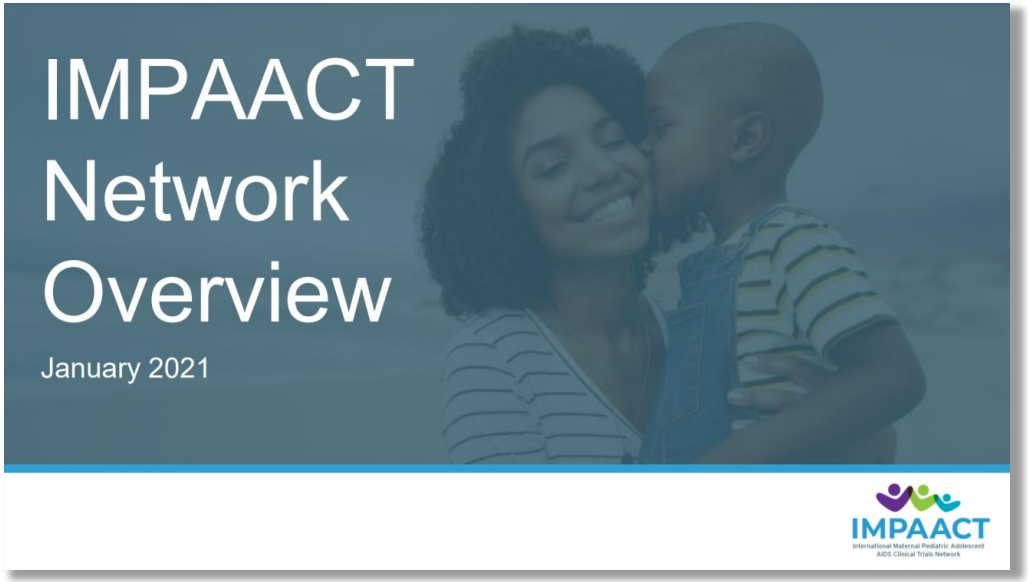
International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Please Visit Our Website



To learn more about the overall Network, please review the Overview presentation



https://www.impaactnetwork.org/sites/default/files/2021-03/IMPAACT%20Overview_JAN2021-PDF.pdf

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Network Organization

IMPAACT Network Manual of Procedures,
Sections 1 and 2, Organization and Network Groups

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History

- Formed in 2006 (preceded by PACTG)
- Successfully renewed in 2013 and in 2020
- Funded by US National Institutes of Health
  - Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID)
  - *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
  - National Institute of Mental Health (NIMH)

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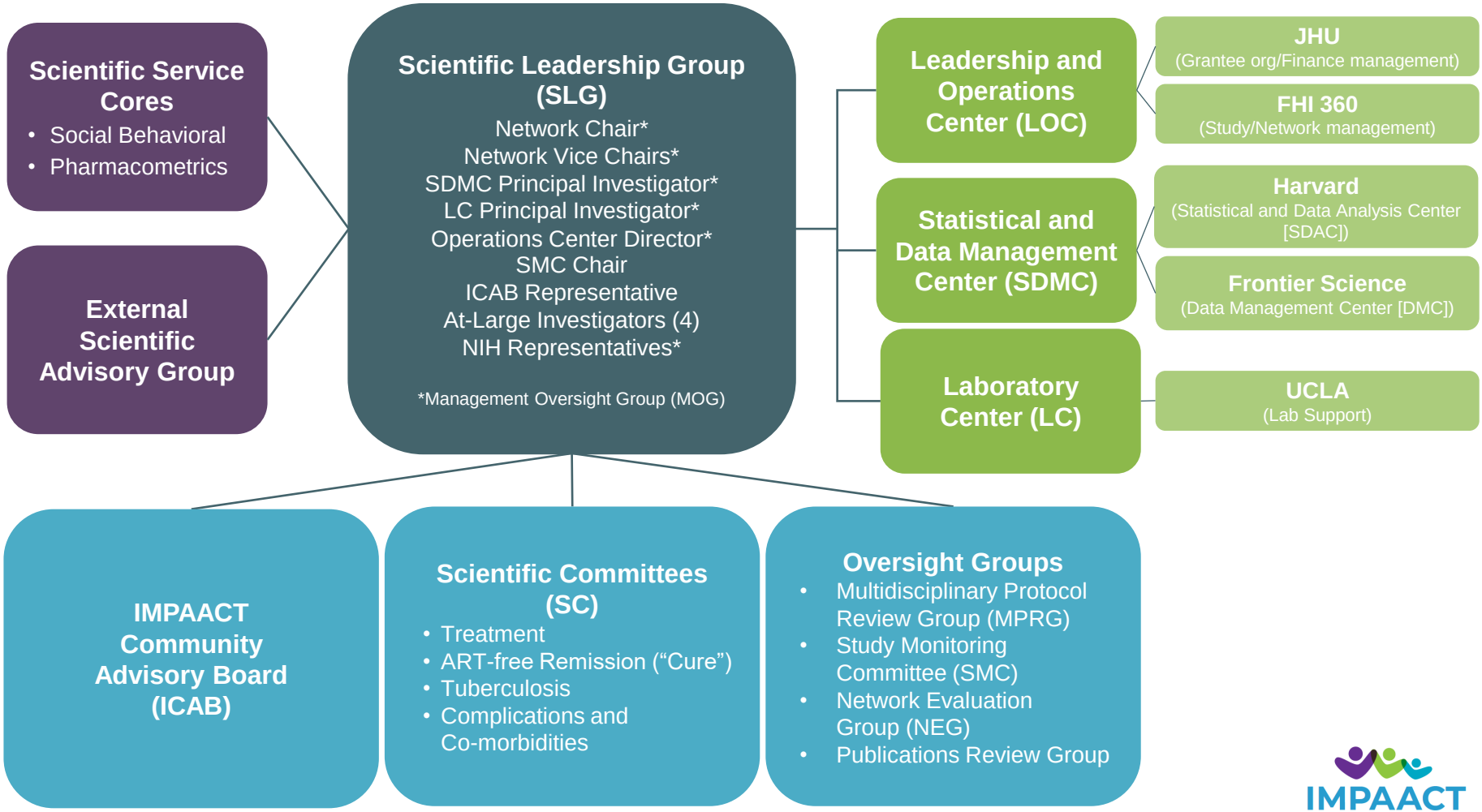
Organization

IMPAACT is comprised of:

- Scientific and management leadership groups
- Central resources that support study operations, data collection and analysis, and laboratory testing for Network studies
- Clinical research sites where studies are conducted



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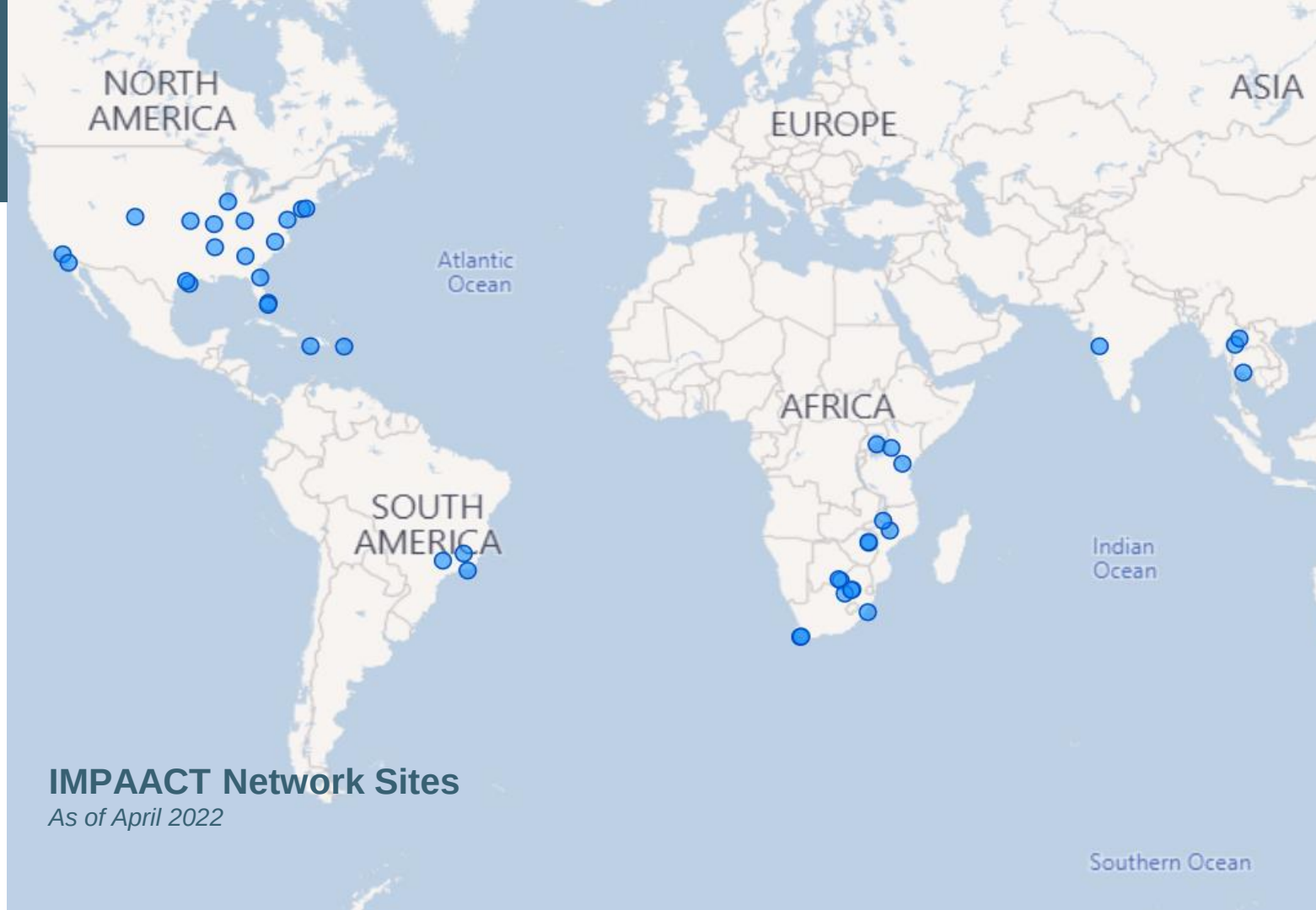

IMPAACT Network Sites

As of April 2022

52
IMPAACT Sites

12
Countries

4
Asian Sites

18
African Sites

25
North American Sites

5
South American Sites

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Protocol Chairs and Vice Chairs

IMPAACT Network Manual of Procedures,
Section 4, Protocol Teams, Subsection 4.1.2

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IMPAACT Network Quick Guide for Protocol Chairs

The IMPAACT Network follows standard policies and procedures for protocol development, site selection, study implementation, and publication processes, as described in the Network Manual of Procedures (MOP), available on the IMPAACT website. Protocols, and other study related documents, will adhere to the NIAID HIV Language Guide, which includes language suggestions for communicating about HIV and related topics. The Representative Studies Rubric (RSR) tool will also be used to guide and monitor enhanced representation in clinical research during protocol development. The NIAID HIV Language Guide and RSR tool are available on the IMPAACT website.

The protocol chair provides scientific and protocol team leadership during the development, implementation, and reporting of the study. The protocol chair assumes responsibility for guiding protocol team members towards completion of protocol team responsibilities such that study milestones are met and Network processes are followed within the budget and timelines approved by Network leadership. The protocol chair may delegate specific areas of responsibility to a vice chair or other team members, but decision-making authority and ultimate responsibility for the full execution of the study rests with the protocol chair. If conflicts on final decisions cannot be resolved within the protocol team, the protocol chair may refer the issue to the Scientific Leadership Group.

Please feel free to contact the Network Chair and Vice Chairs, Sharon Nachman, Pat Flynn, and Philippa Musoke with any questions (Sharon.Nachman@stonybrookmedicine.edu; pat.flynn@stjude.org; pmusoke@mujhu.org).

Protocol Chair Responsibilities

Provide scientific leadership during the development, implementation, and reporting of the study and facilitate final decision making within the team

- Assume responsibility for completion of protocol team responsibilities and other study activities within the approved budget and timeline
- May delegate specific areas of responsibility to a vice chair, but decision-making authority and ultimate responsibility for the execution of the study rests with the protocol chair
- Plan and manage protocol team business with the Clinical Research Manager (CRM), in consultation and with the support of other protocol team members

General Responsibilities

Throughout the lifecycle of the study

Leading and Ensuring Compliance	Coordinating and Collaborating	Monitoring	Communicating
• Leading team meetings and calls • Complying with ICH/GCP • Complying with IMPAACT Network MOP	• Establishing and dissolving study-specific groups • With team member activities to meet study targets and timelines • With team members on development and execution of study activities and materials	• Progress in relation to established timelines and working with team members as needed to address delays • Quality and progress of study conduct & working with team members and sites	• Providing status updates to IMPAACT leadership • Acting as a liaison between the protocol team, the study sponsor, and network leadership and oversight groups • Provide active and timely scientific and operational guidance to support sites

Pre-Implementation Responsibilities

From initiation of protocol development through first enrollment

Work with the CRM to complete the site selection process
(MOP Section 10)

Work with the CRM to develop the study budget
(MOP Section 11.1.11)
budget negotiations with study partners are handled at the Network level

Lead protocol development process with the CRM
(MOP Section 9)

Work with the CRM to develop and carry out study-specific training plans
(MOP Section 16)

Ensure timely development and sign-off of study implementation plans and materials
(MOP Section 11)

Protocol Team Members

IMPAACT Network Manual of Procedures,
Section 4, Protocol Teams, Subsection 4.2.1

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Formation of the protocol team is the first step in the process and is coordinated centrally by the IMPAACT Operations Center

<table>
<tr><td colspan="6">Protocol Chair and Vice Chair
(one protocol chair and one vice chair are typically proposed in the concept sheet)</td></tr>
<tr><td colspan="6">NIH Representatives</td></tr>
<tr><td colspan="2">DAIDS Medical Officer</td><td colspan="2">NICHD Medical Officer</td><td>NIMH Medical Officer
(if applicable)</td><td>DAIDS Pharmacist
(if applicable)</td></tr>
<tr><td rowspan="2">Clinical Research Manager
(FHI 360)</td><td colspan="3">SDMC Representatives
(Harvard and Frontier Science)</td><td colspan="2">LC Representatives</td></tr>
<tr><td>Statistician</td><td>Protocol Data Manager</td><td>Laboratory Data Manager</td><td>Laboratory Center Representative
(UCLA)</td><td>Laboratory Technologist</td></tr>
<tr><td>Community Representative</td><td>Pharmaceutical or Industry Representative</td><td colspan="2">Investigators</td><td>Westat Representative
(if applicable)</td><td>Site Representatives</td></tr>
</table>

Protocol Team Member Roles & Responsibilities

Table 4-1. Roles of Key Protocol Team Members

Team Member	Primary Roles and Responsibilities
Clinical Research Manager (CRM)	• With protocol chair, provide scientific and operational input to the protocol and coordinate and lead protocol development and any subsequent protocol modifications, as applicable • Organize and document protocol team conference calls and meetings • Prepare study budget with Operations Center financial staff, in collaboration with the protocol chair and, as applicable, with input from other protocol team members and site representatives • Submit protocol for required IMPAACT and DAIDS reviews (MPRG, applicable Sciences Review Committee, Regulatory, MO, Regulatory Affairs Branch) and manage response/revision process as needed (see Section 9) • Coordinate the site selection process (see Section 10) • Develop and produce the study-specific manual of procedures (MOP) with input from DMC, LC, and other protocol team members, as applicable (see Section 11) • Collaborate with protocol team members to coordinate the completion of study open to accrual requirements (see Section 11) • Coordinate and develop the training plan and materials and provide study-specific training with DMC, LC, and other protocol team members, as applicable (see Sections 11 and 16) • Coordinate the site activation process (see Section 11) • Assess the performance of and provide operational guidance to sites during study conduct, enabling the sites to respond to problems and issues that arise during implementation of studies and dissemination of findings • Provide information on study progress to the sites, protocol teams, Network leadership, pharmaceutical representatives (if applicable), and/or DAIDS • With the SMC or DSMB coordinator, collaborate with SDMC on SMC and/or DSMB reviews and reports • Contribute to study close-out procedures (see Section 14) • Participate in publication activities and facilitate as needed (see Section 19) • See Section 2 for further details of Operations Center responsibilities

- All members are expected to provide scientific, operational, or site-specific input, as appropriate, to protocol team activities
- A listing of specific team member roles is provided in MOP Section 4, Table 4-1

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Protocol Development

IMPAACT Network Manual of Procedures,
Section 9

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IMPAACT Manual of Procedures

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

Section 9, Protocol Development and Modifications
Version 3.0, January 2021

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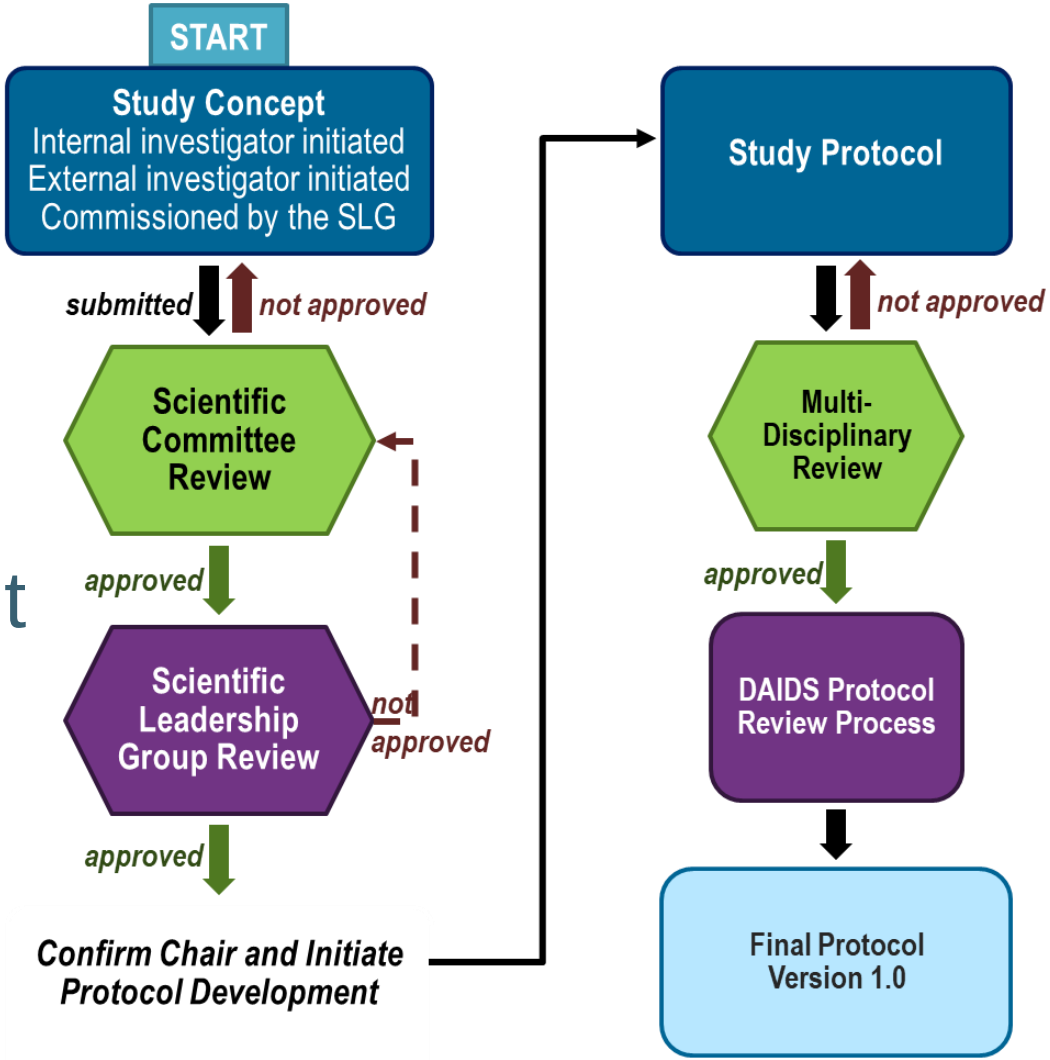
Overview of Protocol Development Process



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Necessary Precursors

- Commitment from company to provide study product
- Availability of investigational agent in the formulation needed for the proposed study population
- Availability of data from prior studies of the investigational agent considered necessary to enable evaluation in the proposed study population

Necessary Precursors

- In close consultation with IMPAACT leadership and DAIDS as applicable, protocol chairs communicate with pharma companies regarding study agent needs and other key considerations for the study-specific collaboration, including required timelines*
  - DAIDS negotiates confidential disclosure agreements and clinical trial agreements
  - Discussions between study chairs, Network leadership, and DAIDS related to study product acquisition take place

Timelines must consider standard IRB and other regulatory reviews and approvals for international sites (~9-12 months) and single IRB reviews for US sites (~2-4 months)

Getting Started

- The Operations Center coordinates with other Network partners on the formation of the protocol team
- IMPAACT Operations Center Clinical Research Manager (CRM) begins work based on the approved study concept and coordinates with the protocol chair to specify timelines and determine key writing assignments
- Protocol team meets frequently via conference call and actively communicates, drafts, and reviews sections between calls

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Protocol Development Steps

IMPAACT Reviews
Development of full draft protocol (including early CSRC review, if applicable, and internal SDAC review)
Protocol team sign-off
IMPAACT MPRG review (including advance submission, and post-review revisions/response)
NIAID Division of AIDS Reviews
Protocol team sign-off
DAIDS Clinical or Prevention Sciences Review Committee Review (including advance submission and post-review revisions/response)
DAIDS regulatory review (including advance submission and post review revisions/response)
DAIDS Medical Officer sign-off followed by protocol team response
DAIDS Regulatory Affairs Branch final sign-off

Guidance Documents

- Protocols must adhere to the NIAID HIV Language Guide, which includes language suggestions for communicating about HIV and related topics
- The Representative Studies Rubric (RSR) tool will also be used to guide and monitor enhanced representation in clinical research during protocol development
- The NIAID HIV Language Guide and RSR tool are available on the IMPAACT Website

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Protocol Development through Team Sign-Off

IMPAACT Network Manual of Procedures,
Section 9, Subsections 9.2.1-9.2.3

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First Things First

- The protocol team should prioritize development of the study **schema**, which includes the study **objectives** and **design**, and **eligibility criteria** first, followed by the **schedule of evaluations**.
- It is counterproductive to develop other sections before these sections are fully discussed and agreed upon by the team. Once agreement is achieved, these sections should generally **not** be re-visited.

Protocol Development Within the Team

Protocol Section	Primary Author	To Team	Review Due	Finalized			
Schema							
Eligibility							
Design							
SoE							

Protocol Section	Primary Author	Sent to Ops	To Team	Review Due	Back to Team	Review Due	Sign-Off
1							
5							
6							
7							
8							
etc.							

Protocol Development Within the Team

Protocol Section	Primary Author	To Team	Review Due	Finalized			
Schema	Ops	Dec 4	Dec 6	Dec 15			
Eligibility	Ops	Dec 7	Dec 11	Dec 15			
Design	Ops	Dec 7	Dec 11	Dec 15			
SoE	Ops	Dec 15	Dec 20	Dec 22			

Protocol Section	Primary Author	Sent to Ops	To Team	Review Due	Back to Team	Review Due	Sign-Off
1	Chairs	Dec 22	Jan 8	Jan 15	Jan 22	Feb 5	At in-person meeting
5	Ops+Rx	Dec 22	Jan 8	Jan 15	Jan 22	Feb 5	
6	Ops	NA	Jan 8	Jan 15	Jan 22	Feb 5	
7	Ops	NA	Jan 8	Jan 15	Jan 22	Feb 5	
8	Ops+Chairs	Dec 22	Jan 8	Jan 15	Jan 22	Feb 5	
etc.	etc.	etc.	Jan 8	Jan 15	Jan 22	Feb 5	

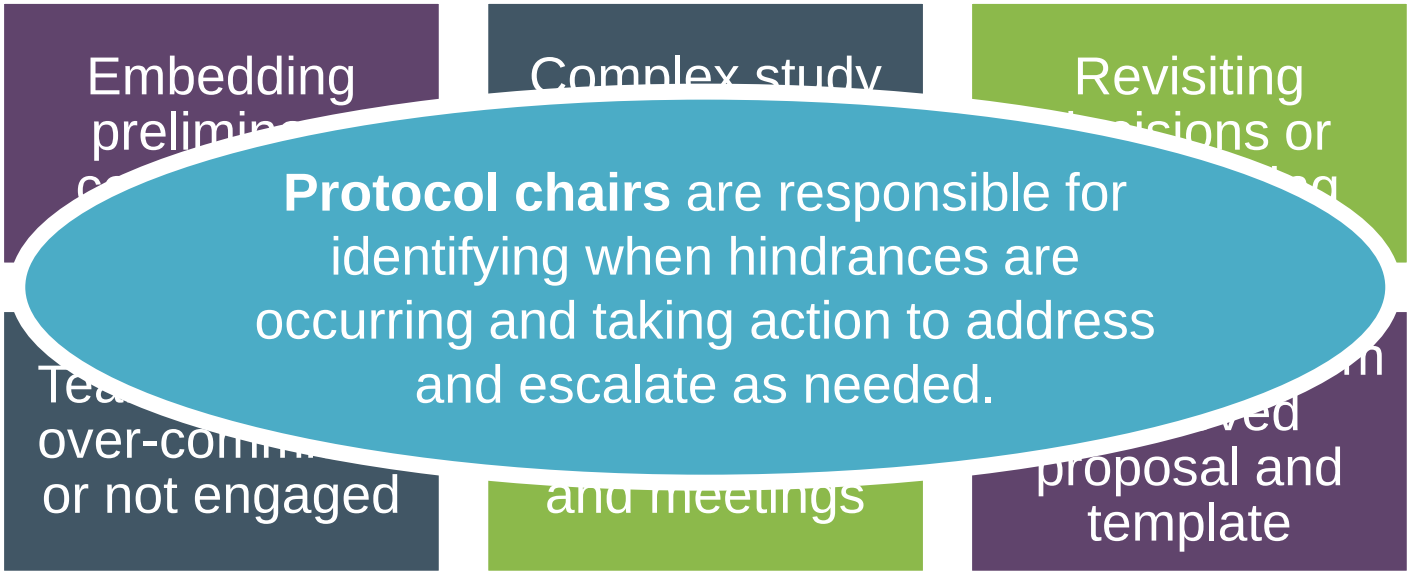
Team Member Input

- Critical input is sought from **all team members** throughout the process but is most important upon first review of each section
  - Otherwise, prior decisions are more likely to be revisited, which leads to delays
- Internal organizational reviews should be discussed with the team and planned for in advance, aligned within the overall timeline

Common Hindrances

- Embedding preliminary components
- Complex study design with add-ons
- Revisiting decisions or backtracking
- Team members over-committed or not engaged
- Lack of activity between calls and meetings
- Divergence from approved proposal and template

Common Hindrances



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Common Facilitators

- Clear understanding of regulatory commitments
- Simplest possible design with no add-ons
- No re-visiting or back-tracking throughout process
- All team members engaged and responsive throughout process
- All team members committed to timelines
- Avoid divergence from DAIDS and IMPAACT standards

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Common Facilitators

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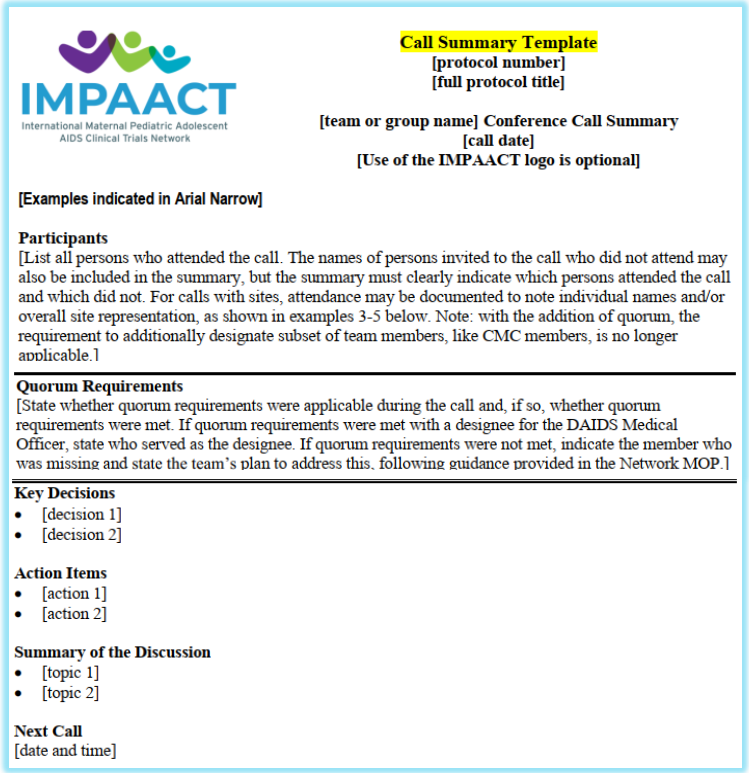
Practical Tips for Chairs

Preparing ahead of time for calls

- Review prior call summary and materials previously distributed
- Think through agenda items and what's needed
- Prepare what's needed with sufficient time for distribution in advance of next call
- Have relevant documents open on your computer
- Keep calls within time provided and ensure relevant agenda items are covered
- As needed, communicate with Network leadership to ensure key team members consistently attend conference calls



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Call Summary Template
[protocol number]
[full protocol title]

[team or group name] Conference Call Summary
[call date]
[Use of the IMPAACT logo is optional]

[Examples indicated in Arial Narrow]

Participants
[List all persons who attended the call. The names of persons invited to the call who did not attend may also be included in the summary, but the summary must clearly indicate which persons attended the call and which did not. For calls with sites, attendance may be documented to note individual names and/or overall site representation, as shown in examples 3-5 below. Note: with the addition of quorum, the requirement to additionally designate subset of team members, like CMC members, is no longer applicable.]

Quorum Requirements
[State whether quorum requirements were applicable during the call and, if so, whether quorum requirements were met. If quorum requirements were met with a designee for the DAIDS Medical Officer, state who served as the designee. If quorum requirements were not met, indicate the member who was missing and state the team's plan to address this, following guidance provided in the Network MOP.]

Key Decisions
- [decision 1]
- [decision 2]

Action Items
- [action 1]
- [action 2]

Summary of the Discussion
- [topic 1]
- [topic 2]

Next Call
[date and time]

Practical Tips for Chairs

- Frequently review timelines and progress towards meeting them
- Ensure issues are not being revisited, once decisions are made
- Follow Network Manual of Procedures and standard practices/language within the Network
- Establish a strong communication mechanism with the CRMs (e.g., through email, call summaries and other documents, or routine check-in calls)

Capitalize on experience and expertise within the team

- CRM will follow up with individual team members as needed to ensure accuracy and consistency of protocol wording throughout the document
- CRM, SDMC, and LC representatives will help ensure wording consistent with Network standards
- CRM, Statistician, and Medical Officers will identify issues likely to raise questions/comments/concerns in protocol review steps and make recommendations to avoid these
- Protocol team members based at a CRS should gather input from other CRS staff members, particularly on operational feasibility

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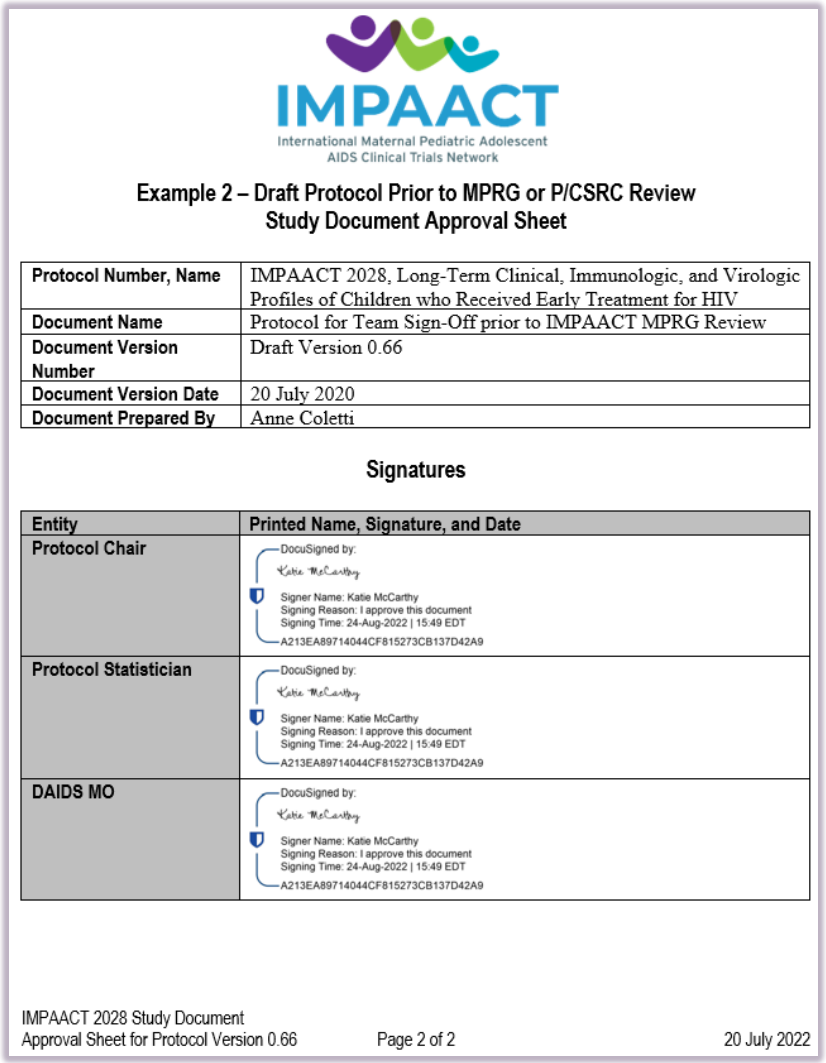
Protocol Team Member Sign-Off

Protocol Team Sign-Off is met once approvals are obtained from:

- One protocol chair (chair, co-chair, or vice chair)
- One statistician/epidemiologist
- DAIDS medical officer

The Operations Center uses DocuSign to obtain signatures (email is not sufficient).



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Example 2 – Draft Protocol Prior to MPRG or P/CSRC Review
Study Document Approval Sheet

Protocol Number, Name	IMPAACT 2028, Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV
Document Name	Protocol for Team Sign-Off prior to IMPAACT MPRG Review
Document Version Number	Draft Version 0.66
Document Version Date	20 July 2020
Document Prepared By	Anne Coletti

Signatures

Entity	Printed Name, Signature, and Date
Protocol Chair	DocuSigned by: Katie McCarthy Signer Name: Katie McCarthy Signing Reason: I approve this document Signing Time: 24-Aug-2022 | 15:49 EDT A213EA89714044CF815273CB137D42A9
Protocol Statistician	DocuSigned by: Katie McCarthy Signer Name: Katie McCarthy Signing Reason: I approve this document Signing Time: 24-Aug-2022 | 15:49 EDT A213EA89714044CF815273CB137D42A9
DAIDS MO	DocuSigned by: Katie McCarthy Signer Name: Katie McCarthy Signing Reason: I approve this document Signing Time: 24-Aug-2022 | 15:49 EDT A213EA89714044CF815273CB137D42A9

IMPAACT Multidisciplinary Protocol Review Group Review

IMPAACT Network Manual of Procedures,
Section 9, Subsections 9.2.4

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IMPAACT MPRG Review

The purpose of MPRG review is to ensure IMPAACT protocols are scientifically rigorous, accurate, consistent, complete, and standardized to the extent possible. The MPRG critically reviews protocols for scientific and design integrity, operational feasibility, focusing on key issues such as site participation, infrastructure and capacity, relevance to the community, and any ethical, logistical, or potentially regulatory concerns. The MPRG conducts reviews on behalf of the SLG. The review is multidisciplinary to streamline and avoid multiple sequential review steps.

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Composition of MPRG

- Network Chair or Vice Chair
- Scientific Committee Chair or Vice Chair
- External Expert
- Operations Center Representative
- Statistical and Data Management Representative
- Laboratory Center Representative
- ICAB Representative
- IMPAACT Pharmacist
- NIH Representatives

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MPRG Process

- Reviews are scheduled as needed – protocols can be submitted any time after team sign-off
- Reviews are conducted via conference call, with written comments prepared in advance and then finalized after the review takes place
- Protocol chairs are invited to join an open review session during the review call
- Multiple MPRG reviews may be required
- Final review summary is provided to the team as soon as possible

DAIDS Scientific Review

IMPAACT Network Manual of Procedures,
Section 9, Subsection 9.2.5

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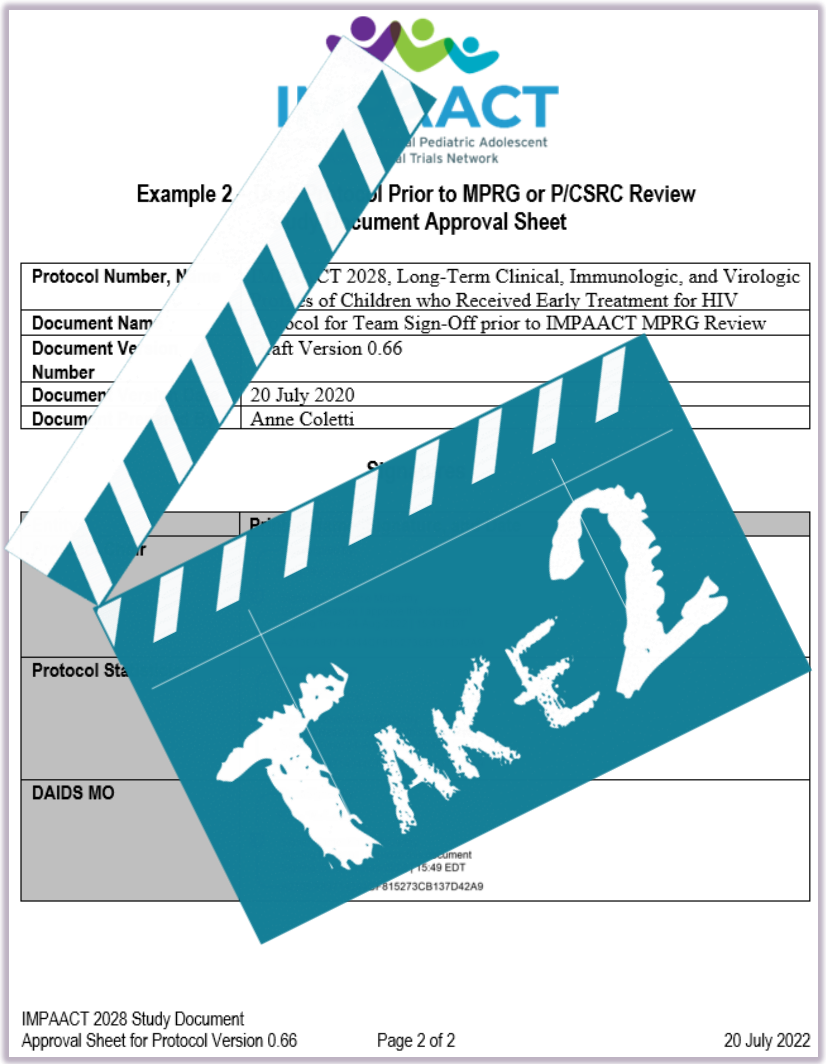
Protocol Team Member Sign-Off

Protocol Team Sign-Off is met once approvals are obtained via DocuSign from:

- One protocol chair (chair, co-chair, or vice chair)
- One statistician/epidemiologist
- DAIDS medical officer

The Operations Center uses DocuSign to obtain signatures (email is not sufficient).



Clinical Science Review Committee

Evaluates the research plan specified in the protocol on the basis of:

- NIAID's and other co-sponsoring institutes' research agenda, priorities, and other NIH clinical studies
- Scientific merit and study design
- Human subjects considerations and participant safety
- Compliance with US federal regulations and ethics
- Study oversight and monitoring
- Feasibility of timely completion
- Pharmacy and regulatory considerations
- When appropriate, plans for interim monitoring and analysis

CSRC Process

- Reviews are scheduled on Thursdays
- Protocols must be submitted at least two weeks in advance
- Protocol chair and other (limited) team members are invited to attend remotely, provide a brief presentation, and respond to selected review comments
- Final review summary is provided two weeks after the review

Subsequent DAIDS Review Steps

IMPAACT Network Manual of Procedures,
Section 9, Subsections 9.2.6-9.2.9

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DAIDS Review Steps after CSRC

- Regulatory Review
- Medical Officer Review and Sign-Off
- Final Regulatory Affairs Branch Review and Sign-Off
  - Review comments are provided within two weeks
  - Responses are typically completed within one week
  - Completion of the final review step results in submission of the protocol (Version 1.0) to the FDA (for IND studies) or final DAIDS approval (for non-IND studies) and distribution to sites for submission to their review bodies

DAIDS Review Steps after CSRC

DAIDS Regulatory Review

- CRM submits the "Regulatory Review Version" of the draft protocol with the ClinicalTrials.gov checklist
- Regulatory review is expected within 10 working days of receipt
- Comments are sent back to the CRM to address with the team's input, as needed
- Anticipate submitting for next step within ~5 working days of receipt

DAIDS Medical Officer Review

- CRM submits the "Medical Officer Review Version" of the draft protocol
- DAIDS MO review is expected within 10 working days of receipt
- Comments are sent back to the CRM to address with the team's input, as needed
- Timeline for submitting for next step depends on the scope and nature of comments

Final DAIDS RAB Review

- CRM submits the "Final Version" of the protocol
- RAB review is expected within 10 working days of receipt
- Approval is sent to the CRM (either submission to FDA [IND studies] or approval [non-IND studies])
- CRM distributes final protocol to team and sites

Study Development Sequencing

To help teams efficiently manage protocol development, Network leadership has begun sequencing protocol development timelines and priorities.

Site Selection

IMPAACT Network Manual of Procedures,
Section 10

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Objectives of the Site Selection Process

- Earlier involvement of site investigators, coordinators, and other key site staff in protocol development and preparation for study implementation
- Improved ability to determine study feasibility and predict timing of key study milestones based on projections for each site
- Increased site investment in successful study implementation

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All currently supported IMPAACT sites should be invited to participate

- Unless there are strong scientific rationale or unless there is a concern around post-study access to the investigational product, all IMPAACT sites should be invited to participate
- Protocol team members should clearly state the key evaluation criteria in the site selection materials

Process Initiated Soon After Protocol Development Begins

- Short application to determine site interest and rule out sites that cannot meet minimum study-specific requirements
- Protocol team members (minimally, protocol chair, vice chair(s), and CRM) review the applications to determine next steps.
- Sites should ideally be selected and approved by MOG prior to submitting the protocol for MPRG review.

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Process Initiated Soon After Protocol Development Begins

Given site experience and Network knowledge of IMPAACT sites, most studies have confirmed site selection through use of a site application only. However, if additional information is needed to determine appropriate sites, teams may consider a two-step process, to include a Site Implementation Plan (SIP).

Sites that meet minimum requirements submit a SIP, including sufficient operational detail to optimize selection

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Protocol Chair Role During Site Selection

- Protocol team members, minimally including the protocol chair, vice chair(s), and CRM, should critically review all site applications and determine which sites meet minimum requirements to conduct the study
- Chairs should consider the requirements of the study, optimizing allocation of Network resources and involving site investigators and other key staff early in protocol development
- CRM can help incorporate estimated timelines for site activation (including IRB/EC approval timelines)

Site Selection and Accrual Plan

Table 3. Site Selection and Accrual Plan for IMPAACT 2010

CRS#	CRS Name, Country	Monthly Projected Accrual													Total Projected Accrual
		M1	M2	M3	M4	M5	M6	M7	M8-10	M11	M12	M13	M14	M15	
4201	Pediatric Perinatal HIV, Miami, FL, US	1	0	1	0	1	0	1	Accrual paused to evaluate TAF PK	0	1	0	1	0	6
5051	Univ. of Florida Jacksonville, US	0	1	0	1	0	1	0		1	0	1	0	0	5
5115	Siriraj Hospital Mahidol Univ, Thailand	0	1	1	1	1	1	1		1	1	1	1	1	11
31784	Chiang Mai Univ, Thailand	1	1	2	2	2	2	2		2	2	2	2	1	21
8051	Shandukani, South Africa						5	7		10	10	10	10	9	61
8052	Soweto, South Africa†						5	7		10	10	10	10	9	61
8950	FAM-CRU, South Africa†						1	1		2	2	2	2	2	12
12001	UNC Lilongwe, Malawi						5	7		10	10	10	10	9	61
12701	Gaborone, Botswana						2	3		4	4	4	4	4	25
12702	Molepolole, Botswana						2	3		4	4	4	4	4	25
30293	MUJHU, Uganda†						5	7		10	10	10	10	9	61
30300	CAPRISA Umlazi, South Africa†						2	3		5	5	5	5	5	30
30301	Blantyre, Malawi†						5	7		10	10	10	10	10	62
30303	St. Mary's, Zimbabwe†						2	3		5	5	5	5	5	30
30306	Seke North, Zimbabwe†						2	3		5	5	5	5	5	30
31798	Baylor-Uganda						1	2		3	3	3	3	3	18
31890	Harare Family Care, Zimbabwe†						2	3		5	5	5	5	5	30
30273	George Clinic, Zambia														0
31441	BJ Medical College, India														0
5118	KCMC, Tanzania														0
5071	Inst de Puericultura e Pediatria, Brazil														0
5072	Hosp dos Servidores, Brazil														0
5073	SOM Federal Univ Minas Gerais, Brazil														0
Cumulative Accrual		**2**	**5**	**9**	**13**	**17**	**60**	**120**		**207**	**294**	**381**	**468**	**549**	**549**

†P1084s DXA site

Process results in site selection and participant accrual plan for review and approval by the IMPAACT Management Oversight Group (MOG)

Beyond Protocol Development

IMPAACT Network Manual of Procedures,
Sections 11, 12, 13, 14, and 19

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Study Budget

Background/ Development

- The Operations Center develops the study-specific budget inclusive of:
  - Site and protocol-specific specialty laboratory costs
  - Costs for central resources (Operations Center, SDMC, and LC)
  - Any other study-specific costs as needed

Team Review

- The Operations Center requests input from the protocol chair and other team members as appropriate

Timing

- The Operations Center typically coordinates MOG review of the study budget soon after the draft protocol is reviewed by the MPRG

Study Implementation Responsibilities

From first enrollment through closing to follow-up

- Participate in study data reviews consistent with the study monitoring plan
- Together with the protocol statistician, report on the status of the study to the Study Monitoring Committee (SMC) and/or Data and Safety Monitoring Board (DSMB)
- Lead the study Clinical Management Committee
- Ensure timely development of study closure plans and materials

Study Implementation Responsibilities

From first enrollment through closing to follow-up

- Ensure appropriate and timely communication with sites, Network leadership, study sponsors
  - *With sites:* study progress, milestones, key reminders, and other study-specific considerations
  - *With Network leadership:* may be formal (e.g., through memoranda) or informal emails or calls to escalate key study issues or concerns
  - *With sponsor:* may be formal (e.g., through memoranda or FDA communications) or via protocol team calls and communications through the DAIDS Medical Officer

Notify Network leadership as soon as possible of any issues that could significantly compromise study outcomes or integrity, require additional time or resources to resolve, affect other Network studies, and/or require specific communications with pharmaceutical collaborators.

Publications

- Oversee analysis and writing teams (MOP Section 19)
  - Designate writing team members
  - Review schedules
  - Monitor progress
  - Prioritize analyses
  - Communicate publication plans
  - Respond to IMPAACT Publications Committee review
  - Advocate for additional resources as required
- Ensure review and approval of all study-related manuscripts, abstracts, and presentations

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Other IMPAACT Protocol Chairs

Study	Chairs
IMPAACT 2037, Open-Label, Phase I Study of the Safety and Pharmacokinetics of PGT121.414LS alone and in combination with VRC07-523LS in Infants Exposed to HIV-1	Coleen Cunningham, Univ California, Irvine, United States Elizabeth (Betsy) McFarland, Univ Colorado Denver, United States
IMPAACT 2039, Phase I/II Study of the Safety, Immunogenicity, Efficacy of HIVconsvX Vaccines in Children Living with HIV	Mark Cotton, FAMCRU/Stellenbosch, South Africa Avy Violari, PHRU Chris Hani Baragwanath, South Africa Elizabeth (Betsy) McFarland, Univ Colorado Denver, United States
IMPAACT 2040, Phase I/II Pharmacokinetics, Safety, and Tolerability of Long-Acting Injectable Cabotegravir and Rilpivirine in People with Virally Suppressed HIV-1 during Pregnancy and Postpartum (CRAYON)	Rachel Scott, MedStar, United States Adrie Bekker, FAMCRU/Stellenbosch, South Africa
Concept 5032, Safety and Pharmacokinetics of Glecaprevir/Pibrentasvir (GLE/PIB) in Pregnant Persons with Hepatitis C with or without HIV	Proposed: Ahizechukwu Eke, JHU, United States Nathan Furukawa, CDC, United States
Capsule 554, Phase I Study of the Infectivity, Safety and Immunogenicity of two Recombinant, Live-Attenuated, Bovine/Human, Parainfluenza Virus Type 3 (B/HPIV3) Vector Vaccines Expressing the Fusion Glycoprotein of Respiratory Syncytial Virus (RSV) Engineered for Increased Immunogenicity, Delivered in Single Doses as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 18 Months of Age	Proposed: Coleen Cunningham, Univ California, Irvine, United States Elizabeth (Betsy) McFarland, Univ Colorado Denver, United States

Additional Resources

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DAIDS and NICHD

- Developing protocols: https://rsc.niaid.nih.gov/networks-protocol-teams/developing-protocols
- SCORE manual, in particular, *Introduction to DAIDS Systems*: https://www.niaid.nih.gov/research/daids-score-manual
- Manual for EAE Reporting to DAIDS: https://rsc.niaid.nih.gov/clinical-research-sites/manual-expedited-reporting-adverse-events-daids
- Grading Tables: https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables
- DAIDS and NICHD Medical Officers

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IMPAACT Central Resources

- Network Manual of Procedures: https://www.impaactnetwork.org/resources/manual-procedures
- Staff from the Network Central Resources (Clinical Research Managers, Statisticians, Protocol Data Managers, Laboratory Center representatives)
- Network Chairs and Vice Chairs

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THANKS!

Any questions?

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