

IMPAACT Manual of Procedures, Version 7.0, dated 5 June 2026
Overview of Section Contents and Summary of Changes

Section	Summary of Changes
Section 1 Overview of the IMPAACT Network	<ul style="list-style-type: none"> • Clarified mission and scientific research agenda aims and priorities • Updated Network leadership structure to account for multiple Chairs • Added role of DAIDS Clinical Laboratory Oversight Team (DCLOT) • Added role of NICHD contractor to operate in similar function as DAIDS OCSO
Section 2 Network Groups	<ul style="list-style-type: none"> • Added note that Scientific Committee and Core Chairs may be invited to participate in Scientific Leadership Group Meetings • Clarified that Scientific Committee and Core chairs also serve as representatives on applicable oversight groups (e.g., Study Monitoring Committee or Multidisciplinary Protocol Review Group) • Added the Implementation Science Core • Clarified that the IMPAACT Finance and Contracts Office may also provide resources to NICHD sites
Section 3 Good Documentation Practice	<ul style="list-style-type: none"> • Updated to ALCOA++, to include reference to traceable data • Updated to align terminology with ICH GCP E6(R3) • Clarified best practices for signatures, referencing the DAIDS SCORE Manual and Electronic Information Systems Policy
Section 4 Protocol Teams	<ul style="list-style-type: none"> • Updated protocol team formation and membership to align with protocol template • Added Protocol Pharmacologist, Community Program Manager, and Westat Laboratory Representative to Table 4-1 (Roles of Key Protocol Team Members)
Section 5 Community Participation and Engagement in the IMPAACT Network	<ul style="list-style-type: none"> • Added reference to the TB-lived experience • Added in-person meetings as a method for ICAB participation
Section 6 Network Meetings and Communications	<ul style="list-style-type: none"> • Clarified information and materials that are available on the IMPAACT website • Added reference to the “study snapshot” • Added guidance for study-specific questions and applicable study contacts • Clarified the public information policy, including directions related to study investigators and limits around proprietary information
Section 7 IMPAACT General Policies and Procedures: Funding, Conflict of Interest, Certificate of Confidentiality, and ClinicalTrials.gov	<ul style="list-style-type: none"> • Clarified that NICHD sites may receive funding through JHU’s Finance and Contracts Office for select studies • Added language to include the funding process from government or other non-governmental partner-supported studies • Added details for sign-off of invoices sent to sites for payment processing • Added guidance for unutilized study-specific funds • Clarified that FDA Financial Disclosure form must be completed at certain timepoints, unless otherwise specified by the sponsor • Clarified ClinicalTrial.gov activities for IND and non-IND studies in Table 7-1
Section 8 Human Subjects Considerations	<ul style="list-style-type: none"> • Added information on electronic informed consent

IMPAACT Manual of Procedures, Version 7.0, dated 5 June 2026
Overview of Section Contents and Summary of Changes

Section	Summary of Changes
Section 9 Protocol Development and Modifications	<ul style="list-style-type: none"> • Updated elements of IMPAACT concepts in Figure 9-3, to align with concept form template • Added <i>Fast Track</i> protocol development process and timelines in Table 9-1 • Updated requirements for responses to MPRG comments • Clarified distinctions between PSRC and CSRC review processes • Clarified role of the DAIDS Medical Officer in responding to P/CSRC comments • Added requirement for protocol team to sign-off on memos for a proposed amendment to the SLG • Clarified role of DAIDS Regulatory Affairs Branch Sponsors Authorized Representative in determining appropriate method for proposed protocol changes • Added process for centralized submissions of Clarification Memos to SAHPRA, via the DAIDS Regulatory Support Center
Section 10 Site Selection for IMPAACT Studies	<ul style="list-style-type: none"> • Clarified when site selection is generally initiated in relation to protocol development • Added when team members beyond the protocol chair, vice chair, and CRMs may be involved in the site application review process and noted that process will be similar for site implementation plans (SIPs, if applicable) • Clarified steps for adding new sites during study accrual period and steps for expanding beyond IMPAACT sites
Section 11 Study-Specific Pre- Implementation Activities: Open to Accrual and Site-Specific Study Activation	<ul style="list-style-type: none"> • Clarified when sign-off on the LPC is not required • Clarified elements of study laboratory readiness • Added guidance related to use of external or third-party questionnaires for data collection and clarified guidance related to translation of data collection instruments • Added Table 11-1 to specify steps and timeline related to development of data collection instruments • Added requirement for DAIDS OPCRO data manager review of the SPDSMP • Revised guidance and process for development of the study budget • Added other activation requirements that may be applicable for IMPAACT studies • Revised distribution requirements of activation checklists to sites and added required sign-offs from noted protocol and site team members for completed site checklists • Re-ordered subsections under Site-Specific Study Activation for improved flow and grouping of like items • Updated process related to payment for Clinical Trials Insurance • Added guidance related to STAs or MTAs in laboratory requirements • Clarified financial disclosure requirements and process related to study-specific site activation • Added subsection related to the MTA tracker
Section 12 Study Implementation	<ul style="list-style-type: none"> • Clarified distribution of participant identification numbers (PIDs) to sites • Removed inconsistency regarding closed to accrual notification • Revised guidance on source records, to align with ICH E6 (R3) • Added requirement for IMPAACT protocols to specify any direct data entry requirements • Added further details related to the Memorandum of Understanding between DAIDS and NICHD regarding Medical Officer delegation

IMPAACT Manual of Procedures, Version 7.0, dated 5 June 2026
Overview of Section Contents and Summary of Changes

Section	Summary of Changes
	<ul style="list-style-type: none"> • Added reference to availability of routine site data management metrics on the DMC portal • Updated ICH guideline cross-references and quoted text related to protocol deviations
Section 13 Study Oversight	<ul style="list-style-type: none"> • Aligned language regarding clinical site monitoring with approved protocol template text • Added note regarding distribution of study monitoring reports for protocol team review • Clarified requirements related to leadership oversight • Added requirement for agreement to SMC procedures, confidentiality, and conflict of interest for all SMC members • Clarified SMC process for decision-making related to reviews via email and reviews with SMC member designees • Clarified process for response to initial SMC reviews • Added Section 13.5.5, Protocol Team Communications to SMC, and clarified sign-off requirements more fully in Section 13.5.6, Protocol Team Review and Sign-Off • Expanded Section 13.7.1 to include overall expectations related to issue escalation • Clarified the site suspension process and communications related to site suspensions
Section 14 Site Study-Specific Close-out	<ul style="list-style-type: none"> • Added site procedures for completing study close-out early • Clarified procedures for distribution of specimen shipment request lists in Table 14-2 • Revised listing of study close-out considerations in Section 14.3; aligned with order and changes made to subsequent subsections • Added Section 14.3.1, Completion of Study Visits and Additional Contacts (subsequent sections renumbered) • Added guidance regarding quality control/quality assurance activities related to management of stored specimens • Added directions related to disposition of study product, consistent with DAIDS pharmacy guidelines • Added guidance regarding participant casebooks • Replaced reference of the DAIDS SOP regarding essential documents with the DAIDS SCORE Manual; and added directions for closure of the delegation of duties log and QA/QC for essential records • Revised and clarified record retention requirements, with updated links
Section 15 Ancillary Studies, Investigations, and Access to Study Data	<ul style="list-style-type: none"> • Added guidance related to ancillary proposals for early career investigators • Removed reference to secondary analyses defined by the protocol team in Table 15-1 • Clarified initial steps to be completed following submission of a NWCS • Added option for Network leadership designee to review ancillary proposals and clarified process for these reviews • Updated distribution group emails • Added guidance related to the NWCS Site Approval spreadsheet for studies involving non-US sites

IMPAACT Manual of Procedures, Version 7.0, dated 5 June 2026
Overview of Section Contents and Summary of Changes

Section	Summary of Changes
Section 16 Training for Site Key Personnel and Other Site and Laboratory Staff	<ul style="list-style-type: none"> • Clarified required personnel for study-specific and data management center trainings • Updated training option for research ethics for community representatives • Clarified site staff training requirements (e.g., specify study-specific site staff)
Section 17 Laboratory Considerations	<ul style="list-style-type: none"> • Updated Westat and IMPAACT Laboratory Center (ILC) delegation for oversight of NICHD- vs. NIAID-sponsored site-affiliated laboratories and associated responsibilities of each organization • Updated study-specific laboratory activation requirements for NIAID and NICHD sites, both within and outside of the US, including additional details about the domestic analyte list and protocol analyte list • Enhanced guidance related to use of LDMS, including clarifying the required LDMS modules for specimen management and shipping and proper procedures for specimen labeling • Updated guidance related to external quality assurance and proficiency testing • Added guidance for labs under ILC oversight about using the MiPAL system for adding instruments and/or methods to a PAL or changing test methods, kits, or instruments mid-study • Updated guidance on specimen shipping, including references to 2024 memos issued by the ILC and Westat related to the Network policy on specimen shipping frequency, and changes in shipping box requirements • Updated list of specimen destruction reasons and clarified that if a site chooses to retain samples after MOG guidance to destroy them, the Network will not provide assistance with funding, management, or regulatory/ethical compliance • Added reference to the Material Transfer Agreement Tracker and updated guidance related to the establishment of material transfer agreements for IMPAACT studies • Added section on laboratory evaluation by the Network Evaluation Group • Updated list of additional resources
Section 18 Network Evaluation	<ul style="list-style-type: none"> • Removed laboratory PIs and directors from distribution of evaluation reports • Clarified that the site evaluation report includes all sites affiliated with IMPAACT (clarifications added when metric applies only to specific subsets) • Removed percentages from measures for laboratory quality assurance
Section 19 Data Analysis and Publications Procedures	<ul style="list-style-type: none"> • Clarified when IMPAACT Network review is required for abstracts and manuscripts and updated expectations related to the timing of various types of publications in relation to the primary publication • Removed Table 19-1, which included definitions already provided throughout this and other sections of the MOP to reduce redundancy • Added section to describe the IMPAACT publications coordinator role • Removed guidance related to sub-studies • Updated timelines throughout the section, including from primary completion date to draft manuscript submitted for IMPAACT review, and timeline for primary analysis planning • Consolidated tables outlining timelines for manuscript development and review into a single table that incorporates guidance for primary, secondary, exploratory, and ancillary study manuscripts (Table 19-3)

IMPAACT Manual of Procedures, Version 7.0, dated 5 June 2026
Overview of Section Contents and Summary of Changes

Section	Summary of Changes
	<ul style="list-style-type: none"> • Reorganized the IMPAACT publication review process section such that each sub-section now focuses on a different review step (co-author review, protocol team review, publications review group review) • Clarified requirements for the timing of finalization of non-eCRF laboratory data • Added CRM responsibility to notify applicable parties of changes in protocol status • Incorporated additional guidance on the prioritization of data analyses and publications • Updated guidance related to publications from ancillary studies and laboratory projects and added guidance around encore or repeat presentations • Added text describing publication updates in quarterly Study Operations Reports for MOG review, including a review of any delays • Clarified lead author responsibilities related to conference and journal submissions, including ensuring adherence to the 2024 NIH Public Access Policy • Clarified selection criteria for site authorship and expectations for listing contributors • Updated section on public access to align with the current NIH Public Access Policy • Updated guidance on dissemination of study results, including development of materials for protocol teams, participants, community, and key stakeholders • Revised guidance on publication costs • Removed guidance on specimen storage and shipment (covered in Section 17 of the MOP)
Appendix I Unblinding Procedures	<ul style="list-style-type: none"> • Revised availability of DMC user support • Changed endpoints to outcomes • Added reference to Stars system
Throughout	<ul style="list-style-type: none"> • Updated Network leadership structure to account for multiple Chairs • Updated to align with ICH E6 (R3) guidance (e.g., revised source and essential documents to source and essential records) • Updated all Frontier Science references from FSTRF to Frontier Science (including email address domains) • Added reference to Stars system, in addition to Study Enrollment System (SES) • Removed “statistical” from pharmacokinetics analysis plan • Expanded Laboratory Center responsibilities for site laboratory oversight to include select NICHD sites • For consistency, updated references to site clinicians, staff, etc., to site investigator, where applicable; similarly, updated references to protocol, study, clinical trial, etc., as most applicable • Updated and corrected all hyperlinks and cross-references • Other minor clarifications and updates (e.g., making verb tenses consistent, correcting typos, making formatting consistent)