IMPAACT Manual of Procedures
Overview of Section Contents and Identification of Current Section Versions

Section	Current Version	Comments
Section 1 Overview of IMPAACT Network	3.0, 20JAN2021	• Updated version number for consistency with other sections • Updated scientific agenda and Network organization as per the new NIH grant award
Section 2 Network Groups	3.0, 20JAN2021	• Updated version number for consistency with other sections • Updated scientific agenda and Network organization as per the new NIH grant award • Added review of accrual and site selection plans to MOG responsibilities • Updated section on Scientific Service Cores • Added section on Electronic Case Report Forms Committee • Added responsibilities for LOC, SDMC and LC • Added Publications Review Group description
Section 3 Good Documentation Practices	3.0, 20JAN2021	• First implementation version • Updated version number for consistency with other sections
Section 4 IMPAACT Protocol Teams	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added responsibilities for Protocol Chair(s) to ensure compliance with ICH/GCP and IMPAACT policies; coordinate team member activities to meet targets and timelines; collaborate with team members to develop study materials; and work to develop training plan and materials • Added responsibilities of Westat lab representative to review study activation requirements as applicable
Section 5 Community Partnership	3.0, 20JAN2021	• Updated version number for consistency with other sections • Updated ICAB membership criteria • Clarified ICAB participation requirements • Updated ILG membership specifications, including regional and site representation • Updated ILG member term limits and added guidance for vice chair moving into position of ICAB chair
Section 6 Network Meetings and Communications	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added information on coordination of in-person meetings and conference calls • Added section on Newsletter and Social Media
Section 7 General Policies and Procedures	3.0, 20JAN2021	• First implementation version • Updated version number for consistency with other sections

Section	Current Version	Comments
Section 8 Human Subjects Considerations	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added requirements for a single IRB for US sites • Added reference to DAIDS SCORE Manual • Added key considerations for informed consent SOPs • Added summary of considerations for obtaining informed consent from illiterate consenters • Clarified restriction on sites submitting participant identifying information to the SDMC • Added guidance for referrals for HIV care and treatment
Section 9 Protocol Development and Modifications	3.0, 20JAN2021	• Updated version number for consistency with other sections • Removed reference to capsules, and updated section on concept development and review • Updated SLG voting requirements for approving concepts for protocol development • Clarified role of Protocol Chairs and NIH representatives to monitor for adherence to the protocol template as well as NIH and IMPAACT policies • Clarified team review and sign-off of the protocol • Added review of the draft protocol by the ICAB • Added considerations for protocol modifications based on changes to study procedures and entry of study data • Clarified that the process for LoA and Amendment review is identical to the process for protocols in development
Section 10 Site Selection for IMPAACT Studies	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added review of site resources to enroll target populations and perform procedures as part of initial site selection • Included site selection review factor of preference to expand or limit site locations driven by scientific gaps

Section	Current Version	Comments
Section 11 Study Specific Pre-Implementation Activities	3.0, 20JAN2021	• Updated version number for consistency with other sections • Clarified process for ClinicalTrials.gov registration • Clarified process for development of the laboratory processing chart (LPC), roles and responsibilities • Added guidance on translation of data collection instruments • Added section on collection of gender identity • Clarified that majority of lab considerations is included in the LPC, rather than the study specific MOP • Added role of authorship in study-specific MOP responsibilities • Clarified process for review and finalization of the statistical analysis plan • Clarified role of team members review and sign off of activation checklists items • Added role of sIRB oversight for US sites • Added DAIDS guidance on DOD Logs and reference to DAIDS SCORE Manual • Clarified that financial disclosures must be completed before signing the Form FDA 1572 • Added information on the laboratory activation checklists
Section 12 Study Implementation	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added review of updated accrual projections throughout the course of the study • Clarified that a study is considered to have met the DAIDS status of "enrolling" on the date that the first participant is enrolled • Added section on closing to accrual • Added reference to the DAIDS SCORE Manual • Clarified representatives on the Clinical Management Committee (CMC) and procedures for submitting and archiving queries to the CMC • Added guidance for submitting site level-protocol deviations or deviations that involve more than one participant

Section	Current Version	Comments
Section 13 Study Oversight	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added LC representative to SMC membership • Added process for assigning alternate members to the SMC, including SMC chair and representatives from the Operations Center, LC and SDAC • Clarified process for SMC review including roles and responsibilities; added Protocol Chair to summary listing of roles and responsibilities • Added instructions for sufficient time to be allowed for team members to review data reports prior to the SMC meeting • Clarified timing and materials development for initial SMC reviews • Clarified timing and reasons for interim analysis reviews • Added timing and GDP expectations for distribution of SMC reviews
Section 14 Study Close-out	3.0, 20JAN2021	• First implementation version • Updated version number for consistency with other sections
Section 15 Ancillary Studies and Investigations	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added reference to letters of support • Clarified roles and responsibilities for ancillary studies • Reordered section for flow and ease of review • Added section on procedures for access to study data during trial conduct and after trial completion
Section 16 Training	3.0, 20JAN2021	• Updated version number for consistency with other sections • Added reference to DAIDS SCORE Manual • Added information on data management center training requirements • Added reference to LDMS training resources • Clarified procedures for various training methods, including self-study
Section 17 Laboratory Considerations	3.0, 20JAN2021	• Updated version number for consistency with other sections • Clarified role of the laboratory center and Westat for DAIDS and NICHD-funded sites • Added reference to the laboratory activation checklists • Clarified procedures for data corrections • Added requirements for data transfer agreements for sending external data to the DMC • Clarified procedures and roles for shipments to testing laboratories • Clarified procedures, and added roles, for specimen destruction processes

Section	Current Version	Comments
Section 18 Network Evaluation	3.0, 20JAN2021	• Updated version number for consistency with other sections • Clarified role of MOG and NEG reviews • Added SMC and DSMB reviews, and subsequent updates to the MOG, as a component of ongoing evaluation • Added role of protocol teams to review site performance, and their notification of issues or concerns to the MOG • Added NEG membership • Updated clinical data management performance measures and standards
Section 19 Publications Requirements and Procedures	3.0, 20JAN2021	• Updated version number for consistency with other sections • Removed reference to executive summaries • Added description of the publications review group • Added section 19.2 on preparation, review and completion of analyses • Added primary analysis planning to Table 19-2 • Updated approximate timelines for analysis and manuscript preparation • Added information on US government review when NIH staff are co-authors • Updated deadline for abstract submission to the publication coordinator • Clarified that Publications Review Group members are not required to comment on abstracts but forfeit their right to do so after the review period has ended • Specified outcomes for abstract reviews • Clarified that IMPAACT endorsement must be obtained before the abstract may be submitted to a conference • Added that IMPAACT leadership and/or as dictated by recommendations from the DSMB or SMC, may select individuals or groups to be briefed about study results prior to public release • Added Section 19.11.1, Communications Plan • Clarified process for development and dissemination of materials for participant and community audiences • Added Section 19.13, Concluding a Study
Appendix I Unblinding Procedures	3.0, 20JAN2021	• Updated version number for consistency with other sections • Clarified roles and responsibilities for varying levels of unblinding (emergency unblinding, early (non-urgent) unblinding, partial unblinding) • Added requirement to inform “protocol team members” following unblinding after the final clinical database lock