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| 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 | 3.1, 14MAY2021 | • Added reference to DAIDS Good Documentation Policy and Job Aid |
| 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 |
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| Section 7 General Policies and Procedures | 3.1, 14MAY2021 | • Updated website link to HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest Guidelines SOP  
• Added reference to the Collection of Financial Disclosure by Clinical Investigators Conducting DAIDS-Sponsored IND Trials Policy  
• Added requirement for the DAIDS SAR, in consultation with the pharmaceutical company and protocol team, to make the final decision regarding which financial disclosure form will be used  
• Clarified types of studies that require results entry to ClinicalTrials.gov |
| Section 8 Human Subjects Considerations | 3.1, 14MAY2021 | • Updated website link to the DAIDS Enrolling Children in Clinical Research Policy |
| 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 |
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| 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 | 3.1, 14MAY2021 | • Removed reference to study-specific MOP in Table 12-1, as described in detail elsewhere  
• Added reference to DAIDS SCORE Manual for essential documents  
• Removed reference to the DAIDS Critical Events Policy |
| 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 |
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| Section 14                      | 3.1, 14MAY2021  | • Updated website link to the DAIDS Storage and Retention of Clinical Research Records Policy  
• Clarified sign-off requirements for the Study Close-Out memorandum  
• Added website link to Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks  
• Updated website link to List of Protocols having CRF/Pharmacy Records that will not be stored by DAIDS. |
| Section 15 Ancillary Studies     | 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 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 |
## IMPAACT Manual of Procedures

### Overview of Section Contents and Identification of Current Section Versions

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| 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 |