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

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| Section 1                      |                |                                                                                                   | Updated version number for consistency with other sections  
| Overview of IMPAACT Network    | 3.0, 20JAN2021 | Updated scientific agenda and Network organization as per the new NIH grant award                                                                                                                       |
| Section 2                      |                |                                                                                                   | Updated version number for consistency with other sections  
| Network Groups                 | 3.0, 20JAN2021 | 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                      |                |                                                                                                   | First implementation version  
| Good Documentation Practices   | 3.0, 20JAN2021 | Updated version number for consistency with other sections                                                                                                                                    |
| Section 4                      |                |                                                                                                   | Updated version number for consistency with other sections  
| IMPAACT Protocol Teams         | 3.0, 20JAN2021 | 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                      |                |                                                                                                   | Updated version number for consistency with other sections  
| Community Partnership          | 3.0, 20JAN2021 | 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                      |                |                                                                                                   | Updated version number for consistency with other sections  
| Network Meetings and Communications | 3.0, 20JAN2021 | Added information on coordination of in-person meetings and conference calls  
|                               |                | Added section on Newsletter and Social Media                                                                                                                                                 |
| Section 7                      |                |                                                                                                   | First implementation version  
<p>| General Policies and Procedures | 3.0, 20JAN2021 | Updated version number for consistency with other sections                                                                                                                                  |</p>
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| 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 |
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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 | 3.0, 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 |
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| 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 |
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| 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 |