

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

<b>Section</b>	<b>Current Version</b>	<b>Comments</b>
Section 1 Overview of IMPAACT Network	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• First implementation version</li> </ul>
Section 2 IMPAACT Leadership	2.0 12 April 2019	<ul style="list-style-type: none"> <li>• First implementation version</li> </ul>
Section 3 IMPAACT Operational Components	Not Yet Available	
Section 4 IMPAACT Protocol Teams	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• First implementation version</li> </ul>
Section 5 Community Partnership	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Corrected section references in Section 5.2.2.1</li> </ul>
Section 6 Network Meetings and Communications	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated DAIDS RSC website link in Section 6.2.2</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>
Section 7 General Policies and Procedures	Not Yet Available	
Section 8 Human Subjects Considerations	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• First implementation version</li> </ul>
Section 9 Protocol Development and Modifications	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Clarified text in Figure 9-1</li> <li>• Clarified text throughout Sections 9.3 and 9.4 related to the protocol development process for consistency with DAIDS policies and procedures</li> <li>• Expanded description of co-endorsement and co-development of protocols in Section 9.5</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>

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Section 10 Site Selection for IMPAACT Studies	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Clarified directions for modified site selection process in Section 10.1</li> <li>• Removed potential limitations to site application distribution to NICHD-funded sites in Section 10.1.2</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>
Section 11 Study Specific Pre- Implementation Activities	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated study open to accrual requirements to include subsections related to ClinicalTrials.gov considerations and statistical analysis plan, and revised and expanded subsections related to the US FDA review, LPC, participant enrollment materials, data collection materials, MOP, study monitoring plan, and study budget</li> <li>• Updated site-specific study activation requirements to include subsections related to the delegation of duties log, financial disclosures, clinical trials insurance, data management requirements, SOPs, and SOPs for regulatory inspection readiness, and revised and expanded all additional subsections</li> <li>• Updated DAIDS RSC website links throughout</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>
Section 12 Study Implementation	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated Section 12.3.2 to expand description of the study-specific Clinical Management Committee</li> <li>• Added Section 12.5 to provide references to DAIDS critical events reporting</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>
Section 13 Study Oversight	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated DAIDS RSC website links throughout</li> <li>• Clarified timelines associated with development and distribution of reports to the SMC in Sections 13.3 and subsections of Section 13.5 (and as relevant in Table 13-1)</li> <li>• Throughout the section, “study monitoring plan” replaced with “Study Progress, Data, and Safety Monitoring Plan (SPDSMP)”</li> <li>• Minor clarifications and revisions throughout following routine review</li> </ul>

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Section 14 Study Close-out	Not Yet Available	
Section 15 Ancillary Studies and Investigations	21 Aug 2018	<ul style="list-style-type: none"> <li>• Clarified responsibilities of network leadership for data requests to align with current practice in Section 15.2.1</li> <li>• Minor clarifications and formatting changes throughout</li> </ul>
Section 16 Training	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• First implementation version</li> </ul>
Section 17 Laboratory Considerations	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated links</li> <li>• Minor clarifications and formatting changes throughout</li> </ul>
Section 18 Network Evaluation	2.0 20 Nov 2018	<ul style="list-style-type: none"> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Updated entire section to align with current procedures and evaluation criteria</li> <li>• Minor clarifications and formatting changes throughout</li> </ul>
Section 19 Publications Requirements and Procedures	31 Jul 2018	<ul style="list-style-type: none"> <li>• Throughout the section, “endpoints” replaced with “outcome measures”</li> <li>• Added reference to updated requirements for primary and secondary outcomes entry into ClinicalTrials.gov in Sections 19.2.1 and 19.2.2</li> <li>• Updated process to compile appendix of contributors and appropriate acknowledgements in Sections 19.4, 19.6.3, and 19.7.1 (and as relevant in Tables 19-2 and 19-3)</li> <li>• Updated guidelines for authorship consistent with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals in Section 19.6.1</li> <li>• Updated grant acknowledgement and disclaimer on behalf of NIH in Section 19.7.1</li> <li>• Other minor corrections and edits incorporated throughout</li> </ul>
Appendix I Unblinding Procedures	10 Dec 2018	<ul style="list-style-type: none"> <li>• Changes related to access to and procedures for the Emergency Unblinding Utility on the DMC Portal were updated in the rows Table I-1 related to DMC User Support and Site IoR or designee; as well as in Section I.5.1</li> <li>• Added version number and updated footer for consistency with other sections</li> <li>• Minor clarifications and formatting changes throughout</li> </ul>