

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

| Section | Current Version | Comments |
|--|------------------------|--|
| Section 1 Overview of IMPAACT Network | Not Yet Available | |
| Section 2 IMPAACT Leadership | Not Yet Available | |
| Section 3 IMPAACT Operational Components | Not Yet Available | |
| Section 4 IMPAACT Protocol Teams | Not Yet Available | |
| Section 5 Community Partnership | 3 October 2017 | <ul style="list-style-type: none"> • Added details related to regional and site representation on the ILG to Section 5.3.2 |
| Section 6 Network Meetings and Communications | 7 April 2017 | |
| Section 7 General Policies and Procedures | Not Yet Available | |
| Section 8 Human Subjects Considerations | Not Yet Available | |
| Section 9 Protocol Development and Modifications | 17 March 2017 | <ul style="list-style-type: none"> • Updated links throughout • Clarified procedures in Section 9.1.3 related to SLG review of capsules • Updated expected timelines in Table 9-1 and Sections 9.3.3 and 9.3.5.3 • Clarified implementation requirements for CM and LoA if updates to implementation materials are needed in Sections 9.4.1 and 9.4.2 • Other minor clarifications and revisions throughout |
| Section 10 Site Selection for IMPAACT Studies | 12 August 2016 | |
| Section 11 Study Specific Pre-Implementation Activities | 31 January 2018 | <ul style="list-style-type: none"> • Added recipients to open to accrual notification in Section 11 • Updated Section 11.1.6 to reflect sign-off requirements for eCRF changes • Updated training language in Section 11.2.3 |
| Section 12 Study Implementation | 10 April 2017 | <ul style="list-style-type: none"> • Updated language related to case report forms in Section 12.2.2 and queries and reports in Sections 12.3.3 and 12.3.4, consistent with new data management systems (i.e., Rave) • Other minor clarifications and revisions throughout |

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| Section 13 Study Oversight | 12 August 2016 | |
| Section 14 Study Close-out | Not Yet Available | |
| Section 15 Ancillary Studies and Investigations | 12 August 2016 | |
| Section 16 Training | Not Yet Available | |
| Section 17 Laboratory Considerations | 4 April 2018 | <ul style="list-style-type: none"> • Updated links throughout • Updated language related to ILC responsibilities in Section 17.1 • Clarified process related to expectations related to audit findings and resolution of outstanding issues prior to study-specific site activation in Section 17.5.1 • Clarified process related to ILC review of HIV testing algorithms as part of study-specific site activation in Section 17.5.3 • Updated Section 17.5.4 to incorporate language related to the use of the MiPAL system • Updated Section 17.8 to note that IMPAACT Network Pharmacology Specialty laboratories should coordinate with the CPQA on review of their assay validation plans and SOPs and associated EQA • Updated language in Section 17.12 related to validation plans for new methods/instruments |
| Section 18 Network Evaluation | 12 August 2016 | |
| Section 19 Publications Requirements and Procedures | 26 May 2017 | <ul style="list-style-type: none"> • Revised language in Section 19.5 related to journal requests for data availability |
| Appendix I Unblinding Procedures | 3 March 2017 | <ul style="list-style-type: none"> • Updated Section I.6.1 to note treatment information communication methods may be made via email |