

## TABLE OF CONTENTS

<b>1</b>	<b>OVERVIEW OF THE IMPAACT NETWORK .....</b>	<b>1-1</b>
1.1	Background of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network ....	1-1
1.2	IMPAACT Mission and Scientific Agenda.....	1-2
1.3	IMPAACT Network Organization .....	1-4
1.4	IMPAACT Operational Policies.....	1-5
1.5	Governmental Organizations Involved in IMPAACT Research.....	1-6
<b>2</b>	<b>NETWORK GROUPS .....</b>	<b>2-1</b>
2.1	Network Leadership .....	2-1
2.2	Advisory Groups.....	2-5
2.3	Central Resources .....	2-6
2.4	Oversight Groups .....	2-12
2.5	Protocol Teams.....	2-13
2.6	Clinical Research Sites .....	2-13
<b>3</b>	<b>GOOD DOCUMENTATION PRACTICE .....</b>	<b>3-1</b>
3.1	Introduction to Good Documentation Practices within the IMPAACT Network.....	3-1
3.2	General Guidelines for Document Creation, Review, and Management.....	3-2
<b>4</b>	<b>PROTOCOL TEAMS .....</b>	<b>4-1</b>
4.1	Protocol Chair and Vice Chair.....	4-1
4.2	Protocol Team.....	4-3
4.3	Relationship of Protocol Team to IMPAACT Management Oversight Group (MOG) .....	4-9
4.4	Conflict Resolution within Protocol Teams .....	4-9
<b>5</b>	<b>COMMUNITY PARTICIPATION AND ENGAGEMENT IN THE IMPAACT NETWORK.....</b>	<b>5-1</b>
5.1	Confidentiality .....	5-1
5.2	IMPAACT Community Advisory Board (ICAB).....	5-2
5.3	ICAB Leadership Group (ILG).....	5-4
5.4	IMPAACT Site Community Advisory Boards .....	5-8

5.5	Community Input into the Protocol Development Process.....	5-8
5.6	Cross Network Collaborations and Community Partners.....	5-9
<b>6</b>	<b>NETWORK MEETINGS AND COMMUNICATIONS .....</b>	<b>6-1</b>
6.1	Meetings .....	6-1
6.2	Communication Mechanisms and Material Distribution .....	6-2
6.3	Release of Information to the Public.....	6-4
<b>7</b>	<b>IMPAACT GENERAL POLICIES AND PROCEDURES: FUNDING, CONFLICT OF INTEREST, CERTIFICATE OF CONFIDENTIALITY, AND CLINICALTRIALS.GOV.....</b>	<b>7-1</b>
7.1	IMPAACT Funding Procedures.....	7-1
7.2	Conflict of Interest and Financial Disclosure Policies .....	7-3
7.3	NIH Certificate of Confidentiality .....	7-5
7.4	Processes for Registration and Results Entry for IMPAACT Studies in ClinicalTrials.gov.....	7-6
7.5	Letters of Support .....	7-9
<b>8</b>	<b>HUMAN SUBJECTS CONSIDERATIONS.....</b>	<b>8-1</b>
8.1	Applicable US Federal Regulations and Guidelines .....	8-1
8.2	Training Requirements: Good Clinical Practice and Human Subjects Protection .....	8-2
8.3	IRB/EC Review and Approval .....	8-4
8.4	Other Regulatory Entities.....	8-5
8.5	Informed Consent and Assent .....	8-6
8.6	Special Populations .....	8-10
8.7	Confidentiality .....	8-14
8.8	Participant Costs for Study Participation.....	8-14
8.9	Participant Reimbursement for Study Participation .....	8-15
8.10	Access to HIV-Related Care.....	8-15
8.11	Local Reporting Requirements .....	8-15
<b>9</b>	<b>PROTOCOL DEVELOPMENT AND MODIFICATIONS.....</b>	<b>9-1</b>
9.1	Concept Development and Review.....	9-3
9.2	Protocol Development and Review.....	9-6
9.3	Protocol Modifications.....	9-13

9.4	Co-Endorsed and Co-Development of Protocols and Other Networks' Studies .....	9-19
<b>10</b>	<b>SITE SELECTION FOR IMPAACT STUDIES.....</b>	<b>10-1</b>
10.1	Initial Site Selection for New Studies .....	10-1
10.2	Addition of Sites During Accrual of Ongoing Studies.....	10-3
10.3	Expansion Beyond the IMPAACT Network Affiliated Sites .....	10-4
<b>11</b>	<b>STUDY-SPECIFIC PRE-IMPLEMENTATION ACTIVITIES: OPEN TO ACCRUAL AND SITE-SPECIFIC STUDY ACTIVATION.....</b>	<b>11-1</b>
11.1	Study Open to Accrual Requirements.....	11-2
11.2	Site-Specific Study Activation .....	11-10
<b>12</b>	<b>STUDY IMPLEMENTATION .....</b>	<b>12-1</b>
12.1	Participant Accrual.....	12-1
12.2	Follow-Up Visits .....	12-3
12.3	Data Collection .....	12-6
12.4	Study Team Communications.....	12-10
12.5	Protocol Deviations.....	12-17
<b>13</b>	<b>STUDY OVERSIGHT .....</b>	<b>13-1</b>
13.1	On-Site Clinical Quality Management.....	13-1
13.2	Clinical Site Monitoring .....	13-2
13.3	Protocol Team Monitoring.....	13-2
13.4	IMPAACT Leadership Oversight.....	13-3
13.5	IMPAACT Study Monitoring Committee Review .....	13-4
13.6	Sponsor Oversight.....	13-11
13.7	IMPAACT Network Issue Escalation.....	13-11
13.8	Data and Safety Monitoring Board Reviews .....	13-12
<b>14</b>	<b>SITE STUDY-SPECIFIC CLOSE-OUT.....</b>	<b>14-1</b>
14.1	Overview, Key Principles, and Definitions .....	14-1
14.2	Timeline for Study Close-Out.....	14-2

14.3	Study Close-Out Communications and Considerations for Sites.....	14-6
<b>15</b>	<b>ANCILLARY STUDIES, INVESTIGATIONS, AND ACCESS TO STUDY DATA.....</b>	<b>15-1</b>
15.1	Scope and Definitions.....	15-1
15.2	Responsibilities and Procedures for Development and Review of Ancillary Studies .....	15-3
	Development and Submission .....	15-3
15.3	Special Considerations for Proposals Requiring Genetic Analyses.....	15-6
15.4	Specimen and Data Usage Agreements.....	15-7
15.5	Responsibilities and Procedures for Completion of Ancillary Studies.....	15-8
15.6	Publications Resulting from Data Requests.....	15-9
15.7	Procedures for Access to Study Data During Trial Conduct and After Trial Completion.....	15-9
<b>16</b>	<b>TRAINING FOR SITE KEY PERSONNEL AND OTHER SITE AND LABORATORY STAFF.....</b>	<b>16-1</b>
16.1	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training .....	16-3
16.2	Laboratory Related Training .....	16-3
16.3	Data Management Training .....	16-4
16.4	Research Ethics Training for Community Representatives.....	16-5
16.5	Study-Specific Training .....	16-5
16.6	Documenting Training.....	16-10
<b>17</b>	<b>LABORATORY CONSIDERATIONS.....</b>	<b>17-1</b>
17.1	Network Laboratory Center.....	17-1
17.2	IMPAACT Laboratories .....	17-5
17.3	Protocol-Specified Testing.....	17-6
17.4	IMPAACT Laboratory Network Requirements: US Laboratories .....	17-6
17.5	IMPAACT Laboratory Network Requirements: Non-US Laboratories.....	17-7
17.6	Laboratory Data Management System (LDMS).....	17-13
17.7	Data Corrections.....	17-13
17.8	External Quality Assurance (EQA) Participation and Proficiency Testing Providers.....	17-14
17.9	Testing Backup Plans .....	17-14
17.10	Instrument and Method Validation .....	17-15
17.11	Management and Testing Plans .....	17-16
17.12	Shipping Capabilities .....	17-17

17.13	Specimen Shipping.....	17-17
17.14	Specimen Archive and Destruction.....	17-18
17.15	National Approval Requirements and Material Transfer Agreements.....	17-19
17.16	IMPAACT Quality Assessment Monitoring .....	17-20
17.17	Introduction of Novel/Non-Standard Analytes into IMPAACT Studies .....	17-20
17.18	Changes in Laboratory Personnel .....	17-23
17.19	Laboratory Relocation.....	17-23
17.20	Additional Resources.....	17-24
<b>18</b>	<b>NETWORK EVALUATION .....</b>	<b>18-1</b>
18.1	Network Evaluation Plan and Performance Measures.....	18-2
18.2	Performance Criteria for IMPAACT-affiliated NIAID-funded Clinical Research Sites.....	18-3
18.3	Overall Network Productivity.....	18-7
18.4	Outcomes and Actions.....	18-7
<b>19</b>	<b>DATA ANALYSIS AND PUBLICATIONS PROCEDURES.....</b>	<b>19-1</b>
19.1	Overview, Key Principles, and Definitions .....	19-1
19.2	Key Responsibilities.....	19-5
19.3	Preparation, Review, and Completion of Analyses.....	19-6
19.4	Development and Review of Publications .....	19-11
19.5	Tracking of Manuscript Preparation .....	19-19
19.6	IMPAACT Publication Review Process.....	19-19
19.7	Journal Submission .....	19-21
19.8	Conference Submission.....	19-21
19.9	Authorship.....	19-22
19.10	Acknowledgements.....	19-24
19.11	Public Access Policy .....	19-24
19.12	Communications Plans and Dissemination of Study Results.....	19-25
19.13	Publication Costs .....	19-27
19.14	Concluding a Study.....	19-27

<b>APPENDIX I</b>	<b>UNBLINDING PROCEDURES.....</b>	<b>1</b>
I.1	Purpose .....	1
I.2	Scope.....	1
I.3	Definitions.....	1
I.4	Roles and Responsibilities.....	2
I.5	Reasons and Guidelines for Unblinding.....	5
I.6	Procedures .....	9
I.7	References .....	10
I.8	Questions.....	10