Ethiopian Public Health Institute

Institutional Review Board (EPHI-IRB)

STANDARD OPERATIONAL PROCEDURES

SECOND VERSION

SEPTEMBER 1, 2019

List of EPHI-IRB SOPs

Number	List of SOPs	Code
1.1	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for IRB	EPHI-IRB-001
1.2	Preparation of Guidelines	EPHI-IRB-002
2.1	Constituting Institutional Review Board	EPHI-IRB-003
2.2	Confidentiality / Conflict of Interest Agreements	EPHI-IRB-004
2.3	Training Personnel and IRB Members	EPHI-IRB-005
2.4	Selection of Independent Consultants	EPHI-IRB-006
3.1	Management of Protocol Submission	EPHI-IRB-007
3.2	Use of Study Assessment Form	EPHI-IRB-008
3.3	Exemption of protocol review	EPHI-IRB-009
3.4	Expedited Review	EPHI-IRB-010
3.5	Initial Review of Submitted Protocol	EPHI-IRB-011
3.6	Review of New Medical Device Study/Evaluation	EPHI-IRB-012
4.1	Review of Resubmitted Protocol	EPHI-IRB-013
4.2	Review of Protocol Amendments	EPHI-IRB-014
4.3	Management of Protocol Continuing Reviews	EPHI-IRB-015
4.4	Review of Final Reports	EPHI-IRB-016
5.1	Intervention in Protocol Deviation/Non-compliance/Violation	EPHI-IRB-017
5.2	Response to Research Participants' Requests	EPHI-IRB-018
5.3	Management of Study Termination	EPHI-IRB-019
6.1	Review of Serious Adverse Event (SAE) Reports	EPHI-IRB-020
7.1	Site Monitoring Visits	EPHI-IRB-021

8.1	Agenda Preparation, Meeting and Minutes Taking Procedures	EPHI-IRB-022
8.2	Emergency Meeting	EPHI-IRB-023
8.3	Communication Records	EPHI-IRB-024
9.1	Maintenance of Active Study Files	EPHI-IRB-025
9.2	Archive and Retrieval of Documents	EPHI-IRB-026
9.3	Maintaining Confidentiality of IRB's Documents	EPHI-IRB-027
10.1	Auditing and Inspection of the IRB	EPHI-IRB-028
11.1	Glossary of Terms and Definitions	EPHI-IRB-029