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1. Purpose

The purpose of this SOP is to provide instructions for review and approval of medical device studies submitted to the IRB.

2. Scope

This SOP applies to the submission and the review processes of protocols involving the study of new medical devices (Not registered by responsible regulatory authority in Ethiopia) in human study participants.

3. Responsibility

During the review of medical device studies, the IRB may make some different decision than those made during the review of drug studies. The IRB must determine if the proposed investigation has *Significant Risk (SR)* or *Non-significant Risk (NSR)*, and then the IRB should decide if the investigation is approved or not. In determining *SR* or *NSR*, the IRB must review all information submitted by the sponsor.

4. Flow chart

No.	Activity	Responsibility
1	Submission of documents	Investigator/IRB Secretariat
	↓	
2	Activities before a Board meeting	IRB Secretariat / members / Reviewers
	↓	
3	Activities during a Board meeting	IRB members / Secretariat / Chairperson
	↓	
4	Activities after the meeting	IRB Secretariat
	↓	
5	Notify the investigators	IRB Secretariat
	↓	
6	Storage of the documents	IRB Secretariat

5. Detailed instructions

5.1. Submission of documents

- Receive a new medical device study protocol
- Check the submitted package for completeness
- Receive Memorandum of Understanding (MoU) among collaborating parties for projects to be executed by two or more institutions
- Receive Material Transfer Agreement (MTA) between provider and recipient institutions for any biological material to be exported outside Ethiopia
- Document the checking procedure by completing a checklist form (EPHI-IRB AF 01-007/02.0, Contents of a submitted package).
- At a minimum, the IRB must receive the following documents prior to review/approval of a medical device study:
  - Proposed investigational plan
  - Informed consent form
  - Description of the device
  - Description of participant selection criteria
  - Monitoring procedures
  - Reports of prior investigations conducted with the device
  - Investigator's Curriculum Vitae
  - Investigator's professional license (s)
  - Risk assessment data / information
  - Statistics used in making the risk determination.
  - Application for Review (EPHI-IRB AF 01-011/02.0)
  - Document Received Form (EPHI-IRB AF 05-007/02.0)
  - Copies of all labeling for investigational use only
- The sponsor should inform the IRB whether other IRBs have reviewed the proposed study and what determination was made.
- The sponsor should inform the IRB of the Agency's assessment of the device's risk if such an assessment has been made.
- If the Sponsor believes the study is *NSR*, supporting information must be submitted.
- Contact the applicant to submit additional information or documents, if the application is complete.

5.2. Before the Board Meeting

- Assign reviewers to review the study, according to the assessment form
- Prepare the documents for distribution to each IRB member
- Send the documents to each IRB member

- Place the new medical device study on the meeting agenda

5.3. During the Board Meeting

- Reviewers present a brief oral or written summary of the protocol, ICF and relevant issues
- The chairperson opens discussion about whether the study is Significant Risk (*SR*) or Non-Significant Risk Device (*NSR*) (see examples in Annex 1 and 2: EPHI-IRB AF 01-012/02.0; EPHI-IRB AF 02-012/02.0)
- The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigator's and site qualifications, advertisements).
- Decide the degree of risk.
- Consider whether or not the study should be approved.
- The Chairperson calls for a separate vote on each element in review. The IRB votes to either:
  - Approve the study to start as presented with no modifications
  - Approve the study to start with minor modifications to item(s) noted at the convened meeting and to be followed-up by the Secretariat and Chairperson, after receiving the requested modifications
  - Require major modifications and/or request further information to be resubmitted and subjected to review in the next full Board meeting.
  - Disapprove the study and state the reason.
- Record the vote of risk assessment in the decision form (EPHI-IRB AF 03-008/02.0) and the meeting minutes (EPHI-IRB AF 02-022/02.0).
- Note the recommendations for changes to the protocol and/or informed consent recommended by IRB members in the minutes as 'with modifications made by Ethiopian Public Health Institute' and will be communicated to the investigator.
- Determine the frequency of Continuing Review for the approved study.

5.4. After the Meeting

5.4.1 Prepare Meeting Minutes

- Follow the procedure in EPHI-IRB SOP/022/02.0

5.4.2 Notify the Investigators

- The Secretariat sends an action letter along with the approved documents to the investigator. The letter contains, at a minimum, a listing of each document approved, the date set by the IRB for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- If the Board votes not to approve the study, the Chairperson or Secretariat immediately notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting EPHI-IRB. This process is stated in the action letter provided to the investigator.
- If the IRB votes to require modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the EPHI-IRB.

5.4.3 Storage of the Documents

- Prepare an appropriate label.
- Store the document packages in the shelf for active files.

6. Glossary

Investigational Medical Device	Any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized and do not cause more than minimum risk/s. Medical devices may include but not limited to items such as diagnostic test kits, electrodes, prescribed beds, Blood pressure apparatus, stethoscope, A medical device which is the object of clinical research to determine its safety or effectiveness.
Non-significant Risk Device (NSR)	An investigational device that does not pose more than minimum risk/s significant risk. A list of examples is found in Annex 1 (EPHI-IRB AF 01-012/02.0)
Risk	The probability of harm or discomfort to study participants.

	Acceptable risk differs depending on the conditions for which the product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.
Significant Risk Device (SR)	An investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the participant, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participant. A list of examples is found in Annex 2 (EPHI-IRB AF 02-012/02.0)

7. References

1. CFR – Code of Federal Regulation Title 21, Part 812, Food and Drug Administration, USA, 2018. https:/accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1, accessed July 28, 2019
2. Associated SOP: EPHI-IRB SOP/007-010/02.0; EPHI-IRB SOP/022/02.0

8. Annex

Annex 1: Non-Significant Risk Device Studies
(EPHI-IRB AF 01-012/02.0)

EXAMPLES:

- Point of care laboratory technologies and conventional methods
  - HIV early infant diagnosis
  - HIV viral load testing
  - TB diagnosis except radiation emitting equipments
  - Rapid diagnostic tests
  - Other disease specific diagnostic tests.

Annex 2: Significant Risk Device Studies
(EPHI-IRB AF 02-012/02.0)

EXAMPLES:

General Medical Use

Catheters:

- Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra-aortic balloon with control system
- Gastroenterology and Urology – biliary and urologic
- General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
- Neurology – cerebrovascular, occlusion balloon
- Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
- Lasers for use in Ob/Gyn, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
- Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

Anesthesiology

- Respiratory Ventilators
- Electro-anesthesia Apparatus
- Gas Machines for Anesthesia or Analgesia
- High Frequency Jet Ventilators greater than 150 BPM

Cardiovascular

- Arterial Embolization Device
- Artificial Heart, permanent implant and short-term use
- Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
- Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, antitachycardia, esophageal
- Cardiovascular/Intravascular Filters
- Coronary Artery Retroperfusion System

- DC-Defibrillators
- Implantable Cardioverters
- Laser Coronary Angioplasty Device
- Pacemaker Programmer
- Percutaneous Conduction Tissue Ablation Electrode
- Replacement Heart Valve
- Vascular and Arterial Graft Prostheses

DENTAL

- Endosseous Implant

Ear, Nose and Throat

- Cochlear Implant
- Total Ossicular Prosthesis Replacement
- Gastroenterology and Urology
- Anastomosis Device
- Endoscope and/or Accessories
- Extracorporeal Hyperthermia System
- Extrocorporeal Photophersis System
- Extracorporeal Shock-Wave Lithotriptor
- Kidney Perfusion System
- Mechanical/Hydraulic Impotence and Incontinence Devices
- Implantable Penile Prosthesis
- Peritoneal Shunt

General and Plastic Surgery

- Absorbable Hemostatic Agents
- Artificial Skin
- Injectable Silicone
- Implantable Prostheses: chin, nose, cheek, ear
- Sutures

General Hospital

- Infusion Pumps: Implantable and closed-loop, depending on infused drug

- Implantable Vascular Access Devices

Neurology

- Hydrocephalus Shunts
- Implanted Intracerebral/Subcortical Stimulator
- Implanted Intracranial Pressure Monitor
- Implanted Spinal Cord and Nerve Stimulators and Electrodes

Obstetrics and Gynecology

- Cervical Dilator
- Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
- Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

Ophthalmics

- Extended Wear Contacts Lens
- Intraocular Lens (investigations subject to 21 CFR 813)
- Eye Valve Implant
- Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluoropropane

Orthopedics

- Implantable Prostheses: ligament, tendon, hip, knee, finger
- Bone Growth Stimulator
- Calcium Tri-Phosphate/Hydroxyapatite Ceramics
- Xenografts

Radiology

- Hyperthermia Systems and Applicators