PCMC IR-EC SOP 14.0: Management of Protocols on Medical Device

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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14.0 MANAGEMENT OF PROTOCOLS ON MEDICAL DEVICE

14.1 Policy Statement

The IR-EC shall accept protocols involving medical devise only if it has an FDA certification regarding its level of safety (Non-Significant Risk, or Significant Risk) and submission of the required complete protocol package.

14.2 Purpose of the Activity

To ensure protection of human participants and appropriate use of the technology.

14.3 Scope

This SOP includes the procedures for the management of protocols on medical device that begins from the receipt of the initial protocol package and verification of documents and ends with preparation of protocol folder.

14.4 Process Flow/Steps for Management of Protocols on Medical Device

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt of Initial Protocol Package and Verification of Documents	IR-EC Secretariat
2	Determining IR-EC Action/Type of Review	Chair/Secretary
3	Assignment of Primary Reviewers	Chair/Secretary
4	Conduct Review using Assessment Forms	Chair/IR-EC Members
5	Notify the PI of Decision	IR-EC Secretariat
6	Preparation of Protocol Folder	IR-EC Secretariat

14.5 Detailed Instructions

14.5.1 Receipt of the Initial Protocol Package and Verification of Documents

14.5.1.1 The same procedures shall be followed when the protocol is submitted for initial review.

14.5.1.2 When reviewing a medical device protocol, the Primary Reviewer shall consider the following:

a. Proposed investigational plan
b. Informed consent form
c. Description of the device/Product information
d. Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk)

e. Description of study participant selection criteria
f. Safety monitoring procedures
g. Reports of prior investigations conducted with the device
h. Principal investigator's curriculum vitae
i. Statistical plan and analysis
j. Copies of all labeling for investigational use

14.5.1.3 The sponsor shall inform the IR-EC whether other RECs have reviewed the proposed study and what decision was made.

14.5.2 Determining IR-EC Action/Type of Review

14.5.2.1 The Chair/Secretary shall verify risk classification of the medical device whether Significant Risk (SR) or Non-Significant Risk (NSR) as stated in the submitted documents. The Chair shall ensure that the classification (SR or NSR) are consistent with US and local FDA regulations, the ASEAN Agreement on Medical Device Directive and DOH AO No.2018-0002.

14.5.2.2 The Chair shall determine type of review depending on the risk classification. NSR devices shall undergo Expedited Review and SR devices shall undergo Full Review.

14.5.3 Assignment of Primary Reviewers

14.5.3.1 The Chair/Secretary shall assign Primary Reviewers with appropriate expertise to review the protocol related documents. For high-risk medical devices (SR), a bioengineer with appropriate experience related to the medical device or a medical doctor with related clinical experience are among those who shall be assigned.

14.5.4 Conduct Review using Assessment Forms

14.5.4.1 High risk medical devices (SR) shall require full review (SOP 10) whereas medical devices classified as NSR shall undergo expedited review.

14.5.4.2 The assigned Medical Reviewer shall review the protocol and the Informed Consent Form and the non-medical/non-scientific member shall review the Informed Consent Form using the Assessment Forms (Forms 10.1 and 10.2).

14.5.4.3 The discussion and decision on the protocol and related documents shall be written in the minutes.

14.5.5 Notify the PI of Decision

14.5.5.1 The IR-EC shall notify the decision to the investigators PI as follows:

a. Disapproval: If the board votes not to approve the study, the Secretariat sends Decision Letter (Form No. 27.1) signed by the Chair to the PI. The Decision Letter shall state reason/s for disapproving the study.

b. Major Modification Requiring Re-evaluation: The Secretariat shall prepare the Decision Letter (Form No. 27.1) stating required revisions in the protocol, the ICF or any related document. The Decision Letter shall be signed by the Chair and sent to the PI. The resubmitted documents shall be referred to the designated Primary Reviewers shall be discussed at Full Board Meeting once more before a final decision is granted.
c. Minor Modification/Revisions: The Secretariat shall prepare the Decision Letter (Form No. 27.1) detailing the specific changes required. The Decison Letter shall be signed by the Chair and sent to the PI. The PI shall resubmit the documents with the necessary revisions to the IR-EC for expedited approval.
d. Approval: The Decision Letter and Notice of Research Protocol Approval (Forms 27.1 and 10.3) shall be prepared by the Secretariat to be signed by the Chair and communicated to the PI. The letter contains, at a minimum, a listing of each document approved, the date set by the IR-EC for frequency of continuing review, and a review of other post-approval obligations and expectations from the investigator throughout the course of the study.

14.5.6 Preparation of Protocol Folder

13.5.6.1 The relevant documents shall be kept in the protocol file and the IR-EC database entry shall be updated by the IR-EC Secretariat.

14.6 Forms

Form 10.1 V.2.0 Protocol Assessment Form
Form 10.2 V.2.0 Informed Consent Assessment Form
Form 10.3 V.3.0 Notice of Research Protocol Approval
Form 27.1 V.3.0 Decision Letter of IR-EC

14.7 Glossary

Medical Device - means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the \anatomy or of a physiological process; supporting or sustaining life; control of

conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Additional Reference:
https://www.who.int/medical_devices/full_deffinition/en/

ANNEXES

ANNEX 1: Non - Significant Risk Devise Studies
ANNEX 2: Significant Risk Devise Studies

ANNEX 1

NON-SIGNIFICANT RISK DEVICE STUDIES

EXAMPLES:

- Bio Stimulation Lasers for treatment of pain
- Carries Removal Solution
- Daily Wear Contact Lenses and associated cleaners and solutions
- Dental Filling Materials, Cushions or Pads made from traditional materials and designs
- Denture Repair Kits and Re-aligners
- Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)
- Externally worn Monitor for Insulin Reactions
- Jaundice Monitor for Infants
- Magnetic Resonance Imaging (MRI) Devices within specified physical parameters
- Menstrual pads
- Menstrual Tampons of "old" materials (used prior to May 28, 1976)
- Non-implantable Male Reproductive Aids
- Ob/Gyn Diagnostic Ultrasound (within specified parameters)
- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain
- Wound Dressings, excluding absorbable hemostatic devices and dressings

ANNEX 2

SIGNIFICANT RISK DEVICE STUDIES

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, gastroenterology, urology, pulmonary, ophthalmology and neurology
- Tissue Adhesives for use in neurology, gastroenterology, 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, anti-tachycardia, 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
- Extracorporeal Photopheresis 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