Table of Contents

1. Purpose

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

2. Scope

This SOP applies to the submission and the review processes of protocols involving the study of new medical devices in human subjects.

3. Responsibility

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

The CHH IRB should consider the nature of the harm that may result from the use of the device. If a device being investigated might cause significant harm to any one of the participants, the study will be considered *SR*. In deciding if a device presents significant or non-significant risks, the CHH IRB should consider the device's total risks, not those compared with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the CHH IRB should consider the risks of the procedure in conjunction with the risks of the device. The CHH IRB may also consult with the regulatory agency to form its opinion.

The CHH IRB may agree or disagree with the sponsor's initial *NSR* assessment. If the CHH IRB agrees with the sponsor's initial *NSR* assessment and approves the study, the study may begin without submission of an IDE (Investigational Device Exemption) application to the regulatory agency. If the CHH IRB disagrees, the sponsor must notify the regulatory agency that an *SR* determination has been made. The study can be conducted as an *SR* investigation following regulatory approval of an IDE application.

4. Flow chart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Receipt of submitted documents	Applicant/ CHH IRB Secretariat
II	Assignment of Primary Reviewer	CHH IRB Chair
III	Reporting of Protocol Assessment	CHH IRB Members / Reviewers
IV	Notification to the investigators	CHH IRB Secretariat
V	Storage of the documents	CHH IRB Secretariat

5. Detailed instructions

5.1 Receipt of submitted documents

- Receive a new medical device study.
- Check the submitted package for completeness.
- Document the checking procedure by completing a checklist form (HRP-IRB-008, Contents of a submitted package).
- At a minimum, the CHH IRB must receive the following documents prior to review/approval of a medical device study:
  - Research Protocol
    - Title of the Protocol
    - Principal Investigator
    - Sponsor
    - Abstract
    - Type of Protocol (screening, survey, clinical trial and phase)
    - Objectives
    - Anticipated Outcome
    - Inclusion/Exclusion Criteria
    - Withdrawal or discontinuation Criteria
    - Modes of Treatment Studied
    - Methodology (synopsis of study design)
    - Analysis (methods)
    - Activity plan / Timeline
    - IND Number (if applicable)
    - Schedule and Duration of Treatment
    - Efficacy or Evaluation Criteria (Response/Outcome)
    - Safety Parameters Criteria (Toxicity)
  - Investigator's Brochure
  - Informed consent form
  - Additional Information Sheet
    - 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)
  - GCP training certificate the past 2 years
  - Risk assessment data / information
  - Statistics used in making the risk determination.
  - Case Record Form (CRF)
  - Study budget and budget justification

- Agreement of the study
- Application Form and Questionnaire (HRP-IRB-010)
- Document Received Form (HRP-IRB-011)

5.2 Assignment of Primary Reviewer

- CHH IRB Chairman assigns primary reviewer to review the study, according to the assessment form (refer to SOP/009/05).
- Prepare the documents for distribution to each CHH IRB member.
- Place the new medical device study on the meeting agenda.
- Primary reviewer clarifies the device according to the level of Risk involved (see Glossary).

5.3. Reporting of Protocol assessment

- Primary Reviewers present a brief oral or written summary of the study design related to the level of risk
- The Chairperson opens discussion about whether the study is *SR* or *NSR* (see examples in ANNEX 1).
- The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigator's and site qualifications, advertisements).
- Consider whether or not the study should be approved.
- The Chairperson calls for a separate vote on each element in review. The CHH IRB votes to either:
  - Approve the study to start as presented with no modifications
  - Require further clarifications 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 CHH IRB assessment form for Methodology (refer to ANNEX 3: HRP-IRB-013a ver01) and the meeting minutes (HRP-IRB-028).
- Note the recommendations for changes to the protocol and/or informed consent recommended by CHH IRB members in the minutes and will be communicated to the investigator.
- Determine the frequency of Continuing Review for the approved study.

5.4 Notification to the investigators

- The Secretariat sends an action letter along with the approved documents to the investigator. (Refer to decision Letter format)

- 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 the CHH IRB Chairperson. This process is stated in the action letter provided to the investigator.
- If the Board members 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 CHH IRB.

5.5 Storage of the documents

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

6. Glossary

Medical Device	Any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other conditions (for example, pregnancy).
Investigational Medical Device	A medical device which is the object of clinical research to determine its safety or effectiveness.
Investigational Device Exemption (IDE)	Investigational Device Exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification submission to the regulatory agency. Clinical studies are most often conducted to support a PMA. Only a small percentage of studies require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

	An IDE is approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by the regulatory agency. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements that would apply to devices in commercial distribution. Sponsors need not submit a PMA (Pre-Market Approval) or Pre-market Notification, registers their establishment, or lists the device while the device is under investigation. Sponsors of IDE's are also exempt from the Quality System (QS) Regulation except for the requirements for design control.
New Study	A study protocol including the informed consent, investigator qualifications, and advertisements presented to the CHH IRB for approval for the first time. This includes re-application for those studies denied approval by the Board Members of CHH IRB.
Non-significant Risk Device (NSR)	An investigational device that does not pose a significant risk. A list of examples is found in ANNEX 1.
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.

7. ANNEX

ANNEX 1: Examples of Non-significant Risk Device Studies

NON-SIGNIFICANT RISK DEVICE STUDIES

EXAMPLES:

- Bio-stimulation Lasers for treatment of pain
- Caries 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: Examples of Significant Risk Device Studies

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, 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

ANNEX 3: Assessment Report Form for Medical Device Study (Methodology)

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ASSESSMENT REPORT FORM
I. Methodology

Form HRP-IRB-013a ver01

IRB REFERENCE NO. I R B - - -

PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW

PROTOCOL NO. & TITLE

QUESTIONS		Comments/Remarks
1) Is adequate information given for the background of the study?	Y☐ N☐	
2) Is the study significant and relevant for the population studied?	Y☐ N☐	
3) Is the scientific rationale of the study sound?	Y☐ N☐	
4) Are the objectives clear, specific and measurable?	Y☐ N☐	
5) Is the study design appropriate for the objectives?	A☐ I☐	
• Are the control arms appropriate? (for clinical trials)	A☐ I☐	
6) Is the setting of the study clearly identified?	Y☐ N☐	
• Are the facilities and infrastructure of the participating sites adequate?	Y☐ N☐	
• Is the duration of the study specified?	Y☐ N☐	
7) Is the approximate number of subjects involved in the trial specified?	Y☐ N☐	
• Are the inclusion criteria appropriate?	A☐ I☐	
• Is the proposed subject population appropriate for the nature of the research?	A☐ I☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐ N☐	
• Are the exclusion criteria appropriate?	A☐ I☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐ N☐	
8) Are the procedures to be done in the study clearly described and understandable?	Y☐ N☐	
• Are blood/tissue samples sent abroad?	Y☐ N☐	
9) Are research data recorded and maintained with strict confidentiality?	Y☐ N☐	
10) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	A☐ I☐	

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ASSESSMENT REPORT FORM
I. Methodology

Form HRP-IRB-013a ver01

	QUESTIONS		REMARKS
11)	If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐ N☐	
12)	Is the mechanism for providing information to the IRB in the event that unexpected results are discovered appropriate?	A☐ I☐	
13)	If the research involves the evaluation of a medical device clarify the device accordingly: a) No-significant Risk b) Significant Risk	 Y☐ N☐ Y☐ N☐	
14)	Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐ N☐	
15)	Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐ N☐	
16)	Does the institution have a data and safety monitoring board?	Y☐ N☐	
	a. If so, should it be asked to monitor the project under review?	Y☐ N☐	
	b. If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐ N☐	

8. References

8.1 Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government Printing Office via GPO Access

8.2 Associated SOP: SOP# FE 007-010 and 028