SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study

SingHealth
Defining Tomorrow's Medicine

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Research involving Investigational Medical Device

An Investigational Medical Device (MD) refers a MD being assessed for clinical performance, effectiveness, or safety in a clinical investigation. The use of a MD as part of a study does not necessarily mean that it is a MD Clinical Research. For example, if the study does not involve investigating (collecting safety or efficacy data) of a MD, then the device is not an investigational MD.

Examples when a MD is considered investigational:

- The MD is not registered in Singapore.
- The MD is registered in Singapore but is being clinically evaluated for a different indication.

Please refer to First Schedule of the Health Product Act 2007 for the legislative definition of MD.

All investigational MD studies involving human subjects must be submitted to CIRB for review and approval before the research can begin.

Digital Health Device >>>

Digital health device intended for medical purposes such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process will be classified as a medical device subject to HSA's regulatory controls.

Digital health includes diverse categories of products comprising telehealth and telemedicine, mobile health, wearable devices, health information technologies and personalised medicine. It refers to the usage of connected devices, wearables, software including mobile applications (apps) and artificial intelligence (AI) to address various health needs via information and communications technologies.

MD as Clinical Research Materials (CRM) >>>

CRM refer to any registered or unregistered therapeutic product, medicinal product, medical device, applicable cell, tissue and gene therapy product or placebo, that is manufactured, imported or supplied for the purpose of being used in clinical research, by way of administration to a trial participant in accordance with the research protocol or for a clinical purpose.

Health Sciences Authority (HSA) regulates the import, manufacture, export and supply of medical devices in Singapore under the Health Products Act and its Health Products (Medical Devices) Regulations 2010.

The CRM regulations govern the import and supply of therapeutic or medicinal products and medical devices used in clinical research, including regulated clinical trials. Although the conduct of medical device studies is not regulated by HSA, the manufacture, import and supply of CRMs in Singapore must comply with the respective regulatory controls for CRM. Hence, submission of CRM notification to HSA may be required for research involving medical devices. Please check with your institution research office on submission of CRM notification to HSA.

IRB Submission >>>

For research involving an investigational MD, besides the usual information for clinical research, information about the MD must be provided in the [A] ECOS Application Form [B] the Informed Consent Document and other supporting documents as applicable or upon request.

[A] ECOS Application Form

- **Section D3:** Select "Medical Device".
- **Section G7:** Describe Research Methodology.
- **Section G19:** Attach Protocol
- **Section I1. (b) [Device Registration/ Approval]:** For MD registered with HSA, please state the classification (e.g. Class C). For MD approved by FDA, please state the classification. In addition, please state if the research is to study the intended purpose of the registered/ approved MD.
- **Section I1.(c) – CRM Notification:** If CRM Notification has been submitted, please indicate and attach the CRM Notification at 'Other Attachments Section'.
- **Section I1.(d) – Investigational Device Exemption (IDE):** Check the appropriate box.
- **Section I1.(f) – Electrical Connection**: For investigational MD that requires electrical connection (e.g. plug-in to wall outlet) for use within SingHealth Institutions, the device should be commissioned by respective Biomedical Engineering (BME) department. Please indicate if the device had been commissioned or the study team will be doing so.
- **Section I1.(f) – Device (Data Confidentiality):** If the MD is collecting data, please describe the security measures and procedures for maintaining data confidentiality, and record retention period.
- **Section I1.(f) / I1.(j) – Device Information:** Describe the MD at I1.(f) and attach supporting documents atI1.(j) E.g. Device Brochure, Product Information sheet/ leaflet, Trade (Brand) Name, Manufacturer, Directions/ Instructions for use, Insert, Labelling, if appropriate and/ or available.
- **Section I1.(f) / I1.(j) – Device Information (for Prototype):** Please submit a detailed description of the MD:
    - Photographs/diagrams of the MD.
    - Device construction materials, if implanted.
    - How the device achieves its goals?
    - Safety/ effectiveness data to date in human trials, if available.
    - Safety/ effectiveness data in preclinical studies, if applicable.
    - Objective data that the device functions as intended, if applicable.
    - Instructions for the proper use of the device.
    - Summary of adverse device effects and potential risks (including adverse effects due to misuse of the device).
    - How device operators will be trained in proper administration/ use of the device.
- **Section J9 – Witness during Informed Consent Process:** Informed consent must be obtained in a presence of a witness, unless the presence of a witness is exempted.
- **Section X – Monitoring:** Describe Data and Safety Monitoring Plan.
- **Other Attachments Section:** Attach other materials for research participants (E.g. Instruction Sheets), if appropriate and/ or available.

IRB Submission >>>

[B] Informed Consent Document (ICD)

The ICD for the study can be drafted using the SingHealth Informed Consent Document Template, which contains the necessary consent elements for research. The ICD provided by the Sponsor may also be used. Please ensure that all consent elements of HBRA Section 12(1) and Section 12(2) (where applicable for the removal, donation or use of human tissue) are included in the ICD. Information specific to the MD clinical research must be included in the following sections of the ICD:

- **Study procedures & your responsibilities in this study:**
  - Include a statement that the device is investigational and has not been registered with H.S.A or, if applicable, that the device has been registered for specific clinical indications but not for the use being studied.
  - Include a brief lay description of the device and what it is designed to do.
- **What is not standard care or is experimental in this study:**
  - Describe what is experimental including the device is investigational or, if applicable, not used for approved clinical indication.
- **Alternative Procedures/ Treatments if You do not participate in the study:**
  - Inform participants of any alternatives to participating in the study, including any standard treatment available with registered devices.
- **Costs & Payments if Participating in this study:**
  - Provide information about how the costs of the study device will be covered.
- **Withdrawal from Study:**
  - Include a statement if the study device is to be returned upon study completion/ withdrawal.

Conduct of Medical Device Studies >>>

- The conduct of a MD study falls under the scope of Human Biomedical Research Act (HBRA).
- The MD study may be conducted according to ISO 14155:2020, Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice as a guide.
- As required under HBRA, informed consent must be obtained in a presence of witness and the witness is required to sign and date on the informed consent form, unless the presence of a witness is exempted.
- It is critical for all local manufacturers, importers and suppliers of CRM (including local sponsors and investigators) to maintain the integrity of the CRM supply chain through proper record keeping, labelling and disposal.

Helpful Links and Tools >>>

1) HSA Website on Medical Devices
2) HSA Self-check Decision Tool to check if your device is a medical device
3) HSA Website on Digital Health Device
4) Artificial Intelligence in Healthcare Guidelines (AIHGIe) and recommendations from MOH, IHIS and HSA
5) HSA Medical Device Risk Classification Tool
6) HSA Medical Device Registration Guides
7) HSA Website on Clinical trials of Medical Devices
8) HSA Website on Adverse Events Reporting of Medical Devices

Takeaway message...

While the conduct of the research involving use of Investigational Medical Devices may not be regulated under HSA, the import, manufacture, export and supply of medical devices in Singapore would still be regulated under the Health Products Act and its Health Products (Medical Devices) Regulations 2010 by HSA.

If you have any questions, please contact CIRB at irb@singhealth.com.sg