Expectations for Electrically-Powered Devices used in Research Studies Occurring in Clinical Environment

This guidance document applies to research studies occurring in the **clinical environment**. The clinical environment is defined as areas where care (i.e. diagnosis, treatment) is provided to FHA patients.

For research occurring in a non-clinical environment (e.g. ICORD research lab), please reference the expectations for devices used in a non-clinical environment guidance document.

Please contact BMEclerical@vch.ca or 604 831 4182 for any questions or clarification.

All **medical devices used in research studies** must:

- Have a Health Canada License
- Have an investigational testing authorization (ITA) from Health Canada if unlicensed[1]. For more information on the ITA, visit Health Canada

All **electrically-powered devices** must have:

- Technical Safety BC approved certification labels on all electrical components (e.g. AC to DC power supply). For a list of current Technical Safety BC approved certification labels, visit https://www.technicalsafetybc.ca/alerts/approved-certification-marks-electrical-products. Any label on the list is satisfactory.
- Enclosed wires with intact insulation.
- Hospital grade power cord. This is indicated by a green dot on the terminus of the plug.
- Leakage currents (current escaping its intended path – occurs in all electrical devices to varying degree – important consideration for medical devices) below CSA defined thresholds.
    - Devices which draw high currents tend to have higher leakage currents (e.g. motors, amplifiers).
    - To minimize leakage currents, consider using Technical Safety BC approved isolation transformer, or double-insulate device.

All **wireless-capable devices** must have:

- Broadcast powers lower than 100 mW. Powers greater than 100 mW will be assessed on an individual basis and may be denied.

To expedite the approval process:

- Always try to have CSA approved components.
- Provide any and all device specifications.
- Label components of device indicating what their function is (e.g. switches, circuit boards, etc).

Questions you will be asked:

- **Please provide:**
    - Study protocol
    - Research ethics board application
    - Documentation available for device:
        - Manufacturer, model and serial number of device
        - Device labelling and Instructions for Use
        - Operators manual
        - Service manual
    - Photos of any labelling/markings on device and power supply

[1] A medical device does not require an ITA if there is no sale of the medical device, based on the definition of sale under the Food and Drugs Act. "Sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration. A “sale” includes the transfer of a device between two corporate entities

- **Is the device in question considered a medical device (does the device provide therapy, diagnosis or monitoring)? (Y/N)**
    - If this is a medical device, please identify whether it is:
        - Health Canada Licensed
        - Unlicensed and has a Health Canada Investigational Testing Authorization (ITA)
        - Unlicensed and does not have a Health Canada Investigational Testing Authorization (ITA)
- **How many devices will be used in the study?**
- **Where will the device be used?** Are you aware of any other medical equipment operating within the vicinity of the device?
    - Hospital (describe where within hospital)
    - Research pavilion
    - Private clinic
    - Participant home (circle highlight all that apply)
    - Other (please describe)
- **Will the device connect to the Health Authority network? (Y/N)**
- **Will the device store patient information? (Y/N)**
    - If yes, please provide information on what patient information will be stored on the device.
- **Is there any real-time wireless transmission during the research activity? (Y/N)**
    - What frequency (range) is used to transmit data?
    - What is the output power for wireless transmission?
- **Will there be any modifications made to the device during the course of the study? (Y/N)**
    - If yes, please provide more details
- **Any other important device information**

Researcher Responsibilities:

- Assess the risks associated with the use of the device(s)
- Obtain informed consent from study participants
- Ensure that the device(s) used in the study are maintained appropriately

Important Notes

- A hands-on inspection will likely be required for device approval
- International certifications are not recognized in Canada (European certification (CE), FDA certification, etc).
- Investigational devices used in clinical trials whose results are intended to be submitted to Health Canada require Health Canada authorization for use in the HA.