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

This guidance document applies to research studies occurring in the **non-clinical environment**. The non-clinical environment is defined as areas intended for research purposes where FHA patients do not receive care (ie. diagnosis, treatment). Some examples include research labs at ICORD and non-clinical research rooms at GF Strong.

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

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

Requirements for electrically-powered devices used in non-clinical environment:

- The equipment should be in generally good physical condition:
  - Clean
  - Undamaged (e.g., case intact without unguarded openings, no missing parts)
  - Readable labels; intact controls

- The equipment should not have apparent hazards:
  - No obvious physical hazards (e.g., sharp edges, unguarded moving parts, instability)
  - No obvious energy hazards (e.g., noise, heat, bright light, radiation)

- Cables should be intact:
  - Communication cables should be undamaged, with no exposed conductors
  - Power cables and power strip should be undamaged, with intact plugs (no adapters), intact receptacles, undamaged strain reliefs, and no exposed conductors

Questions you will be asked:

- **Please provide:**
  - Study protocol
  - Research ethics board application
  - Device type (e.g. vital signs monitor)
  - Manufacturer, model and serial number of device

- **Where will the device be used?**
  - 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.

- **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 visual inspection will likely be required for device approval
- Researchers do not need to seek Biomedical Engineering approval for devices inspected within the previous year. If the device has been inspected within the previous year, the date on the Biomedical Engineering inspection label will reflect this