

# Biomedical Engineering Device Assessment

All electrically powered medical devices that interact with a research participant in some way must be screened using the tool below. This is not limited to investigational devices but also includes all powered devices used as part of the study procedures such as vital signs monitors, EEG machines, etc. This includes devices used in both patient care and non-patient care areas of PHSA-owned property.

**Study Title and PI:**

	Yes	No
1. Is an electrically powered medical device used in the study (including battery-operated devices)? This includes any devices that are used for treatment, diagnosis, monitoring, or data collection.	<input type="checkbox"/>	<input type="checkbox"/>
2. Are all the electrically powered medical devices used in the study on the <i>device exclusions list</i> provided below?	<input type="checkbox"/>	<input type="checkbox"/>

If you have answered **Yes** to question 1 and **No** to question 2, please contact [BMEdclerical@vch.ca](mailto:BMEdclerical@vch.ca) or **604 831 4182**.

## Device Exclusions List:

This list contains items that are exempt from biomedical engineering assessment. If you are unsure whether a medical device meets the criteria to be exempt, please contact biomedical engineering.

Device	Conditions	Example
Previously inspected devices used in non-clinical areas	Researchers do not need to seek Biomedical Engineering approval for devices used in non-clinical areas that have a LMBME research device inspection label with an inspection date within the last year.	ECG machine with an LMBME research device label used in non-clinical area in ICORD that has an inspection date within the last year.
Devices used in private clinic	Researchers do not need to seek Biomedical Engineering approval for devices used in private clinics on PHSA property.	Vital signs monitor used in physician's private clinic.
Devices used in homecare environment	Researchers do not need to seek Biomedical Engineering approval for devices used in homecare environment.	Holter monitor used in homecare environment.
PHSA Owned Assets	Exempt if the intended use of the device in the study matches the intended use the device was designed for.	Health authority owned vital signs monitor.
Consumer Tablet/Smartphone	Exempt if the device is unmodified and has no patient applied parts.	iPad
Activity monitors	Exempt unless used in a critical care or operating room environment.	Fitbit