| | |
|---|---|
| **Number:** | **RRSM : 20.1** |
| **Date:** | **January 2021** |
| **Page:** | **1 of 2** |

**Guidance Concerning Sterilization Instructions for Research and Project Medical Devices.**

Vancouver Coastal Health has standards which must be followed and, if deviation is required, we must ensure safety and regulatory compliance. There is a Reprocessing, Research and Variance Committee to review proposals from staff who find that the existing Manufacturer's Instructions for Use (MIFU) are problematic in practice, or for reprocessing of devices used in research which do not have existing MIFU.

Medical Devices used in VCH Facilities must comply with BC Ministry of Health, CSA and VCH Best Practice Guidelines for Patient Safety and Infection Control when reprocessed between patients.

One such standard is that VCH is required to follow the Manufacturer's Instructions for Use (MIFU). MIFU are the validated reprocessing, cleaning, disinfection, and sterilization procedures for the device, and are the basis on which the device was approved for sale in compliance with regulatory requirements.

Medical Devices used in research projects involving patients in VCH Facilities must comply with BC Ministry of Health and VCH Best Practice Guidelines for Patient Safety and Infection Control. These documents state that all devices used in patient care must follow the MIFU; however, research devices do not have MIFU and so their reprocessing plan must be reviewed and validated. The Reprocessing, Research and Variance Committee will review applications from researchers to advise on and authorize the safe use of the research device at VCH.

As part of the variance process, researchers are required to submit a planned procedure for cleaning, disinfection or sterilization of the device. For newly designed or adapted devices there will also need to be validation of the reprocessing approach from an independent laboratory (there will be a cost associated for this service, be sure to consider the cost in your funding proposal).

**All Research Applicants must complete the VCH Application for Operational Approval form and submit it to VCHRI. If a non-market (i.e. research) device used in the project is critical or semi-critical, a variance is required to enable sign off on the reprocessing section of the operational approval form.**

Use of research devices at VCH may only be done once the protocol for reprocessing the research device has been approved by the VCH Reprocessing Research and Variance Committee (RRVC).
Those seeking comment by the RRVC are asked to complete an application specific to their device:

- Application for Non-Critical Research Device
- Application for Non-Market Research Device
- Application for Market Device in Research
- Application for Variance Market Device

Applicants will be asked to provide:

Confirmation of validated instructions including documentation from a certified lab (FDA, ISO, and Health Canada) concerning:

- Mechanical Testing- to ensure that the device is not negatively affected by the sterilization technique.
- Bioburden Testing- to ensure that the device is in fact sterile after sterilization and
- Dose Mapping- confirmation of the sterilization technique at the parameters determine by bioburden testing.

- Documented comment and input from others who are affected by or can comment on the proposed guidance
    - The users / of the device (effect on budget / workflow?)
    - Medical Device Reprocessing Department (can it be cleaned as proposed?),
    - Infection Control (infection control implications?),
    - Biomedical Engineering (device functionality implications?)
    - Other comments as you deem appropriate.

Once your completed submission is received, RRVC will convene to review the application. Applicants may be invited to attend to the meeting to explain and discuss the submission with the Committee. Potential outcomes include one or more of the following, that:

- The proposed approach will be confirmed, revised, or declined, or
- More information may be necessary before a decision can be made.

For discussion or clarification on any of the foregoing, please contact **reprocessing@vch.ca**

---

**References:**
More information and application forms can be found on the RPIP website:
RPIP Reprocessing Research and Variance Committee

VCH Research Institute application form:
https://www.vchri.ca/services/operational-approval

| **RRSM 20 Revision History** |
|---|
| 2021 January |
| 31 Aug 2011 |
| Review May 2012 |