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Guidance Instructions for Medical Devices used in Research on Human Beings.

VCH complies with the 2011 Ministry of Health Policy Communiqué (link to RPIP Webpage) concerning Reprocessing of Medical Devices and Patient Care Equipment, including new directives concerning research devices.

To facilitate compliance with these guidelines VCH has a Reprocessing Research and Variance Committee to review applications for Critical and Semi-critical medical devices. These devices need sterilization or high level disinfection between patient uses.

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 reprocessing validation from an independent laboratory (there will be a cost associated for this service, be sure to consider the cost in your funding proposal).

Review and approval by the VCH Reprocessing Research and Variance Committee is necessary prior to the medical device being used in the research project. Those seeking approval are asked to complete the relevant application form which can be found on the VCHRI website http://www.vchri.ca/services/operational-research-approval

You will be asked to review the following information which can be found on the VCHRI website and identify which aspects of these regulations and guidelines apply to your research device, to ensure you have met their requirements in your proposal:

- Process for Investigational Medical Devices (VCH Biomed)
- BC MoH Communique (2011-03, 858935) Provincial Reprocessing Policy
- BC MoH Best Practice Guidelines for Cleaning, Disinfection and Sterilization in Health Authorities - December 2011
- VCH Policy: Reprocessing Critical and Semi-Critical Medical Devices CA_4500
- VCH Regional Reprocessing Standards Manual - RRSM section 20
- Health Canada Medical Device Regulations

In your application you will be asked to confirm that the following requirements have been met:

1. The cleaning, high level disinfection or sterilization instructions outlined in the application for this research device achieve:
    - High-level disinfection; defined as achieving a 6-log10 kill of an appropriate Mycobacterium species, or

- A sterilization process is used that destroys or eliminates all forms of microbial life.

2. The cleaning, disinfection and /or sterilization Instructions are validated, device specific, written instructions. These instructions address:
    - Cleaning and decontamination;
    - Disassembly or reassembly as required
        - including detailed instructions with pictures
    - Packaging (if required);
    - High level disinfection or sterilization; and
    - Device maintenance.

3. The validation is specific for the reprocessing equipment that is used in the health care facility.

4. These instructions can be applied in the normal procedures of Medical Device Reprocessing Departments.

5. The instructions have been validated[i] by an independent certified lab (FDA, ISO, Health Canada). A copy of the certificate will need to be attached.

The committee will review the application. You may be asked to attend with the device to explain or discuss your submission with them. At this time the application may be approved; approved in principle, more information may be necessary before a decision can be made; or the matter may need to be referred to another group, such as the VCH Reprocessing Standards Committee for development of device specific guidance; or the application may be declined.

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

[i] **Validation** is a rigorous process of documentation from an independent lab certified by FDA, ISO, or Health Canada) which establishes that the proposed reprocessing steps will consistently yield a sterile outcome for the device. Validation includes:

a) Bioburden Testing- to ensure that the device is in fact sterile after cleaning and sterilization
b) Mechanical Testing- to ensure that the device is not negatively affected by the sterilization technique.
c) Dose Mapping- confirmation of the sterilization technique at the parameters determine by bioburden testing. (applicable to items being reprocessed using radiation)