Application Requirements for Research Involving Medical Devices.

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.

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 high level disinfection or sterilization 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[1] from an independent laboratory (*there will be a cost associated for this service, be sure to consider the cost in your funding proposal*).

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.

The use of a non-critical device or a non-medical device for the project (e.g., electronic monitoring devices [iPads], headphones, goggles etc.) requires a conversation with the RPIP Coordinator about cleaning between patients to ensure infection control safety between uses. Contact the RPIP Coordinator at reprocessing@vch.ca

Additional information for Applicants – Please review the following information (which can be found on the VCHRI website hyperlink or URL) 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

[1] 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)

Application for Approval, Non-Market Device in Research
(Contacting sterile cavities, mucous membrane or non-intact skin)

Please complete all sections.
Once complete, please send to:

Reprocessing Practice Improvement Program (RPIP),
CP 380, 855 12th Avenue West, Vancouver, V5Z 1M9
Or email to: reprocessing@vch.ca

All research studies involving human subjects that utilize medical devices on VCH property, resources, facilities, patients or staff, must receive VCH Reprocessing Research and Variance Committee approval, in addition to the VCH Research Institute approval.

Patient safety is the principal concern in the review of all applications

Device: _____

Submitted by: _____ Date: _____

Summarize the use of the medical device in this research. Does it have contact with a sterile cavity, vascular system, mucous membrane or non-intact skin?

Device Name:			
Is this a prototype device?		☐ **YES**	☐ **NO**
Who manufactures the device?			
Company:		Phone:	Email:
Researcher:		Phone:	Email:
Indicate Device Classification	• CRITICAL ☐	Device Penetrates a sterile body cavity or enters the vascular system	
	• SEMI-CRITICAL ☐	Device Contacts Mucous Membranes or non-intact skin	

Cleaning, Disinfection or Sterilization Information:

Attach a plan with instructions for cleaning and disinfection or sterilization between patient uses. Include Validated Reprocessing Instructions, from a certified Independent FDA, ISO, or Health Canada laboratory.
Validated reprocessing instructions from an independent laboratory will have associated costs.*

Assessment:
Requestor to seek **comment** from resource / consultants concerning proposed device:
Comment should be attached or completed below, and signed off by the resource person

Operations (End User): Name: _____ Phone: _____

Consider the instructions for reprocessing and safe handling of this device and comment on whether the process will impact workflow or resources and how any impact will be addressed.

Signed: _____Date:_____

Biomedical Engineering: Name: _____ Phone: _____

Will the reprocessing instructions impact the functionality of the device? If reprocessing will impact functionality or integrity of the device materials, please provide direction on monitoring and determination of device safety.

Signed: _____Date:_____

Medical Device Reprocessing Department: **Name:** _____ **Phone:** _____

Are there validated instructions* for reprocessing this device? Is high-level disinfection (defined as achieving a 6-log10 kill of an appropriate Mycobacterium species) achieved; or is a sterilization process used that destroys or eliminates all forms of microbial life? Can these instructions be applied in the normal procedures of MDRD?

**Validated reprocessing instructions from an independent laboratory will have costs associated*

Signed: _____Date:_____

Infection Control: **Name:** _____ **Phone:** _____

Are there any Infection Control concerns with this device being reprocessed? Is high-level disinfection (as defined as achieving a 6-log10 kill of an appropriate Mycobacterium species) achieved? Is a sterilization process used that destroys or eliminates all forms of microbial life achievable in health-care facilities by physical or chemical methods?

Signed: _____Date:_____

Declaration of Regulation and Guideline review

1. I have read and identified the regulations and guidelines as they apply to the research device in this application

2. The cleaning, high level disinfection or sterilization instructions outlined in my 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.

3. 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.

4. The validation is applicable for the reprocessing equipment that is in use in the health care facility in which the research will be undertaken.

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

6. The instructions have been validated[i] by an independent certified lab (FDA, ISO, Health Canada). The certificate is attached.

I confirm "Yes" to all of the statement above.

Request to committee:

Please consider approval of this application to use, clean and disinfect this device as indicated in VCH facilities for the duration of this research project.

Signed: _____ Date:_____

Department: _____

Email address: _____

Title: _____

Research & Variance Committee comment / decision: (office use only)
Date: _____