

Application for Approval, Non-Critical Devices in Research (Only contacts intact skin)

Please complete all sections.

Once complete, please send to:

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

All non-critical devices used in research studies on VCH property, resources, facilities, patients or staff, including, electronic monitoring devices (e.g., iPads), goggles, headsets etc. 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:** _____

Device Name:		
Is this a prototype device?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Who manufactures the device?		
Company:	Phone:	Email:
Researcher:	Phone:	Email:
Indicate Device Classification	<input type="checkbox"/> CRITICAL	Device penetrates a sterile body cavity or enters the vascular system
	<input type="checkbox"/> SEMI-CRITICAL	Device contacts mucous membranes or non-intact skin

Summarize the use of the device in this research. Will it be used for multiple patients? Does it have contact non-intact skin? (If so, this is the wrong application form, please use the application form; Non-market Devices in Research).

Provide a reprocessing plan:

Include itemized instructions for cleaning, disinfection and the products to be used for reprocessing the device between patient uses.

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 cleaning 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: _____

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

Is there any Infection Control concerns or specific directions concerning the device being used for this research project?

Signed: _____

Date: _____

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: _____