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),
    CP 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: ___________________________

PRODUCT INFORMATION:

<table>
<thead>
<tr>
<th>Device Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this a prototype device?</td>
<td>□ YES</td>
</tr>
<tr>
<td>Who manufactured the prototype?</td>
<td></td>
</tr>
<tr>
<td>Company:</td>
<td>Phone:</td>
</tr>
<tr>
<td>Researcher:</td>
<td>Phone:</td>
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</tbody>
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Background:

Summarize use of the device in this research. Will it be used for multiple patients? Does it have contact with non-intact skin? (If so this is the wrong application form, please use 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: __________

Biomedical Engineering: Name: _______________ Phone: _____________________

Will the device impact functionality or integrity of the medical equipment in the vicinity of use? Please provide direction on monitoring and determination of device safety.

Signed: ___________________________ Date: __________
Infection Control: Name: ____________________________ Phone: _______________________

Is there any Infection Control 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: ___________________________________________________

Title: _________________________________________________________

Research and Variance Committee comment / decision: (office use only)

Date: ___________________________