Application for Approval, Market Device in Research

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

Reprocessing Practice Improvement Program (RPIP),
CP 380, 855 12th Avenue West, or
reprocessing@vch.ca

Device: _____

Submitted by: _____ **Date:** _____

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

_____

_____

_____

_____

_____

Background:

Device Name:			
Who manufactures the device?			
Address:		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	

Attach either:

1. Validated sterilization instructions, if device is reusable, or
2. Manufacturers' proof of sterilization, if device is single use

Contact the Medical Device Reprocessing Department (MDRD) to ensure and approve the validated sterilization instructions are applicable, for the reprocessing equipment in use in the healthcare facility in which the research will be undertaken.

MDRD: Contact Name: _____ **Phone:** _____

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