ESTABLISHING A PROCESS TO ASSESS AND APPROVE INVESTIGATIONAL MEDICAL DEVICES

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INTRODUCTION

The Vancouver Coastal Health Authority (VCHA) is a teaching healthcare facility affiliated with the University of British Columbia and linked to other post-secondary educational institutions as well. Researchers from these institutions who design and build novel medical devices often need access to VCHA facilities such as the operating rooms to evaluate these devices in clinical trials. To gain access, they must have approval from the UBC Clinical Research Ethics Board (CREB) and the Vancouver Coastal Health Research Institute (VCHRI), the research arm of the health authority. The latter approval requires that the need for licensing or authorizations for the device from Health Canada and the British Columbia Safety Authority (BCSA) has been determined and that they are in place if needed. It also requires that the research, that is the clinical use of the device, has been vetted by appropriate staff in the Health Authority which normally includes clinical representatives, Biomedical Engineering, the Sterile Supply Department (SSD), and Risk Management. The researcher must also be able to show to VCHA that the research meets recently published provincial guidelines[1] for the cleaning, disinfection, and sterilization of medical devices.

There has been no single entity that researchers could approach to obtain all these approvals at one time. The CREB is separate from the VCHRI, as are the individual VCHA departments that have a say in whether a medical device is approved or not. Consequently the approval process has not been easy to understand for the researchers. This situation has worsened with the recent need for the researchers to assure that the necessary cleaning, disinfection, and sterilization of medical devices meet provincial guidelines. This assurance may involve the use of third-party sterilization facilities and microbiology labs whose services may be expensive and might take up to several weeks.

One researcher who experienced unexpected expenses and delays before receiving all the necessary approvals to evaluate her medical device in clinical trials put forth suggestions to streamline the process to have a medical device for research approved, and to make the researcher's obligations much clearer[2]. The text below describes these suggestions which VCHA is in the midst of evaluating and implementing if warranted.

THE MEDICAL DEVICE DEVELOPMENT SAFETY COMMITTEE

The researcher proposed the formation of an in-house committee, the Medical Device Development Safety Committee (MDDSC), to assess and approve investigational medical devices (IMDs). The intent is for the MDDSC to consider IMDs that are designed and built by researchers within or affiliated with VCHA. As these devices are to be used within VCHA and are not for sale or importation, neither a medical device license nor approvals under Parts 2 and 3 of the Canadian Medical Device Regulations are needed.

The committee would comprise representatives from Biomedical Engineering, Risk Management, Infection Control, the Operating Rooms, and the Sterile Supply Department. In order to obtain approval to use IMDs from the committee the researchers must show that the devices have passed necessary electrical and mechanical safety testing, and must have developed and validated an acceptable sterilization method for the IMDs.

This approval process does not replace the CREB, VCHRI, and VCHA approval processes, but instead, provides a means of satisfying several of the VCHRI and VCHA requirements all at once. The MDDSC can provide the researcher with a detailed description of the above mentioned requirements and will vet the researcher's sterilization proposal prior to validation.

The overall approval process is shown in Figure 1 below.

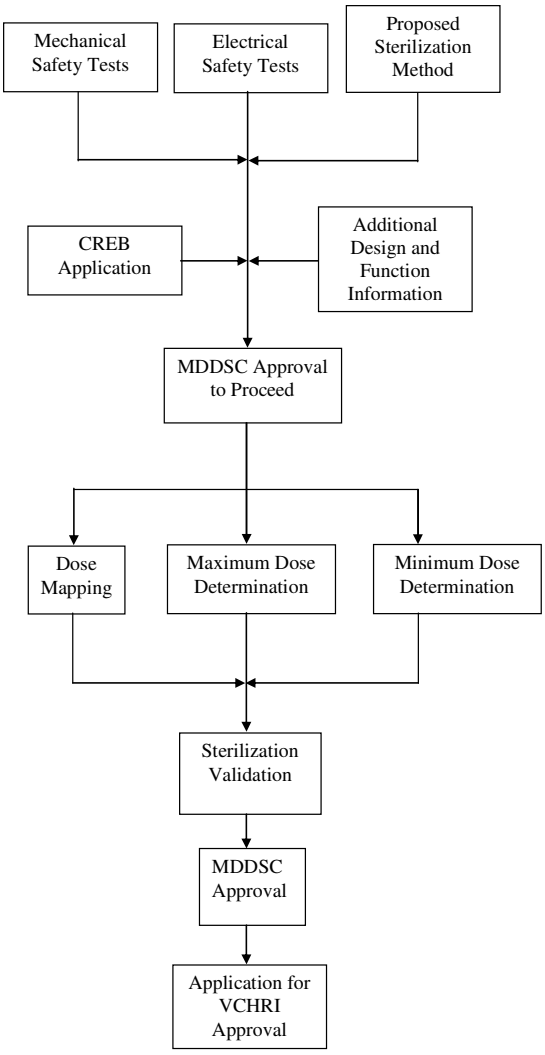

Figure 1: Approval Process

MDDSC APPROVALS

Electrical Testing

The use of electrical equipment in BC is governed through the Electrical Safety Regulation, and is overseen be the British Columbia Safety Authority. This organization is an independent, self-funded corporation that supports the provincial legislation to promote a safe environment in BC. The regulations require all electrical devices to have an acceptable approval prior to use. The VCHA Biomedical Engineering Department will assure the device has the necessary approval, will evaluate the device to assure it is safe to use in the proposed research, and will inspect it using in-house inspection procedures.

Mechanical Testing

The purpose of the mechanical testing is to assure that the IMD remains intact and functional after exposure to the environment and the stresses that it will experience throughout sterilization and use cycles. The number of cycles considered must exceed the allowed number of uses defined for the device. Depending on the device, testing may include an examination under microscope to look for any nicks or cuts that may affect re-sterilization.

Sterilization Method and Validation

The choice of an appropriate sterilization method is an involved process. There are many factors to consider such as the material response to sterilization and the relative costs of both routine sterilization and the validation trial. Once the type of sterilization has been chosen, there are tests that need to occur to validate the sterilization and show the efficacy of the proposed method. Sterilization validation requires the participation of third-party sterilization facilities and testing that may take several weeks. The required tests are: minimum dose determination, maximum dose determination and, when radiation is used, dose mapping.

Minimum Dose Determination

The minimum sterilization dose necessary to ensure sterility must be determined. Four samples of the IMD for each dose of sterilization being considered must be cleaned, packaged, and sterilized according to the proposed method. Depending on the type of sterilization chosen and the volume of devices required for the clinical trial, sterilization may be possible through the hospital SSD. If not, it is the responsibility of the researcher to find a third-party sterilization company. This company should be US FDA or equivalently approved to perform sterilization of medical devices. After sterilization, the device must be sent to a microbiology lab for sterility testing. The laboratory must be accredited by an appropriate organization such as the Standards Council of

Canada, Health Canada, or the US FDA. The testing typically involves washing the device after sterilization in a special solvent for a given amount of time, filtering the solvent and then incubating the filters in both aerobic and anaerobic environments. If the device was not sterile, growth will occur in one of these two environments. It should be noted that the majority of sterility testing at small microbiology labs is performed on small devices or pharmaceuticals and the researcher must assure the laboratory can accommodate the device to be tested. It may be necessary to provide an unsterilized device for the lab to use in the determination of the optimal handling of the device for sterility testing. The suitability of the third-party laboratory will be judged by the MDDSC.

Maximum Dose Determination

Testing must be done to assure that the function or safety of the IMD is not compromised when the device is sterilized using a dose above what would normally be used. The sterilization dose can fluctuate slightly each time the device is sterilized, and can also vary from one part of the device to another. The device must be able to withstand these variations. The function and safety of a single-use device is verified after sterilization with a dose that is twice what would normally be used. Re-usable devices are tested after being subjected to a dose in excess of the total dose that can be applied to the device based on the number of reprocessing cycles allowed. The methods that will be used to test mechanical integrity and function as well as the details of doses that will be applied during maximum dose determination should be discussed with BME in advance.

Dose Mapping for Irradiation Sterilization

Devices that will be sterilized using irradiation techniques must undergo a dose-mapping procedure. Dose mapping allows determination of the zones of minimum and maximum dose in the device package by placing dosimeters at strategic locations. This process allows for the dose being applied at various areas of the device to be correlated to the dose measured at a position outside the device packaging. This is necessary to ensure that the minimum dose is applied to the entire device. The researcher should confirm that the company contracted to complete sterilization is equipped to undertake dose mapping as well.

Sterilization Challenge

The MDDSC may require a sterilization challenge test to be performed in addition to the requisite sterility tests previously described. This may be the case if the device is likely to be difficult to sterilize due to the presence of small lumens or crevasses that may hinder sterilization. The sterilization challenge involves inoculating the device with a known concentration of organisms, processing it with the prescribed cleaning and sterilization technique, and then performing the aforementioned sterility tests. Should it be required, the details of this test should be discussed with the appropriate members of the MDDSC (Infection Control and SSD representatives) in order to determine whether inoculation should be performed by the hospital representatives or by the microbiology lab.

ACKNOWLEDGEMENTS

I would like to acknowledge Katie Beadon who took the initiative to document the process described in this document. Much of the text in this document is from Katie's thesis.

REFERENCES

(1) Best practice guideline for cleaning, disinfection and sterilization of medical devices in health authorities, British Columbia Ministry of Health, 2007.

(2) K. Beadon, Evaluation of a computer-assisted technique for distal locking of femoral intramedullary nails, UBC MASc Thesis, 2007.