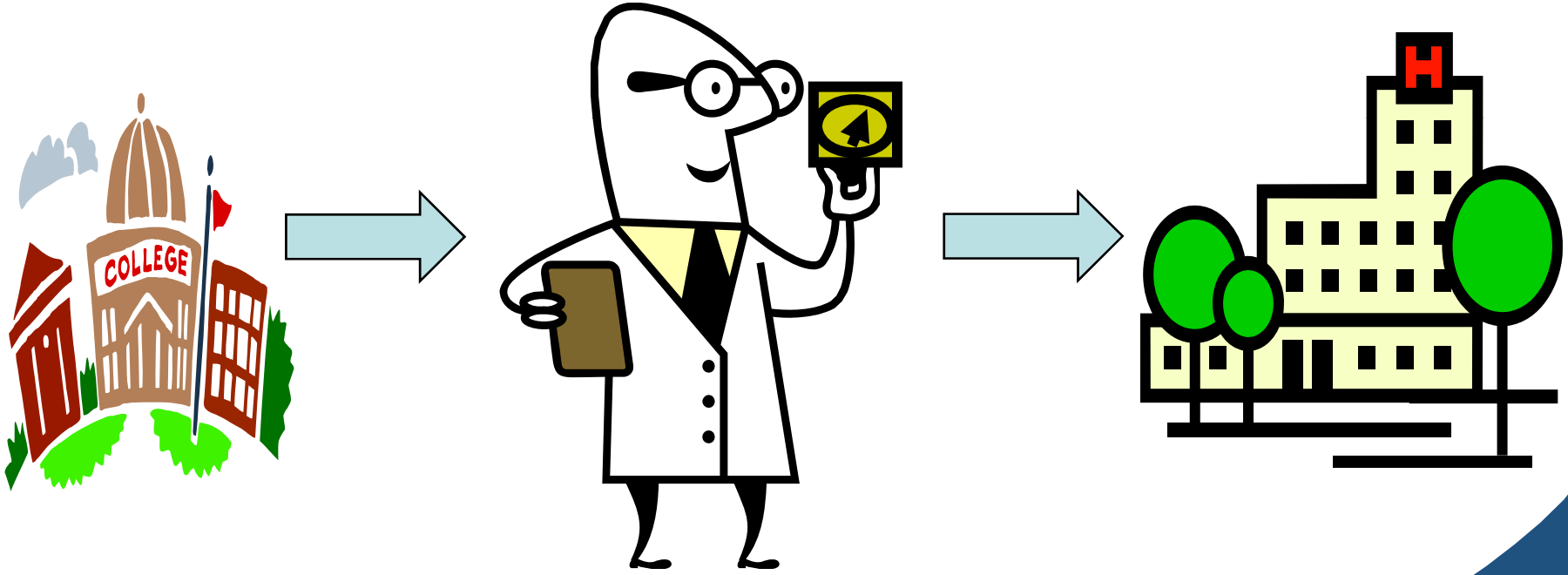
How to Trial a Device in a VCH Facility

Gordon McConnell, P. Eng.
Vancouver Coastal Health Authority

Vancouver CoastalHealth

PROCESS FOR INVESTIGATIONAL MEDICAL DEVICES



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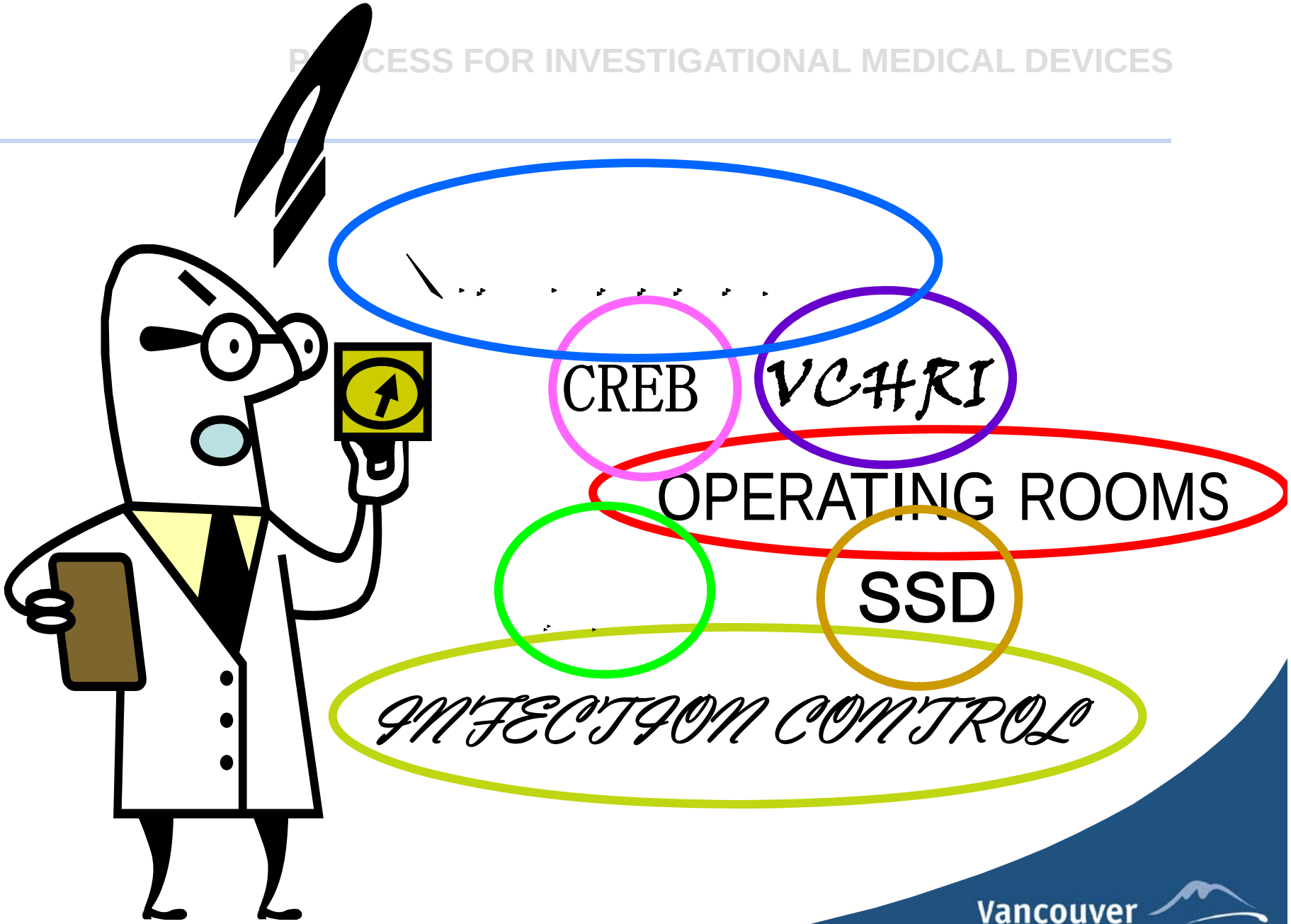
CREB
VCHRI
OPERATING ROOMS
SSD
INFECTION CONTROL

The Medical Device Development Safety Committee

(The Reprocessing Variance Committee)

Committee

- ❑ Risk Management (Medical Affairs)
- ❑ Infection Control
- ❑ Medical Device Reprocessing Department (MDRD)
- ❑ Biomedical Engineering
- ❑ Operating Rooms
- ❑ Diagnostic Imaging

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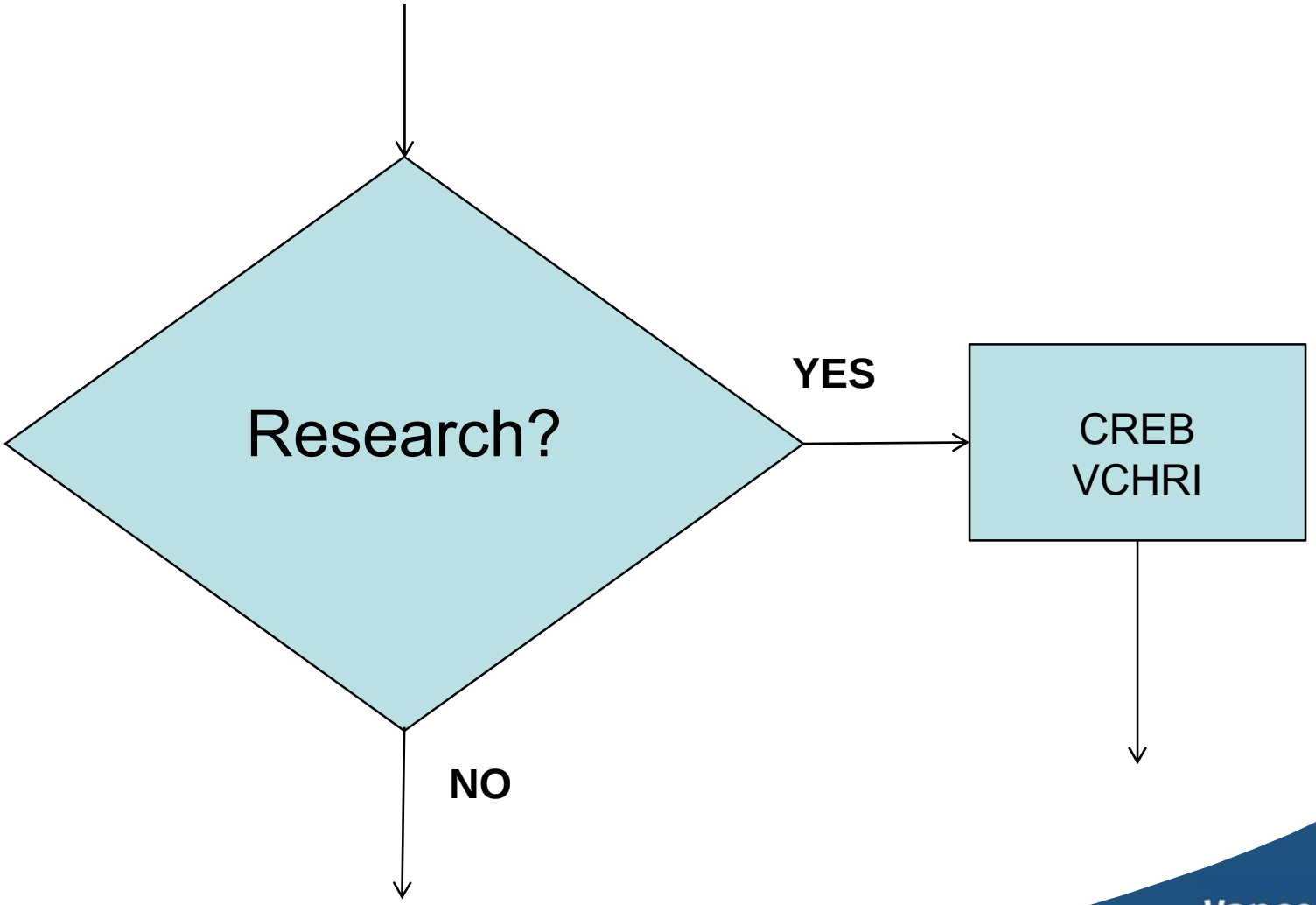
PROCESS FOR INVESTIGATIONAL MEDICAL DEVICES



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- CREB – Clinical Research Ethics Board
- VCHRI – Vancouver Coastal Health Research Institute

All research studies involving human subjects that utilize VCH property, resources, facilities, patients or staff, must receive VCH approval to conduct research in addition to ethical approval.

GUIDELINE FOR OBTAINING APPROVAL TO CONDUCT RESEARCH AT VANCOUVER COASTAL HEALTH

http://www.vchri.ca/

DEFINITION OF RESEARCH

A research study … will be considered … as being research involving human subjects if:

- A human is subjected to procedures, the purpose of which go beyond the subject's need for prophylaxis, diagnosis or therapy; or
- A human is subjected to procedures which are experimental but which do not necessarily go beyond the subject's need for prophylaxis, diagnosis, or therapy; or
- Procedures are used in which an invasion of privacy may be involved, for example, by examination of records, by interviews, by observations, by administration of a questionnaire or test, or by audio or video recording; or
- Human tissue, biological fluids, embryos or fetuses are being studied.

GUIDANCE: WHEN DOES YOUR PROJECT WARRANT REVIEW BY A RESEARCH ETHICS BOARD? http://www.vchri.ca/

Does your project warrant review by a research ethics board?

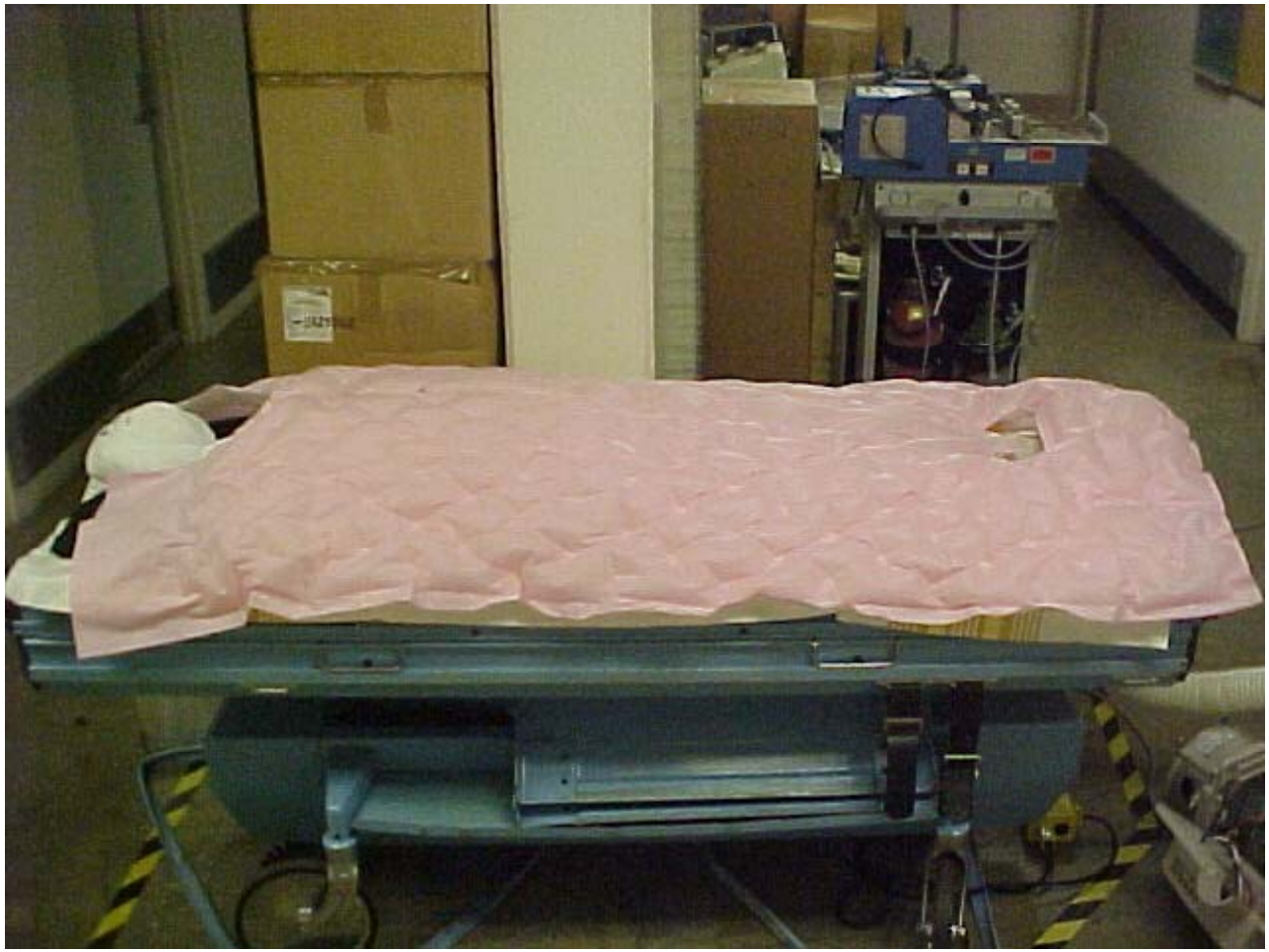
1. …
2. …
3. Does the project involve the use of a medical device … which requires approval from Health Canada …
4. …

Examples of Non-Research Devices:

- ❑ Shuttle
- ❑ Reusable Blanket for a Forced-Air Patient Warmer

Shuttle

Forced-Air Patient Warmer



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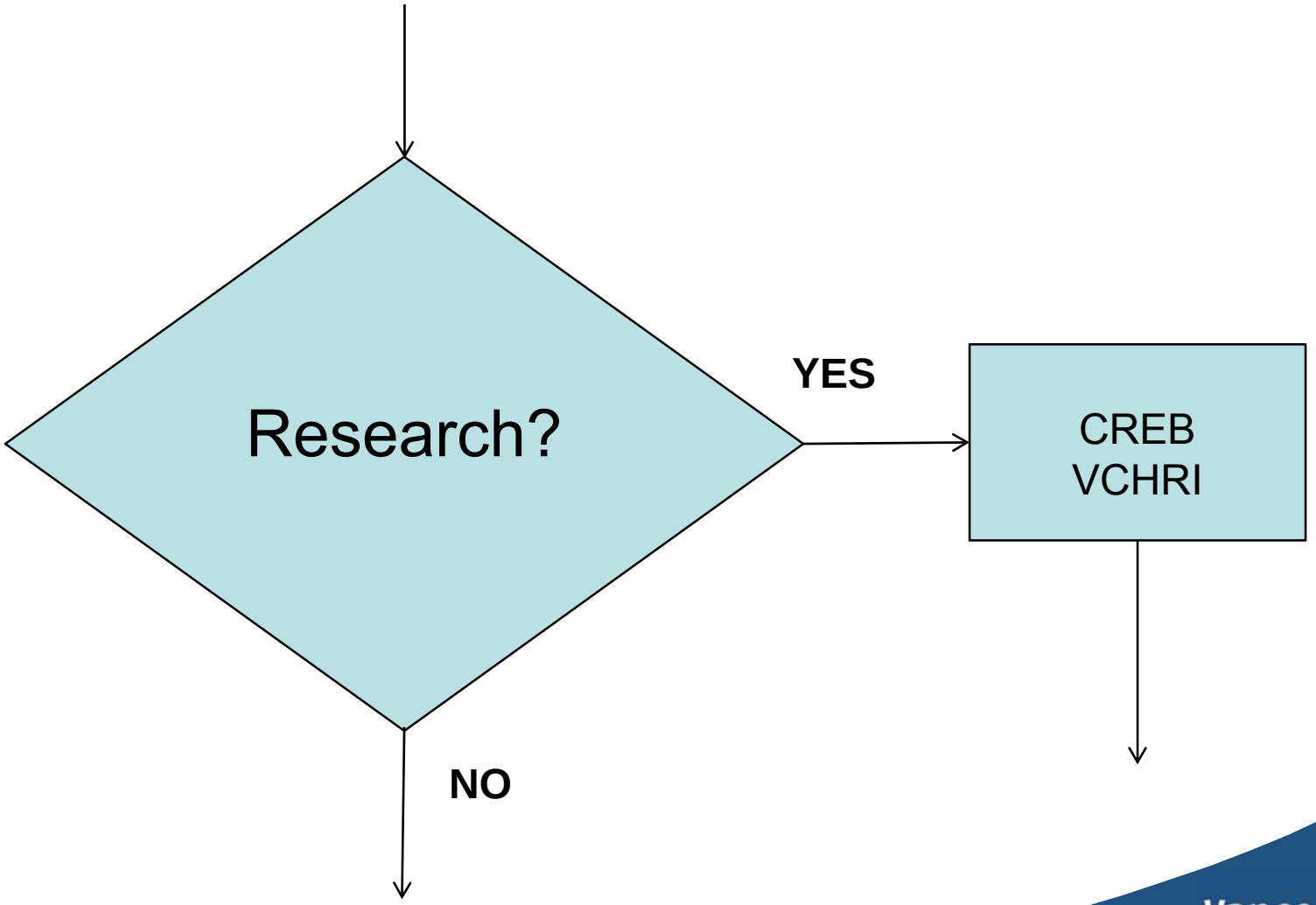

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HEALTH CANADA

Food and Drugs Act
Medical Device Regulations

- Is the item a medical device?
- If so, what is its class?
- Does it have a medical device licence?
- Does the use of the device constitute a “sale”?

The Definition of a Medical Device under the *Food and Drugs Act*

The *Food and Drugs Act* (1) defines a "device" as any article, instrument, apparatus or contrivance, including any component, part of accessory thereof, manufactured, sold or represented for use in:
the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state;
restoring, correcting or modifying a body function or the body structure;
the diagnosis of pregnancy; or
care during pregnancy and at and after birth.

Medical Device Classification:

...

Medical devices are classified into one of Classes I to IV by means of the classification rules … where Class I represents the lowest risk and Class IV represents the highest risk.

...

... no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device …

Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices:

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf

Medical Device Licence

http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php

Medical Devices Regulations

http://laws-lois.justice.gc.ca/eng/regulations/

…

These Regulations apply to

(*a*) the **sale** and advertising for sale of a medical device; and

(*b*) the **importation** of a medical device for sale or for use on individuals, other than importation for personal use.

Therefore, if the medical device “belongs to” VCH and there is no “sale” or “importation” involved with it, the MDR do not apply.

Medical Devices Regulations

- PART 1 GENERAL

Device has a medical device licence if Class 2, 3, or 4.

- PART 2 CUSTOM-MADE DEVICES AND MEDICAL DEVICES TO BE IMPORTED OR SOLD FOR SPECIAL ACCESS

(1) This Part applies to custom-made devices and medical devices that are to be imported or sold for special access.
(2) In this Part, *"special access"* means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable

- PART 3 MEDICAL DEVICES FOR INVESTIGATIONAL TESTING INVOLVING HUMAN SUBJECTS

This Part applies to medical devices that are to be imported or sold for investigational testing involving human subjects

Medical Device Regulations

The medical device that I mentioned is … . The researchers have done substantial bench testing and would now like to test the device in parallel with the conventional means … to validate the technique and to gather data to help with the design of the device. The research proposal was submitted to the Clinical Research Ethics Board and given provisional approval pending contact with Health Canada regarding licensing.

The principle investigator is an orthopedic surgeon on staff at Vancouver General Hospital, and the device is being developed in conjunction with a medical engineering professor and a graduate student at the University of British Columbia as a Master of Applied Science project.

My question to you is whether the device requires a license given that it is custom built for use at VGH, and at this point, is being evaluated only for "proof of principle" which precedes any thought of commercialization (i.e., sale or distribution) of the product.

Medical Device Regulations

...

We have looked at the scenario below and if according to the definition of sell in the Food and Drugs Act, this product is not being sold or distributed to a party outside of the hospital then the product would not need to have a medical device licence.

If however you wish to distribute to other hospitals, then you would need to obtain a medical device licence for the product.

Sincerely,

Nancy Shadeed
Head, Regulatory and Scientific Section
Device Licensing Division
Medical Devices Bureau

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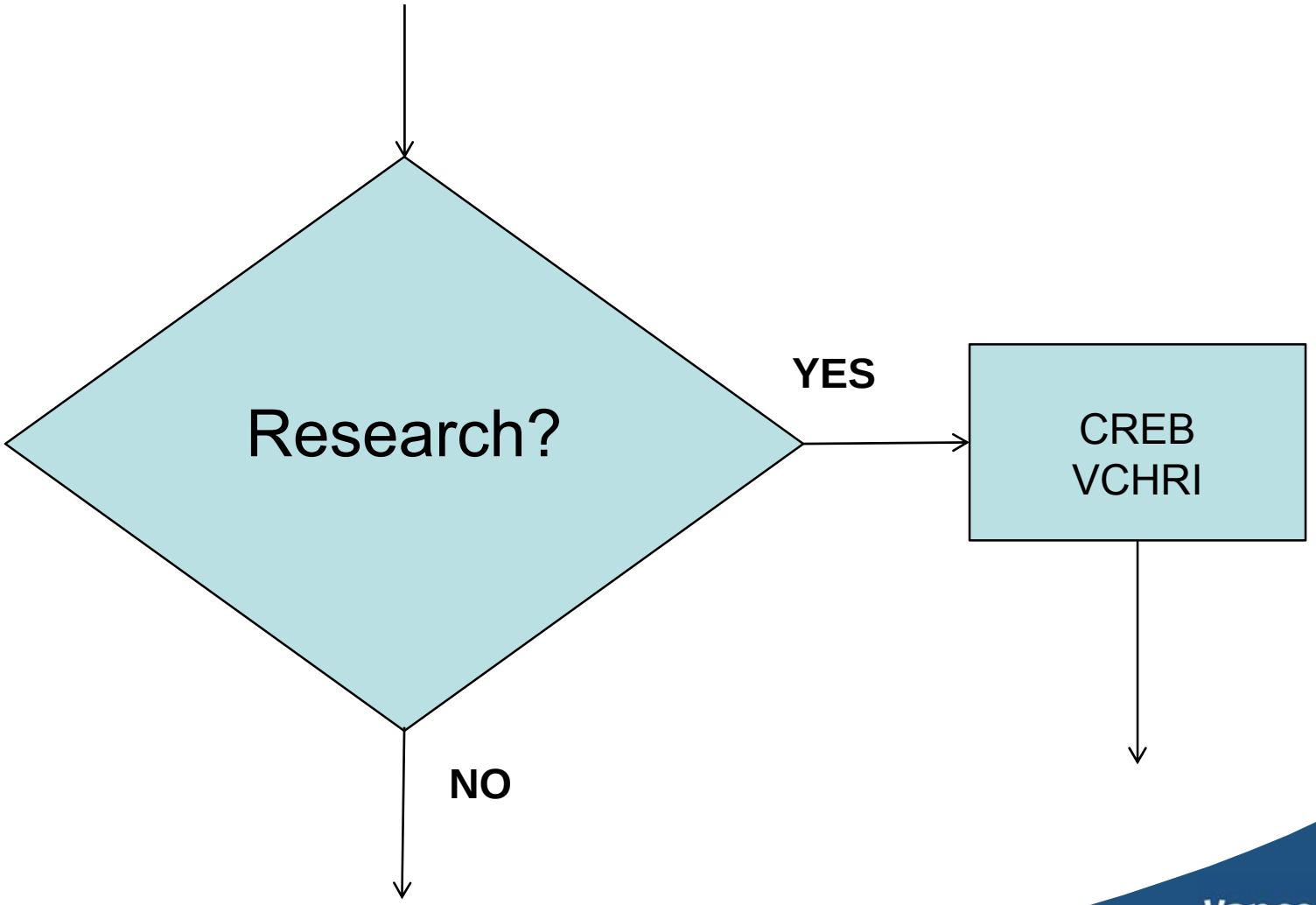

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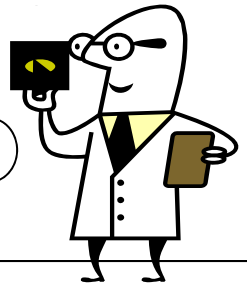
PROCESS FOR INVESTIGATIONAL MEDICAL DEVICES

Process Flow Chart

(Beadon Protocol)



Start

Permission from the OR

Mechanical Safety Tests

Electrical Safety Tests

Proposed Sterilization Method

CREB Application

Additional Design and Function Information

Biomedical Engineering and Reprocessing Variance Committee

Approval to Proceed

Dose Mapping

Maximum Dose Determination

Minimum Dose Determination

Sterilization Validation

Biomedical Engineering and Reprocessing Variance Committee

Approval

Application for VCHRI Approval

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Electrical Testing

The VCHA Biomedical Engineering Department

- ❑ assures the device has the necessary approvals
- ❑ evaluates the device to assure it is safe to use in the proposed research
- ❑ inspects the device using in-house inspection procedures

Mechanical Testing

The VCHA Biomedical Engineering Department

- ❑ evaluates the device to assure it is safe to use in the proposed research

- ❑ assures that the device remains intact and functional after exposure to the environment and the stresses that it will experience throughout sterilization and use cycles.

Sterilization Method

See "Guidance concerning sterilization instructions for research devices for use on humans" at
http://vchconnect.vch.ca/programs_services/client_relations/reprocessing_of_medical_devices/reprocessing_variance_cmtee/page_78970.htm

❑ The necessary level of sterilization (or disinfection) is determined (Spaulding's Classification of Medical Equipment and Required Level of Processing).

❑ The method of sterilization is chosen (MoH Guidelines for the Cleaning Disinfection and Sterilization of Medical Devices in Health Authorities).

❑ A plan for the validation of the sterilization method is chosen. The validation tests are **minimum dose determination**, **maximum dose determination** and, when radiation is used, **dose mapping**.

❑ The Reprocessing Variance Committee may require a **sterilization challenge**.

Minimum Dose Determination

- The minimum sterilization dose necessary to ensure sterility must be determined.
- A sterilization facility will sterilize samples at different doses.
- These sterilized samples sent to a microbiology lab for sterility testing.

Dose Mapping

- Devices that will be sterilized using irradiation techniques must undergo a dose-mapping procedure.

- Dose mapping is the 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.

Maximum Dose Determination

- ❑ Testing is done to assure the function of the device is not compromised when the device is sterilized.

- ❑ The function and safety of a single-use device is verified after sterilization with a dose that is greater than 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.

Sterilization Challenge

- A sterilization challenge test may be needed if the device is likely to be difficult to sterilize.

- 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.

Use of Non-Medical Devices in Patient Care Areas and the Patient Care Environment

CSA Z32: Electrical safety and essential electrical systems in health care facilities

Patient Care Area: An area intended primarily for diagnosis, therapy, or care.

Patient Care Environment: A Zone … that has been preselected for the accommodation of a patient bed … and … equipment involved in patient treatment … which includes space within the room 1.5 m beyond the perimeter of the bed … and to within 2.3 m of the floor.

Use of Non-Medical Devices in Patient Care Areas and the Patient Care Environment

CSA Z32: Electrical safety and essential electrical systems in health care facilities

4.3.4 Non –medial electrical equipment used in patient care areas

4.3.4.1 General

The HCF's nonmedical electrical equipment shall be approved … to the applicable Standard and shall be covered by the HCF's electrical safety program.

4.3.4.2 Patient environment requirements

… non-medical electrical equipment to be used in the patient care environment shall

(a) be battery powered and less than 30 V;

(b) be limited to extra-low-voltage Class 2 circuits; or

(c) have a leakage current, chassis to ground, of less that 500 µA

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Use of Non-Medical Devices in Patient Care Areas and the Patient Care Environment

CAN/CSA-C22.2 NO. 60601-1-1-02 (R06) - Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems

Annex I (informative) ME system aspects

I.1 Combinations of ME Equipment and non-ME Equipment

I.1.1 … This annex provides a summary of situations that could occur when different combinations of equipment are used in various medical environments. …

I.1.2 Localities in a medical environment

The following localities are foreseen
- ❑ The patient environment as part of a medically used room
- ❑ A medically used room, excluding the patient environment
- ❑ The non-medically used room …

Acknowledgements

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UBC Mechanical Engineering

Vancouver CoastalHealth

Promoting wellness. Ensuring care.

Biomedical Engineering

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