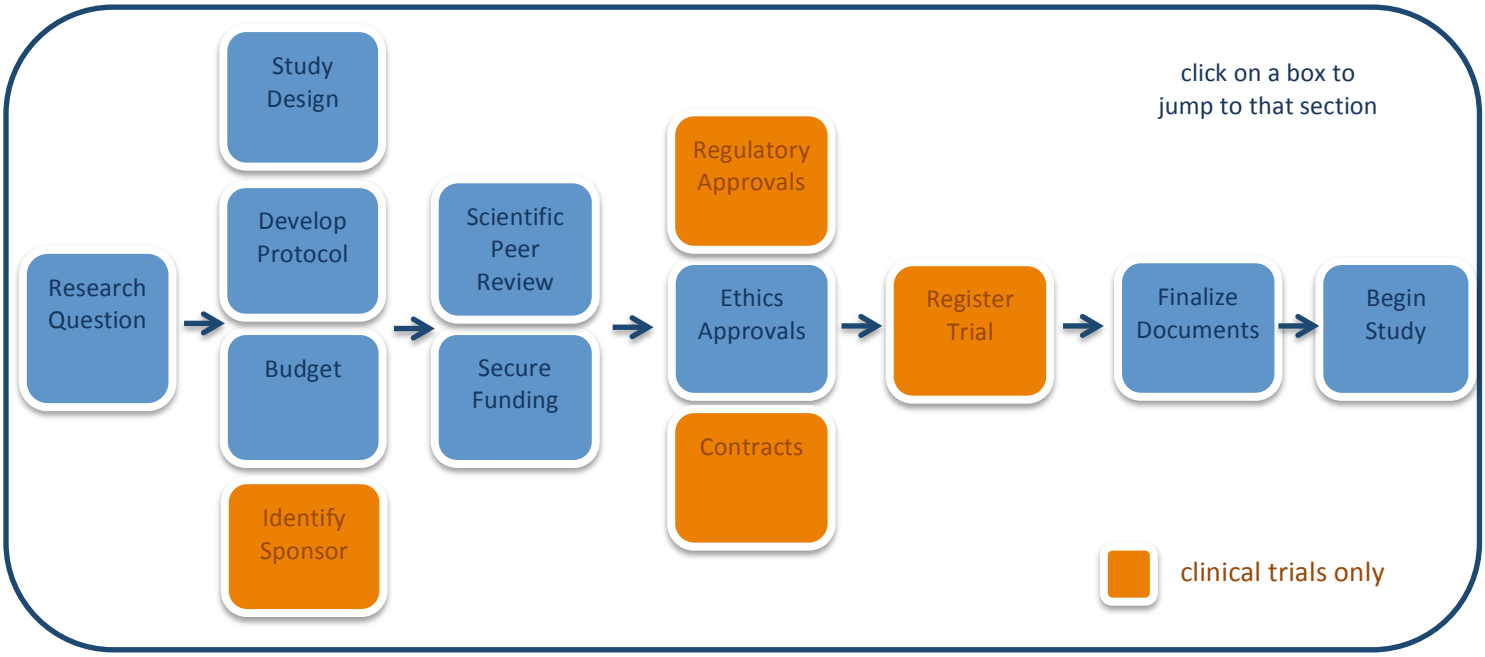
Research

Guidance Document for Research Conducted in the Faculty of Dentistry

Research Planning Flow Map



The Research Question

The first step in planning a research project is to develop a research question. Good research questions are feasible, interesting, novel, ethical and relevant.

If you are looking for research ideas, help in framing a research question or colleagues to collaborate with, consider joining one of the Faculty of Dentistry's research interest groups. These are groups of researchers who share common interests around: clinical oral health research, oral cancer research, the oral health of seniors, aboriginal oral health, and educational research, among others. Some groups meet regularly while others meet on an ad hoc basis. Contact the Research Development Officer if you would like to join a meeting.

The Assistant Dean Research, Dr. Mary McNally is available to advise on research topics, study design and potential collaborators. The Assistant Dean of Clinics and Building Services, Dr. Blaine Cleghorn is also available to discuss ideas for clinical research.

The FINER[1] criteria of a good research question

Feasible
Adequate number of subjects
Adequate technical expertise
Affordable (time & money)
Manageable in scope

Interesting
To both the researcher and potential funders

Novel
Confirms, refutes or extends previous findings
Provides new findings

Ethical
Will be approved by Research Ethics Board or Animal Care Committee

Relevant
To scientific knowledge
To clinical practice and health policy
To future research

Study Design

A well though-out study design will facilitate future steps in the research development process, from budgeting to ethics submissions.

To assist in selecting a study design, refer to the literature for comparable studies, discuss the design with your colleagues and be sure to consult with a statistician.

The Research Methods Unit (RMU) provides research design and statistical consulting to Dalhousie researchers. The initial one-hour consultation is free and subsequent services are $100/hour. See the RMU website for a consultation request form.

Develop Protocol

A protocol is a set of instructions for everyone involved in the study. A thorough protocol will ensure that all aspects of the study are clear to all and that methods are consistent.

It will also ensure that all practical considerations are taken into account and will help inform the budget.

All studies should include the following in the protocol:

- Title
- Contact details for Sponsor, Chief Investigator, Principal Investigators, Statistician
- Background (appropriately cited)
    - Why are you researching the area? What is the previous evidence or gap in knowledge?
- Aims/Objectives/Purpose
- Methodology
    - Study Design
    - Target population, sample size & sampling plan
    - Process for allocation to groups (if applicable)
    - Intervention (if applicable)
    - Data collection tools - surveys, tests, observations
    - Timeline for study visits & data collection
    - Outcome measures & data analysis plan
- Ethical considerations
    - Process for recruitment & informed consent
    - Risks and benefits
    - Approval(s) required
- Plan for dissemination of results
- References
- Appendices (e.g. questionnaire, patient information leaflet)

Several templates for study protocols are available on the internet (such as the Fraser Health template for research protocols available here).

All clinical trials conducted at the Dalhousie Faculty of Dentistry must prepare a protocol using a template that complies with Good Clinical Practice (GCP) guidelines (such as the CHEO template available here).

What is a Clinical Trial?

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.[2]

What Approvals Are Needed to Conduct a Clinical Trial at Dalhousie?

1. All clinical trials require institutional research **ethics board approval**.
2. Some clinical trials require **Health Canada approval**.
3. All clinical trials must be registered with a **clinical trials registry** prior to recruitment of study participants.

Develop Budget

Generally, grant applications require a standard budget template as well as a detailed justification of costs. To help prepare your budget, you may wish to create a timeline and work plan. This will help clarify the various steps in your study and the resources required at each step.

Check the granting agency guidelines to confirm allowable expenses (e.g. CIHR operating grants do not allow equipment costs or office supplies). For research involving the Dalhousie Dental Clinic, a guide to clinic costs (e.g. sterilization, equipment, space, staff time, etc) can be found in Appendix A.

All research involving the Faculty of Dentistry clinic and/or clinic-related resources must have their protocols and budgets reviewed by Dr. Blaine Cleghorn prior to submission to ensure that all clinic-related costs and procedures have been properly accounted for.

Potential Budget Items:

- Research assistants/technicians
- Equipment (portable or fixed)
- Lab supplies, consumables
- Clinic time/ space
- Clinic personnel (e.g. for participant recruitment, greeting/orientation)
- Radiographs
- Sterilization costs
- Computer software
- Statistical consulting
- Travel (for research, meetings, or conferences)
- Participant reimbursement

Identify Sponsor

The sponsor of a clinical trial is "an individual, company, institution, or organization which takes the responsibility for the initiation, management, and/or financing of a clinical trial"[2] but does not actually conduct the investigation.

Manufacturers will sometimes sponsor clinical trials of their products to be conducted by an outside researcher or clinical trials unit.

A sponsor-investigator is an individual who takes on the responsibility of study sponsor and ALSO initiates and conducts the clinical trial. [2] Researchers may fulfill the role of sponsor-investigator when they are conducting investigator-initiated clinical trials or when they are the Canadian investigator on a clinical trial initiated and conducted by others based outside of Canada.

Scientific Peer Review

It is best practice for health research to undergo scientific peer review. In most cases external peer review will occur as a part of the funding process. However, internal peer review *prior* to submission of a grant application is strongly recommended as it may increase the competitiveness of your proposal.

The Research Development Office can help organize an **internal peer review** for you. This process takes time so you must have a fairly complete draft of your proposal completed four weeks before the agency deadline. Please notify the Research Development Officer of your proposal topic and your intention to seek peer review **six weeks** prior to the deadline to allow time for appropriate reviewers to be identified. The RDO will have two reviewers, a subject expert and a non-expert, review your application and provide written critiques.

If your study does not require funding, seek scientific review from your supervisory committee (in the case of student research) or colleagues.

Secure Funding

The funding opportunity you pursue will depend on: cost of your research; area of research; and competitiveness of your project and research team.

Consider tailoring/scaling your project to the funding opportunities where you are most likely to be successful. As you build your research track record you can expand the scope of your research projects and apply to larger, more competitive funding opportunities.

Internal Funding Opportunities

Summer Research Program
The Faculty of Dentistry provides funding for Dentistry and Dental Hygiene students to conduct a summer research project under the supervision of a faculty member. A call for project proposals is issued in January of each year.

Faculty of Dentistry Research Activity Support Award
Funding (up to $2,000) is available to support research related activities of members of the Faculty of Dentistry. Activities such as research training, grant preparation, pilot studies or dissemination are eligible. There are no deadlines, as applications are accepted until funds are expended. Contact mbrillant@dal.ca to learn more about the fund.

Faculty of Dentistry Research Fund
The Faculty of Dentistry Research Fund provides funding (up to $10,000 for one year) for research projects that will help build research capacity within the faculty. Projects must have direct relevance to dentistry, dental hygiene and oral health. Applications will only be considered from within the Faculty of Dentistry. Competitions are held three times per year. See the Faculty of Dentistry website for more information.

External Funding Opportunities

Contract Funding
Funding may be available from industry sponsors or government agencies (e.g. Health Canada) for specific research questions that are of direct interest to them. The Dalhousie Industry Liaison and Innovation Office may be able to help to identify potential industrial partnerships. Researchers who are approached by industry or government to conduct contract research must consult with Jody Rice Gallagher (Research Services Legal Advisor) for guidance in negotiating a contract.

Granting Agencies

- Nova Scotia Health Research Foundation
- Canadian Institutes of Health Research
- Natural Sciences and Engineering Research Council

Writing a Grant Proposal

The specific content and format of your grant proposal will depend greatly on the funding opportunity. Therefore one of the most important things to do is to read the funding opportunity instructions thoroughly and follow them closely.

TIPS:

- Start writing early.
- Write clearly with a logical flow. Use simple declarative sentences. Minimize the use of jargon and acronyms (and never use them in the lay abstract).
- Start each paragraph with a strong lead sentence.
- Don't forget to provide the big picture (why should the reviewer care?) and state your rationale(s) - why this research needs to be done.
- Make your objectives concise and precise – not vague or too general.
- Proof read – don't rely on a spell checker.
- Use up the allowed space but make it easy to read by using standard fonts and line spacing. Use headings and subheadings to organize and break up the text.
- Spend time on your lay abstract and one page summary. These may be the first things your reviewer will read and should convince the reviewer of the excellence of your proposal. This will put them in a positive frame of mind as they proceed with the review.
- Have your application critically reviewed by one or more colleagues who are not experts in your area of research. This means allowing time to have the review done before the submission deadline.
- Take any opportunity to learn how the review process works, whether through attending mock panel reviews at training sessions or by sitting in on the NSHRF Peer Review Observer Program.

Submitting an Application to an External Granting Agency

Submit your application along with a signed Investigator Checklist to the Research Development Officer at least 6 business days prior to the agency deadline. The Research Development Officer will review the application, collect the Dean's signature and forward to Research Services for signing by the V-P Research. Research Services will provide comments and either return the signature page to you for final submission to the granting agency, or electronically approve the grant online.

NOTE:

- As different competitions are at different stages in the transition from hard copy to electronic submission, please follow the instructions given in your specific competition regarding what format to submit your application and signatures.
- Check the Research Services website for instructions on internal submission procedures as deadlines may vary.

These tips and more detailed grants-writing information are available from:

- **CIHR Guidebook for New Principal Investigators**
- **The Art of Grantsmanship** (J Kraicer)

Regulatory Approvals

Clinical trials of drugs or medical devices may be subject to regulation by Health Canada.

Drug Trials

Clinical trials of drugs typically proceed through four phases[2]:

- Phase I clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).
- Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
- Phase IV studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Phase IV drug trials do not require approval from Health Canada if the product is to be used within its approved Notice of Compliance (NOC) or Drug Identification Number (DIN).

Phase I, II and III trials (i.e. drugs not yet marketed in Canada), phase IV trials where a drug will be used outside of its approved Notice of Compliance (NOC) or Drug Identification Number (DIN), and trials of drugs which have a conditional NOC (NOCc), require approval from Health Canada. The trial sponsor (or sponsor-investigator) must file a **Clinical Trials Application** (CTA) with Health Canada. Once approved, Health Canada will grant a No Objection Letter (NOL).

All clinical trials filed with Health Canada must comply with The International Conference on Harmonization (ICH) Guidance for Good Clinical Practice (GCP).

Helpful Links when filing a Clinical Trials Application:

- Health Canada: Clinical Trial Application
- Health Canada: Guidance for Clinical Trial Sponsors

Medical Device Trials

Medical device testing does not necessarily follow the four phases of drug trials. Clinical trials of medical devices may be subject to Health Canada regulation depending on a number of factors including:

- whether the device is licensed for sale in Canada,
- whether it will be used under its licensed indications and
- the class of the device.

To determine whether a trial must be filed with Health Canada, see Appendices B and C.

- Appendix B – Process Flow Map for Medical Devices Licensed in Canada
- Appendix C – Process Flow Map for Medical Devices not Licensed in Canada

To determine the Canadian classification of a medical device see:

- Health Canada: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices
- Appendix D – Canadian TPP Medical Device Classification Worksheet

If it is determined that the device trial is subject to Health Canada regulation, an application for **Investigational Testing Authorization** (ITA) must be filed by the manufacturer (or designate). The applicant must provide evidence of research ethics board approval, for each participating site, before Health Canada can issue authorization.

Contracts

Legally binding agreements between the organizations involved in your research may be needed.

The types of agreements required (if any) depend on the nature of the clinical trial.

Some examples of agreements include:

- drug or equipment supply agreement
- sponsor agreement
- site agreements
- materials transfer agreements

All agreements must be negotiated and signed on behalf of Dalhousie University. Consult with Jody Rice Gallagher (Research Services Legal Advisor) for guidance.

Helpful Links for filing an Investigational Testing Authorization Application:

- Health Canada: Preparation of an Application for Investigational Testing – Medical Devices
- Health Canada: Application for Investigational Testing Authorization
- Health Canada: Investigator's Agreement

Ethics Approval

Research conducted at Dalhousie University involving human participants, human tissue or human data, requires approval from a Dalhousie Research Ethics Board. Research involving animals, animal tissues and cells must be approved by the University Committee on Laboratory Animals.

Human Research Ethics

Dalhousie University has two University Research Ethics Boards which review all faculty and graduate thesis research involving human participants: The Health Sciences Research Ethics Board and the Social Sciences and Humanities Research Ethics Board.

Undergraduate course-based research that poses minimal risk to participants may be reviewed by the Faculty of Dentistry Research Ethics Board. (Contact mbrillant@dal.ca)

*Note: Research that will be conducted using Nova Scotia Health Authority or IWK facilities or data, or that will recruit patients of the NSHA or IWK **must** receive research ethics approval from the relevant health centre. Research that receives ethics approval from the NSHA or the IWK does not require additional approval from the Dalhousie Health Sciences Research Ethics Board.*

Researchers must be familiar with and follow the Dalhousie University Policy on the Ethical Conduct of Research Involving Humans as well as the Tri-Council Policy Statement (TCPS) Ethical Conduct for Research Involving Humans.

For both external and internally funded research, ethics approval must be in place before full funds will be released. Researchers who wish to access partial funding for the early stages of their research project before participants are involved may submit a Request for Release of Funds Agreement form.

Animal Ethics

The University Committee on Laboratory Animals is responsible for reviewing protocols involving the use of animals, animal tissues or cells. The committee determines if the proposed procedures are within established guidelines and are humane.

IS IT RESEARCH or QUALITY ASSURANCE?

Studies conducted for the purposes of quality improvement or program evaluation may also involve human participants, or their information, but are not necessarily considered "research".

To help identify whether your study requires review by a Research Ethics Board, use the Alberta Innovates – Health Solutions ARECCI Ethics Screening tool.

This tool will also help identify the level of risk posed to participants in your study.

Studies deemed to be quality assurance or program evaluation studies will be reviewed by Dr. Martha Brillant for any ethical considerations.

Helpful Links when applying for Ethics Approval:

- Dalhousie Policy on the Ethical Conduct of Research Involving Humans
- Tri-Council Policy Statement Ethical Conduct for Research Involving Humans
- Dalhousie REB application form and instructions
- Dalhousie Animal Ethics website
- Dalhousie Animal Ethics Forms

Register Trial

Registration of a clinical trial on a publicly accessible clinical trials registry is a requirement of Institutional Research Ethics boards, all member journals of the International Committee of Medical Journal Editors, as well as some funding agencies.

Health Canada encourages the registration of clinical trials in publicly accessible registries of clinical trials such as:

1. ClinicalTrials.gov
2. Current Controlled Trials International Standard Randomised Controlled Trials Number Register (ISRCTN)

Trials should be registered before the recruitment of participants begins. The trial sponsor or sponsor-investigator is responsible for registering the trial.

ClinicalTrials.gov

ClinicalTrials.gov is a registry and results database of clinical studies administered by the US National Institutes of Health. To register a study with ClinicalTrials.gov, visit here. To obtain a user account, contact Catherine Connors (Director – Research Ethics). Catherine is the administrator for Dalhousie's Protocol Registration System (PRS) account with ClinialTrials.gov and is responsible for providing investigators conducting trials at Dalhousie with access to the registry. This registry is free of charge.

ISRCTN Register

The ISRCTN is a simple numeric system for the identification of clinical trials worldwide. The ISRCTN Register will provide ISRCTNs to any clinical trial designed to assess the efficacy of health interventions in a human population, including both observational and interventional trials. The unique number enables tracking of the study through publications and reports. To apply for an ISRCTN trial ID visit here. There is a fee to apply.

Searching for Registered Trials

To search for existing trials use The International Clinical Trials Registry Platform Search Portal. This portal searches clinical trials registered on ClinialTrials.gov, ISRCTN, the EU Clinical Trials Register and many other country-specific clinical trials registries.

Clinical drug trials authorized by Health Canada since April 1, 2013 can also be searched on the Health Canada Clinical Trials Database.

Finalize Documents

Finalize all study documentation prior to beginning the study. Much of the documentation will have been prepared at the approvals stage and changes may require Research Ethics Board amendments.

Specific documentation will be dependent upon the nature of the study however clinical trials documentation often include:

Manual of Operations and Procedures (MOP) – The MOP transforms the protocol into specific guidelines that describe all elements of the study. It ensures consistency and quality control, particularly for multi-site trials. Guidelines for developing an MOP can be found here.

Case Report Forms - These are a series of forms used to collect data in a consistent manner. These may be paper or electronic forms. Commonly used forms include:

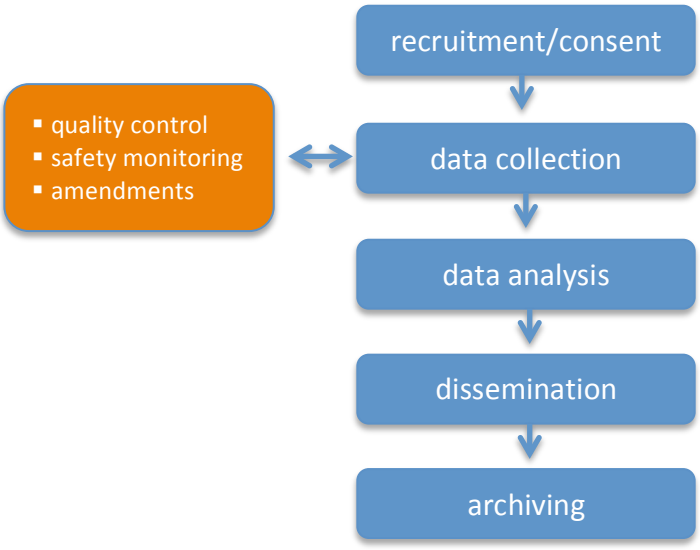
- inclusion/exclusion criteria
- demographics form
- randomization and enrollment form
- adverse event forms
- study completion form
- data collection forms (study specific)

Examples can be found here.

Regulatory Binder (Investigator Binder) – Essential documents that must be organized and retained for clinical studies. These include the protocol change log, REB approvals, blank case report forms, informed consent documents, regulatory approvals etc. Examples can be found here.

Begin Study

Study Flow Map



Reference List:

1. Adapted from: Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. 2007. Designing Clinical Research, 3rd ed. Lippincott Williams and Wilkins.
2. WHO International Clinical Trials Registry Platform http://www.who.int/ictrp/glossary/en/index.html

APPENDIX A

FACULTY OF DENTISTRY October 2012

RESEARCH PROJECTS

(Please contact Roberta at 494-1681 for questions or additional details)

1. DIRECT SALARY AND NON-SALARY COSTS:

Trained, on-site dental assistant and reception staff operate the Centre. Dental assistant and Receptionist employees salaries are charged at a rate of $29.00 per hour, prorated by the 1/2 hour when they are staffing an activity for which charges apply (see Facility Fee below). Time and a half after 4:30 pm and double time on weekends as available.

2. FACILITY FEE:

The following facility fees apply to Supporting Partners; and, study clubs and societies whenever there is a registration fee being charged to attendees. The facility fee is intended to cover equipment maintenance and upgrades, liability insurance, new equipment and infrastructure (building).

Clinical Care Facility		1/2 day	$600	(includes evening until 10pm if scheduled in advance)
(includes 10 complete cubicles & a 4 station KaVo lab)		per day	$1,200	(includes evening until 10pm if scheduled in advance)
(includes basic supplies e.g. masks,	**Per Cubicle**	1/2 day	$150	(includes evening until 10pm if scheduled in advance)
gloves & cubicle set up)	**Per Cubicle**	per day	$300	(includes evening until 10pm if scheduled in advance)
Clinical Care Facility & 3M Conference		1/2 day	$700	(includes evening until 10pm if scheduled in advance)
(includes 10 complete cubicles & a 4 station KaVo lab PLUS the 3M Conference Room)		per day	$1,400	(includes evening until 10pm if scheduled in advance)
3M Conference Room		1/2 day	$150	Rates include use of all a/v equipment in the room. Extra
(maximum 30)		per day	$275	equipment or services are charged as below.
Intra Oral Surgical Microscope in		1/2 day	$150.00	(includes support staff) (waived if paying Faculty fee)
Demonstration Suite		per day	$300.00	(includes support staff) (waived if paying Faculty fee)
Office Space (Room 1414)		per day	$30	(office space, computer, and phone - local calls only)
		weekly	$140	(office space, computer, and phone - local calls only)
		monthly	$280	(office space, computer, and phone - local calls only)

3. OTHER CHARGES:

a. Audio Visual:
- provided through Health Sciences Classroom Services (ISSCC).
- applies to equipment not already in the Centre and special set ups where an on-site technician is required. (e.g. sample rentals: third slide projector - $25.00; pointer - $20.00; video monitor - $20.00; extra computer data projector - $250.00/1/2 day)

b. Phantom Heads (___ available)
- Frasaco Phantom Heads - $30.00 / day ($15.00/half day)
- Dentoforms - $10.00 / day ($5/half day)
- Replacement teeth - will charge the current purchasing price / tooth

c. Portable dental chair
- $30/day; $15/half day

d. Instruments (includes sterilization of dental instruments)
- $15 per bag/tray

e. Radiology Services
- charges based on 100% of the NSDA Generalist Fee Guide

f. Patient Charts
- fees based on needs of individual project

g. Other services
- as invoiced (clinical materials, shipping and handling, security, cleaners, courier, taxi, long distance/fax, food, etc.)

Plus any applicable taxes.

All rates are subject to change with 30 days notice.

DISCLAIMER' REQUIRED

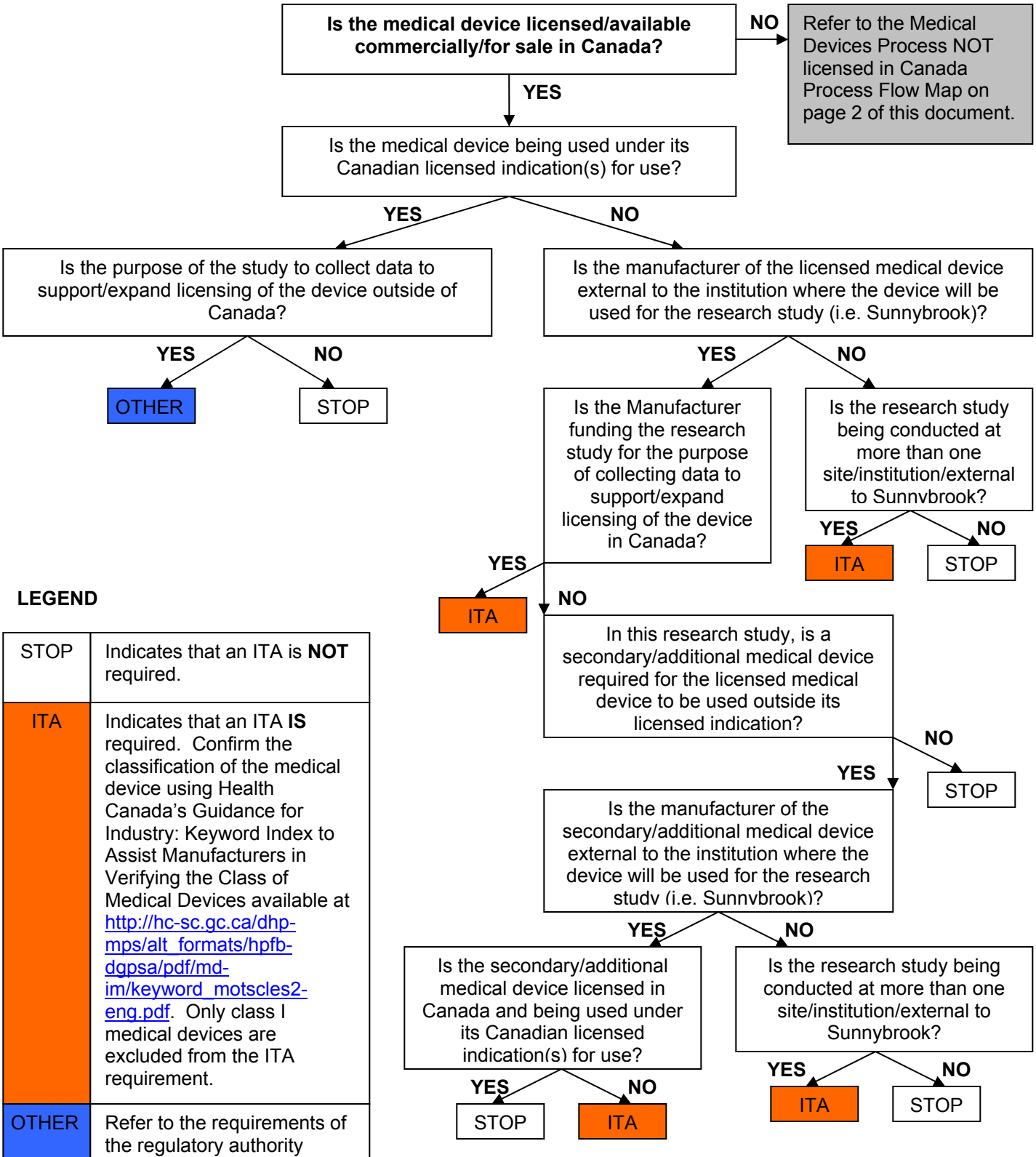
The following 'disclaimer' by the Assistant Dean, Clinic is now required on any **announcements or research outlines** to be held held in **facilities of the Faculty of Dentistry.**

"Disclaimer: This program is not sponsored by the Faculty of Dentistry, Dalhousie University nor does the fact that the program is being held on Dalhousie property in any way suggest that the content is approved by the Faculty or the University."

APPENDIX B

Process Flow Map: Medical Devices licensed in Canada

The purpose of this process flow map is to identify when an Application for Investigational Testing Authorization (ITA) to Health Canada is required for conduct of research using a medical device licensed in Canada.



LEGEND

STOP	Indicates that an ITA is **NOT** required.
ITA	Indicates that an ITA **IS** required. Confirm the classification of the medical device using Health Canada's Guidance for Industry: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices available at http://hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf. Only class I medical devices are excluded from the ITA requirement.
OTHER	Refer to the requirements of the regulatory authority where licensing/expanding of existing licensing is being sought.

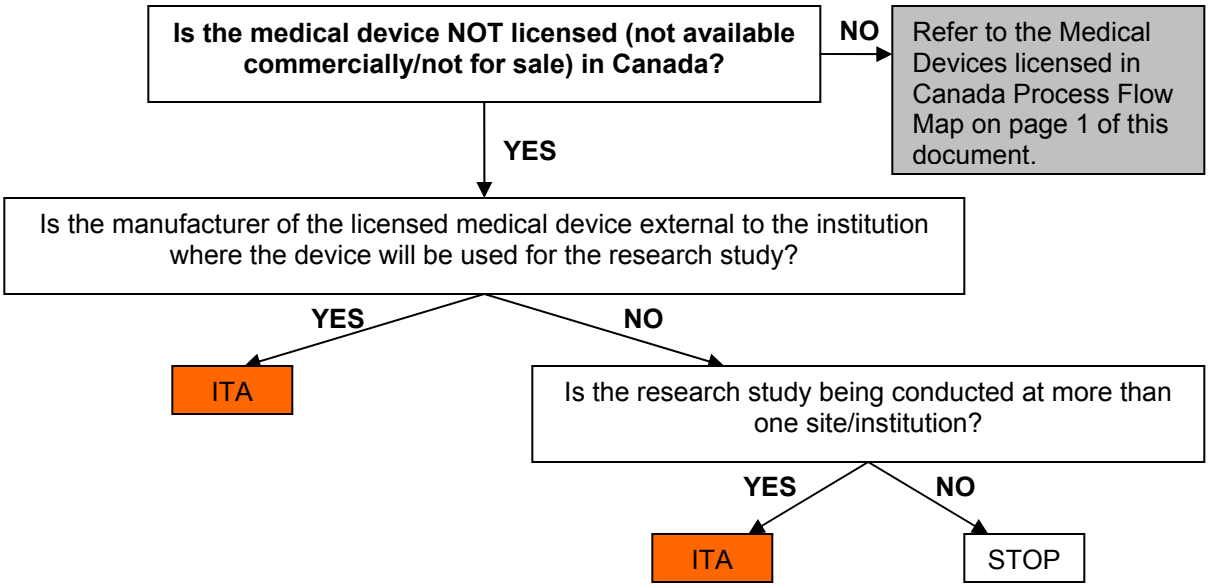
Please forward any exclusions or corrections to J. Michelle Filice, Process Manager, Clinical Studies Resource Centre, Sunnybrook Health Sciences Centre at michelle.filice@sunnybrook.ca or 416-480-6100 extension 88141.

SOURCE: SUNNYBROOK HEALTH SCIENCES CENTRE

APPENDIX C

Process Flow Map: Medical Devices NOT licensed in Canada

The purpose of this process flow map is to identify when an Investigational Testing Application (ITA) to Health Canada is required for conduct of research using a medical device NOT licensed in Canada.



LEGEND

STOP	Indicates that an ITA is **NOT** required.
ITA	Indicates that an ITA **IS** required. Confirm the classification of the medical device using Health Canada's Guidance for Industry: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices available at http://hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf. Only class I medical devices are excluded from the ITA requirement.

Please forward any exclusions or corrections to J. Michelle Filice, Process Manager, Clinical Studies Resource Centre, Sunnybrook Health Sciences Centre at michelle.filice@sunnybrook.ca or 416-480-6100 extension 88141.

SOURCE: SUNNYBROOK HEALTH SCIENCES CENTRE

Purpose:

To determine the classification of a medical device according to Canada's TTP.

Reference:

Based on Health Canada Therapeutic Products Programme Draft Guidance Document "Guidance for the Risk-Based Classification System" (May 4, 1998).

The information herein is based on the above guidance document

Section 1: Introduction

The classification of a medical device (MD) is a "risk based" system using a set of criteria that can be combined in various ways in order to determine the MD classification.

The scope of this document provides guidance for only non in vitro diagnostic devices (IVDD) rules.

Section 2: How to Carry Out the Classification of a MD

Rules for MD can be divided into four sets characterized as:

- Invasive Device – a MD that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.
- Non-invasive Device
- Active Device – a MD that depends for its operation on a source of energy other than the energy generated by the human body or gravity.
- Special Rules

The first step in determining the risk classification of a device is to check Special Rules 13 to 15 and the Table to Rule 16. If a device in question is not described by one of these Special Rules, then it should be determined if the device is either invasive, non-invasive or active.

A device could be described as both non-invasive and active, or invasive and active, and it is not unusual for more than one rule to apply to any give device.

The final classification is determined by the rule which assigns the highest risk classification.

It must be stressed that it is the "intended use" of the device that ultimately determines the devices classification.

Section 2.1: Time

The Canadian rule system only distinguishes between devices whose use if considered to be "Long Term" or not.

Long Term use implies "continuous use" for a period of 30 days or greater.

Section 2.2: Invasiveness

Any device that, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body is an Invasive Device.

A body orifice may be either a natural body orifice or a permanent artificial opening.

A surgically invasive device always implies that it enters through an artificially created opening.

Section 2.3: Application of Rules

a) If a device can be classified according to several rules, the highest possible class applies.
b) Classification must be consistent with the claims that appear on the labeling or that are contained within other information provided with the device such as brochures, operating manuals and directions for use.
c) If the intended use of the device is not clearly specified in the information accompanying the device, then the intended use will be deemed to be that accepted in general medical practice.
d) Multi-application equipment such as laser printers and identification cameras, which may be used in combination with MDs, and are not MDs, unless their manufacturer places them on the market with the specific restriction that they are intended to be used only with MDs.
e) The manufacturer of a MD consisting of component parts has the option of classifying the device as a system, or classifying each of the parts separately.

Sections 2.4: Device/Drug Combination and Classification Rules

The interpretation and approach of the TPP to the issue of Device/Drug Combination products is given in a separate Policy document.

Section 2.5: How to Use the Rule and The Decision Tree

The manufacturer must take into consideration all the rules in order to establish the proper classification of the MD. All device characteristics must be taken into account.

SOURCE: SUSAN BATCHILDER

Section 3: Classification Rules

Section 3.1 Invasive Rules

Section 3.1.1: Rule 1

(1) Subject to subrules (2) and (3), all SURGICALLY INVASIVE DEVICES are classified as Class II.

(2) A SURCIALLY INVASIVE DEVICE that is intended to diagnose, monitor, control or correct a defect of the CENTRAL CARDIOVASCULAR SYSTEM, the CENTRAL NERVOUS SYSTEM or of a fetus in utero, is classified as Class IV.

(3) A SURGICALLY INVASIVE DEVICE that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

Section 3.1.2: Rule 2

(1) Subject to sub-rules (2) and (3), all INVASIVE DEVICES that penetrate the body through a BODY ORIFICE or that comes into contact with the surface of the eye are classified as Class II.

(2) A device described in sub-rule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the eardrum is classified as Class I.

(3) A device described in sub-rule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.

(4) A device described in sub-rule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Section 3.2: Non-Invasive Devices Rules

Section 3.2.1: Rule 3

Despite Rules 1 and 2

(a) All denture materials and orthodontic appliances, and their accessories, are classified as Class II; and

(b) All SURGICAL OR DENTAL INSTRUMENTS are classified as Class I; and

(c) All latex condoms are classified as Class II.

Section 3.2.2: Rule 4

(1) Subject to sub-rule (1), all NON-INVASIVE DEVICES that are intended to come into contact with injured skin are classified as Class II.

(2) A device described in sub-rule (1) that is intended to used as a mechanical barrier, for compression or for absorption of exudations is classified as Class I.

SOURCE: SUSAN BATCHILDER

Section 3.2.3: Rule 5

A NON-INVASIVE DEVICE intended for channeling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Section 3.2.4: Rule 6

(1) Subject to sub-rules (2) and (3), a NON-INVASIVE DEVICE intended for modifying the biological or chemical composition of blood or other body fluids or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.
(2) A device described in sub-rule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.
(3) A device described in sub-rule (1) whose modification is accomplished by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Section 3.2.5: Rule 7

(1) Subject to sub-rule (2), all other NON-INVASIVE DEVICES are classified as Class I.
(2) A device described in sub-rule (1) that is;
   a. Intended to act as a calibrator, tester, or quality control support to another medical, or
   b. To be connected to an ACTIVE DEVICE that is classified as Class II, III or IV is classified as Class II.

Section 3.3: Active Device Rules

Section 3.3.1: Rule 8

(1) Subject to sub-rules (2) and (3), an ACTIVE DEVICE intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is Classified as Class III.
(2) A device described in sub-rule (1) that is intended to be used in radiographic mode is classified as Class II.
(3) Despite sub-rule (2), an ACTIVE DEVICE that is intended to be used for mammographies is classified as Cass III.

Section 3.3.2: Rule 9

(1) Subject to sub-rules (2) and (3), an ACTIVE DEVICE, including any dedicated software, intended to administer or withdraw energy to or from the body is classified as Class II.
(2) If the administration or withdrawal by a device describe in sub-rule (1) is potentially hazardous, taking into account the nature of the

SOURCE: SUSAN BATCHILDER

administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in sub-rule (2) that is intended to control the treatment of a patient's condition through a closed loop system is Class IV.

Section 3.3.3: Rule 10

(1) Subject o sub-rule (2), an ACTIVE DIAGNOSTIC DEVICE, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in sub-rule (1) that is intended to be used to monitor, assess or diagnose disease, a disorder, an abnormal physical state, or pregnancy, where erroneous readings could result in immediate danger, is classified as Class III.

Section 3.3.4: Rule 11

(1) Subject to sub-rules (2) and (3), an ACTIVE DEVICE, including any dedicated software, intended to administer or withdraw drugs, body fluids or other substances to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in sub-rule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

(3) A device described in sub-rule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Section 3.3.5: Rule 12

Any other device is classified as Class I.

Section 3.4: Special Rules

Section 3.4.1: Rule 13

A MD that is intended to be used for:

a. disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and
b. disinfecting or sterilizing a MD is classified as Class II.

Section 3.4.2: Rule 14

(1) Subject to sub-rule (2), any MD manufactured from or incorporating non-viable or viable, animal or human tissue or their derivative, or a product produced through the use of recombinant DNA technology, is classified as Class IV.

(2) A device described in sub-rule (1) that is only intended to come into contact with intact skin is classified as Class I.

Section 3.4.3: Rule 15

Any MD that is a material that is intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished MD.

Section 3.4.5: Rule 16

Despite Rules 1 to 15, a MD set out in column 1 of an item in the talbe to this rule is classified as the class set out in column 2 of that item.

Item	Column 1 – Medical Device	Column 2 - Classification
1	Breast Implants	IV
2	Tissue Expanders for breast reconstruction and augmentation	IV

Canadian Medical Device Classification

Complete one form for each intended use of the medical device

Device Name:	
Device Description:	
Intended Use:	
Duration of Use (check applicable duration)	__ Short-term (≤30d) __ Long-term (>30d)
Invasiveness: (check as applicable)	__ Invasive __ Body Orifice (state: _____) __ Surgically invasive __ Reusable surgical instrument __ Implantable device
Critical anatomical locations:	__ Not applicable __ Central circulatory system __ Central nervous sytem

For each Rule listed below, provide an explanation why the particular rule is applicable or is not applicable (N/A). If a particular Rule is not applicable, state N/A in the Class column, else report the appropriate Class according to the Rule.

Rule	Applicable? (Yes/No)	Explanation	Class (I, II, III, IV or N/A)
1-1			
1-2			
1-3			
2-1			
2-2			
2-3			
2-4			
3(a)			
3(b)			
3(c)			
4-1			
4-1			
5			
6-1			
6-2			
6-3			
7-1			

SOURCE: SUSAN BATCHILDER

7-2			
8-1			
8-2			
8-3			
9-1			
9-2			
9-3			
10-1			
10-2			
11-1			
11-2			
11-3			
12			
13(a)			
13(b)			
14-1			
14-2			
15			
16-1			
16-2			

The highest class listed for the stated used of this medical device is _____
via Rule _____

Completed by: _____ Date: _____

Reviewed by: _____ Date: _____

Approved by: _____ Date: _____

DALHOUSIE UNIVERSITY

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