Office of Research Ethics

UNIVERSITY OF WATERLOO

Human Participant Research Guidelines

Controlled Acts and the Delegation of Controlled Acts

Background

Concern for welfare and respect for persons are two of the three core guiding principles outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2010). This means that researchers and Research Ethics Boards (REB) need to "protect the welfare of participants and in some circumstances promote that welfare in view of any foreseeable risks associated with the research" (Chapter 1, p. 10). It also means that researchers and REBs need to ensure "individuals who participate in research do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible" (Chapter 3, p. 27). "Because research is a step into the unknown, its undertaking can involve harms to participants" (Chapter 2, p. 22) and "while researchers should attempt to estimate the occurrence of the relevant harms, this may be more difficult, or not possible, for new or emerging areas of research where no prior experience, comparable research or publications exist" (Chapter 2, p. 23).

As noted in the TCPS2, "risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur" (Chapter 2, p. 22). Therefore, it is the responsibility of researchers and REBs to conduct a risk-benefit assessment concerning the proposed research and through this process "minimize the risks associated with answering any given research question" and "attempt to achieve the most favourable balance of risks and potential benefits in a research proposal" (Chapter 1, p. 10). "A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk" (Chapter 2, p. 22) and it is the responsibility of both researchers and the REB to ensure prospective participants are provided "full disclosure of all information necessary for making an informed decision to participate in a research project" (Article 3.2, p. 30).

When conducting studies that could pose a risk to participants, researchers are also responsible for complying with any professional or governmental legal and regulatory requirements. There are instances when "the law affects and regulates the standards and conduct of research involving humans in a variety of areas ..." (Chapter 1, p. 12). This means that researchers need to be aware of the applicable laws that may exist in the conduct of their research and be able to identify the legal issues that exist. Moreover, researchers and REBs also need keep abreast of the "legal and regulatory requirements as they may vary depending on the jurisdiction in Canada in which the research is being conducted" (Chapter 1, p. 12).

The Regulated Health Professions Act of Ontario (RHPA, 1991) governs the various medical professions referred to in the RHPA and identifies a number of acts as being "controlled". This means that controlled acts may only be performed by specifically designated regulated health professionals legally authorized to perform designated controlled acts associated with their defined "scope of practice" when providing health care services to others. When an individual pricks his/her own finger for blood glucose monitoring or self-administers insulin or epinephrine by

injection, for example, these would not be considered to be controlled acts. Researchers who want to use a controlled act as a procedure in their research are seen as engaging in acts which can create risks for participants which are similar to those created when providing health care services using the same controlled acts.

The purpose of this guideline is to detail how the RHPA might apply to controlled acts conducted in a research environment at the University of Waterloo. The intent is to ensure that the risk undertaken by participants is not increased simply because the controlled act is conducted in a research environment rather than in the course of providing health care services. Nevertheless, a controlled act may be delegated by a regulated health professional to others who may or may not be members of a regulated health profession, so long as these guidelines and provisions of the RHPA are observed.

Purpose

These guidelines have been created to assist University of Waterloo researchers when planning studies using a "controlled act." These guidelines outline:

- what is a controlled act, the Regulated Health Professions Act, and the implications of using controlled acts in research;
- the process for delegating a controlled act and the responsibilities of the person delegating a controlled act;
- the forms of delegation that may be used and the factors that need to be considered in a supervisory plan for a delegate such as the suitability of the training, the training required by a delegate, and/or a description of their experience; and
- what is required when submitting a research ethics application when the proposed research involves a controlled act.

The appendices list each of the controlled acts and the controlled acts that may be performed by the various regulated health professionals. These guidelines are meant to be a living document. Changes may be required if there are revisions to the RHPA or as the research conducted using controlled acts at the University of Waterloo grows and evolves.

Key Issues to Consider

1. Is the study procedure a controlled act according to the RHPA?
2. Is the person who will be performing the controlled act a member of one of the regulated health professions?
3. Does the person who will be performing the controlled act have adequate skills, training, and competency to perform the act?
4. Is there any special training or certification needed by an individual to perform the controlled act?
5. Who will delegate the controlled act?
6. What level of supervision is required by the delegator given the delegate's training and experience?
7. Is the delegate willing to accept the delegation?

Questions and Answers

1. What is a controlled act?

A controlled act is a medical procedure defined in the Regulated Health Professions Act (RHPA, 1991 as amended), where there may be a high or significant element of risk or harm to an individual. Controlled acts are regulated by provincial legislation and may only be performed, or delegated, by a regulated health professional as outlined in the RHPA.

2. What is the Regulated Health Professions Act (RHPA)?

The RHPA is provincial legislation that directs the scope of practice of health professions in Ontario. There are 21 Health Profession Colleges regulated under the RHPA at present. Some of these include the:

- College of Physicians and Surgeons of Ontario
- College of Nurses of Ontario
- College of Psychologists of Ontario
- College of Optometrists of Ontario
- Ontario College of Pharmacists

3. How do I know if the procedure I would like to use in my research is a controlled act?

The RHPA identifies 14 controlled acts. Some of these controlled acts are:

- performing a procedure on tissue below the dermis (e.g., finger prick or venipuncture);
- performing a procedure below the surface of a mucous membrane, in or below the surface of the cornea;
- administering a substance by injection or inhalation (e.g., anesthetic, oxygen);
- applying or ordering the application of a form of energy (e.g., ultrasound, MRI); or
- prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.

4. *Has there been a legal opinion concerning the use of controlled acts in research?*

The University of Waterloo Secretariat, on behalf of the Office of Research Ethics and the two University of Waterloo Research Ethics Committees, has obtained legal advice that confirmed the legal requirements around the use of controlled acts in research. These include:

- no person shall perform a controlled act in the course of providing health care services to an individual unless the person is a member authorized by a health profession to perform the controlled act as outlined in the prohibition in the RHPA;
- the prohibition outlined above also applies to controlled acts when performed in health-related research;
- the Health Profession Colleges can legally take steps to prevent non-members from administering controlled acts including under an appropriate delegation arrangement supervised by a member; and
- when a non-member administers a controlled act under a delegation arrangement, the standard of care is the same as if the health professional administered the controlled act.

The University of Waterloo is expected to follow the same standard of care for each controlled act as has been established by the regulated Health Profession Colleges through the RHPA. In other words, the main legal principle is that the process of delegating a controlled act should not increase the risk level for participants and the processes and procedures included in the research protocol should reflect the relevant Colleges' requirements.

5. If I am to use a controlled act in my research what is the process for ethics review?

Any research conducted at the University of Waterloo using a controlled act is ineligible for delegated review through the ORE and must be reviewed by the Clinical Research Ethics Committee (CREC) at one of their monthly meetings. All of the 14 controlled acts outlined by the RHPA are considered to be greater than minimal risk. Appendix A outlines the 14 controlled acts.

6. I am planning to use ultrasound in my research. Is this a controlled act?

One of the controlled acts identified in the RHPA is applying or ordering the application of a form of energy. One form of applying energy is sound waves for ultrasound. Most researchers at the University of Waterloo who use ultrasound do so for research purposes only and not for diagnostic reasons. Using ultrasound for diagnostic reasons means a person is using the ultrasound as a device for the analysis or detection of diseases or other medical conditions (Dictionary.com, 2013).

The RHPA currently only regulates sound waves for diagnostic ultrasound as a controlled act; however the RHPA defines "diagnostic ultrasound" as "ultrasound that produces an image or other data" without explicitly stating that it must be used for diagnosis. Although University of Waterloo researchers are not using ultrasound for diagnostic reasons as conventionally understood, according to the RHPA using an ultrasound to produce an image or other data is defined as diagnostic ultrasound and must therefore follow the controlled act and delegation procedures outlined in the RHPA. Moreover, researchers who use ultrasound for research purposes to produce an image or other data must also follow Health Canada's guidelines for the safe use of diagnostic ultrasound in addition to the RHPA.

Ultrasound for therapeutic purposes consists of stimulating tissue beneath the skin's surface using sound waves to aid with the treatment of such things as muscle, tendon, or ligament injuries, chronic pain, or muscle tension or strains. Ultrasound for these purposes is not a controlled act and thus not regulated by the RHPA.

7. I want to use electromyography as one of the procedures in my research. Is this a controlled act?

Faculty and students at the University of Waterloo, such as those in the Department of Kinesiology, use various forms of electromyography in their research. Electromyography, or EMG, involves examining the electrical activity of the muscles. Some forms of EMG require an intramuscular electrode (i.e., needle) being inserted through the skin. A technique such as this would be viewed as greater than minimal risk, and also a controlled act according to the RHPA, and will require review by the Clinical Research Ethics Committee at one of their monthly meetings.

Other forms of EMG, such as surface EMG, is "a technique in which electrodes are placed on (not into) the skin overlying the muscle to detect the electrical activity of the muscle" (MedicineNet.com, 2013). Surface EMG is a non-invasive, passive procedure that does not apply energy to the body

and therefore is not a controlled act. Studies using strictly surface EMG can be reviewed through the ORE delegated review process. However, if an electrical charge will be emitted this would constitute a controlled act and require review by the Clinical Research Ethics Committee

Other examples of surface techniques include electrocardiography (ECG) for recording heart responses and electroencephalography (EEG) for recording brain activity. In all of these techniques the prefix electro refers to the electrochemical physiological properties of the cells/systems from which they are generated and they are all passive recording techniques. The prefix electro does not refer to electricity being applied to the body. Most surface techniques do not apply energy such that they are only a passive receiving function. No extra applied electrical energy is sent to the human body. The passive receiver (i.e., electrode) is attached to the surface of the skin to measure the natural electrical current which already exists within the human body as a result of the activity or movement which naturally occurs.

8. I will be asking study participants to inhale a gas, such as oxygen, for the study I am conducting. Is this a controlled act?

Administering a substance by injection or inhalation is considered a controlled act according to the RHPA regardless of the type of gas or amount. Studies that will ask study participants to inhale a gas will be reviewed by the Clinical Research Ethics Committee at one of their monthly meetings.

9. Am I able to perform a controlled act for my research?

Although the RHPA stipulates that no one can perform a controlled act unless the law that applies to his/her health profession clearly allows him/her to do so, the RHPA does allow for controlled acts to be delegated to a non-member, unregulated health professional.

10. I have been conducting research for many years using controlled acts. What am I now required to do?

All future research ethics applications involving controlled acts must be fully compliant with this guideline and ORE policies. If you are currently conducting research involving the use of a controlled act and wish to determine if you are compliant please contact the staff in the Office of Research Ethics or email ohrac@uwaterloo.ca.

11. What is delegation of a controlled act?

Delegation is a process that grants authority to an unregulated health professional to perform a controlled act. This individual is usually not independently authorized under the RHPA to perform the act and has no statutory authority to perform the act.

12. Who can delegate a controlled act?

Only regulated health professionals specifically authorized under the RHPA to perform a specific controlled act may delegate that specific controlled act. Moreover, regulated health professionals may only delegate acts they are authorized to perform according to the RHPA. To effectively delegate a controlled act, regulated health professionals must be a member in good standing with their respective regulatory College and must follow any guidelines which their College may have enacted concerning delegation of controlled acts (e.g., College of Physicians and Surgeons of Ontario Policy Statement on Delegation of Controlled Acts, College of Nurses of Ontario Reference Document on RHPA: Scope of Practice, Controlled Acts Model).

13. What controlled acts may be delegated?

Regulated health professionals may only delegate a controlled act they are authorized to perform as outlined by the RHPA. A summary can be found in Appendix B. If a researcher, for example, wants to collect blood from study participants using venipuncture they must have a regulated health professional (i.e., a delegator) grant the authority to the researcher (i.e., the delegate) to perform this controlled act.

It is important to note that even though members of the College of Physicians and Surgeons of Ontario, for example, may perform 13 of the 14 controlled acts themselves they may only delegate 12 of those 13 controlled acts. Physicians and surgeons may not perform the controlled act of "fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning" and may not delegate the act of "treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning".

Similar prohibitions as the one outlined above may exist for other regulated health professionals. Researchers and delegators must be familiar with the RHPA to know what controlled acts may be performed or delegated by a regulated health professional, and which may not. A list of the controlled acts that may be performed and delegated by the members of the 21 regulatory Colleges can be found in Appendix B.

14. What requirements are there to be a delegator?

Regulated health professionals must confine their practice to those areas where they are trained and experienced and must not delegate a controlled act if he/she is not competent to perform the controlled act personally. The professional expectations concerning the delegation of a controlled act are to be based on the following principles:

a) in every instance of delegation, the primary consideration must be the best interests of the individual/study participant,
b) an act undertaken through delegation must be as safe and effective as if it had been performed by the delegating health professional, and
c) the responsibility for a delegated controlled act always remains with the delegating health professional.

The delegate must be able to carry out the controlled act as competently and safely as the delegator. Therefore, the delegator must:

- never assume that the delegate has the knowledge, skill, and judgement required to perform the act,
- ensure the delegate has the appropriate knowledge, skill and judgement to perform the delegated act, and
- be satisfied that the individual to whom the controlled act will be delegated has the appropriate knowledge, skill, and judgement to perform the delegated act.

15. What are a delegator's responsibilities?

A delegator's responsibilities are to do the following:

a) Conduct an assessment of risk

A delegator, in conjunction with the principal investigator/faculty supervisor, must analyze and assess the potential harm associated with a controlled act. They must be satisfied that the training, experience, and judgement of the person to whom the controlled act is being delegated is equivalent to what a regulated licensed health professional is expected to know or be able to do. They must also be satisfied that by delegating the controlled act to a non-regulated health professional the risks associated with the procedure are no greater than what might be experienced if the delegate was a regulated health professional.

A delegator may decide that performing certain procedures (or performing them with certain populations or individuals) carries such a high risk that only a regulated health professional should perform the procedure (e.g., physician or nurse). In such instances where the act of delegation would increase the risk to study participants, the delegator should not delegate the procedure to an unregulated health professional.

As part of the risk analysis undertaken to determine whether the act can be appropriately delegated, the delegator may identify resources and equipment necessary to reduce risks to study participants. The principal investigator/faculty supervisor must ensure that such resources and equipment are available on site where the delegated act is being performed.

b) Supervise the delegate

When delegating a controlled act, accountability and responsibility remains with the delegator. A delegator must provide the appropriate level of supervision to ensure the controlled act is performed properly and safely. The nature of the supervision may vary according to the assessment of risk, taking into account the specific controlled act being delegated, the circumstances under which the controlled act will be performed, and the knowledge, skill, and judgement of the delegate.

The delegator must ensure there is a communication mechanism that will enable the delegate to contact the delegator (and principal investigator/faculty supervisor for student research) immediately, if necessary. Researchers must be prepared for situations that may arise if a study participant were to experience significant pain or become hurt or injured as a result of the study procedure and require medical attention. Prior to delegating a controlled act, the delegator must ensure that a process has been put in place to ensure that any adverse event or protocol deviation that could occur will be managed appropriately, either by the delegate, the principal investigator/faculty supervisor, or by themselves, as the delegator. A communication mechanism must be in place so that the delegator is informed of any actions taken by the delegate (or principal investigator/faculty supervisor) to manage the adverse event or protocol deviation. All adverse events must be reported to the Director, Office of Research Ethics, within 24 hours of the event. Protocol deviations are to be reported within 7 days.

c) Conduct ongoing monitoring and evaluation

If the particular controlled act is routinely delegated the delegator must ensure there is ongoing monitoring and evaluation of the controlled act being performed. This includes ensuring the

delegate's knowledge and skills are up to date and current. The delegator will need to determine how often and the time period when evaluations of the delegation process itself should be conducted to ensure the procedures continue to be performed safely and effectively. In certain instances, the delegator may need to monitor the delegate regularly to ensure that directives are being implemented appropriately and are not resulting in unanticipated outcomes or occurrences.

16. What are a delegate's responsibilities?

A delegate performing a controlled act under a delegation arrangement is responsible for the same standard of care as if the regulated health professional, the delegator, was administering the controlled act. There should be no increased risk to individuals because a delegate is performing the controlled act.

Delegates are also responsible for ensuring they follow, for example, the procedures detailed in the approved Standard Operating Procedure (SOP), comply with the approved research protocol, inform the delegator and principal investigator/faculty supervisor if the equipment is not in good working order, notify the delegator and principal investigator/faculty supervisor immediately of any adverse event/occurrences and the ORE within 24 hours, ensure training/certification is current, and notify the delegator and principal investigator/faculty supervisor of any processes that have not been outlined in the SOP. This list is not exhaustive, but given simply by way of example.

17. If the person performing the controlled act is a regulated health professional do they require a delegator?

If the person performing the controlled act is a regulated health professional who is authorized to perform the controlled act they do not require delegation of that act as outlined in Appendix B. However, to effectively perform a controlled act, regulated health professionals must be trained and certified to perform the act, be competent to perform the act, be a member in good standing with their respective regulatory College, and follow the guidelines which their College has enacted concerning delegation of controlled acts. For example, if a nurse is to collect blood samples using venipuncture he/she does not require a delegator. However, if a nurse is to perform ultrasound that produces an image or data for research purposes they need to consult with their College concerning additional training and certification that will be needed to perform this controlled act without delegation. In most instances, if a regulated health professional is to perform a controlled act they are not regulated to perform they must have that act delegated to them by a regulated health professional who is authorized to perform the act.

18. I will be working with a clinic or laboratory to conduct my research and their staff will be performing the controlled act. Is there anything I need to do?

A regulated health professional located external to the university may perform a controlled act for the purposes of a specific research project where the laboratory or clinic is legally able to perform the controlled act. Researchers need to make their own arrangements with the medical laboratory, hospital, or clinic to perform a controlled act with their study participants. The information-consent letter for participants must make it clear these procedures are performed for research purposes only.

Arrangements for performing a controlled act for research purposes may occur in some cases through an agreement or statement of work where the physician or medical director of the laboratory or clinic provides the medical oversight. Researchers need to ensure that any agreements or statements of work indicate the laboratory or clinic has the appropriate licence(s)

in place, employs qualified individuals to perform the procedures needed for the research, and has the appropriate insurance in place. A copy of the agreement or statement of work needs to be made available for review by the REC, if requested. Researchers are encouraged to contact the Financial Reporting and Insurance Analyst in the Department of Finance at the University of Waterloo if they require additional information or advice on insurance, and the Manager of Procurement and Contract Services as they prepare to contract with parties outside of the university.

A list of the controlled acts that may be performed by the various regulated health professionals can be found in Appendix B.

19. What training is required for a delegate who is an unregulated health professional to perform a controlled act?

The delegator is responsible for determining the type of training that would be required for an unregulated health professional to perform a controlled act. Ideally, controlled acts performed in research should be performed by a regulated health professional who is authorized to perform the act. However, other alternatives may be considered suitable if:

a) the delegation of the controlled act is to a regulated health professional, who is not authorized to perform the act, but has the appropriate training/education/certification/skills to perform the act as determined by the regulated health professional giving the delegation,

b) the delegation of the controlled act is to an unregulated health professional who has obtained the appropriate training/education/certification to perform the act and their skills are assessed by the delegator as being equivalent to that of a regulated health professional who is authorized to perform the act, or

c) in instances when there is no current training/education/certification available, delegation of a controlled act to an unregulated health professional may be appropriate when the delegate has completed the appropriate internal training/education, their skills and competency have been assessed by the delegator as being appropriate, and the delegator monitors and supervises the delegation.

20. Are there any restrictions for a delegate to perform a controlled act?

Some regulatory colleges in Ontario place limits on the types of controlled acts that their members may be authorized to carry out through delegation in addition to the limitations set out in the RHPA. The delegate is responsible for informing the delegator of any regulations, policies, and/or guidelines of his/her regulatory body that would prevent him/her from accepting the delegation. If a potential delegate declines to perform a controlled act for any reason, he/she cannot be compelled by the delegator to accept the delegation.

In situations where the delegator becomes aware that the delegate is not permitted to perform a controlled act by reason of restrictions placed on him/her by their regulatory College, the delegator must not delegate the act to that individual. For example, the College of Nurses of Ontario (CNO) places restrictions on nurses performing diagnostic ultrasound as specific training must be completed before a nurse can perform this act. Registered nurses who are members of the CNO should not be asked to perform ultrasound as part of a research protocol if doing so contravenes their College's requirements.

If a delegate has credentials or licences obtained in other jurisdictions but does not have certificates of registration or licenses which are valid in Ontario, a delegator must follow the same protocols that apply when delegating to any other individual who is not a regulated health professional in the province of Ontario. Although a delegator cannot rely exclusively on extra-provincial credentials or licences to determine whether a potential delegate has the requisite knowledge, skill, and judgement to safely perform a controlled act, such credentials or licenses may be taken into account when assessing the individual's competency and when determining the level of supervision required.

21. What are the types of delegation that may be used and what oversight/supervision is required?

According to the policy statement set out by the College of Physicians and Surgeons of Ontario, delegation can take place through either a direct order or a medical directive. A direct order relates to only one person and initiates a specific procedure to be delivered at a specific time. A direct order takes place after a physician-patient relationship has been established.

A medical directive, however, is a written order that pertains to any person who meets the criteria set out in the medical directive and might apply in research environments When the directive specifies controlled acts that require delegation, the directive gives authority to the delegate to carry out the acts specified in the directive, provided that certain conditions and circumstances exist. Although medical directives are commonly given before a physician-patient relationship has been established, it is expected that the physician will establish a relationship with the patient before the patient is no longer under their care or oversight.

A delegator not only has a responsibility to the individuals subject to the controlled act as outlined above but they must also provide oversight and supervision for the delegate performing the act. The delegator must ensure that the appropriate levels of supervision occur given the delegate's specific level of training, experience, and credentials. A medical directive gives authority to the delegate identified to carry out the procedure(s) that are specified in the directive, provided that certain conditions and circumstances exist (e.g., completion of specific training, ongoing monitoring for performing the act, study participants meet specific inclusion/exclusion criteria, etc.) Delegation and supervision arrangements can take many forms but two possible arrangements that researchers may consider are outlined below:

a) Medical Directive with Direct Supervision

- A directive with direct supervision involves the delegate being under the supervision of the delegator such that the delegator may need to be physically present in the laboratory where the act is being performed and/or the delegator is overseeing the procedure at regular intervals.
- Situations requiring this higher level of supervision and scrutiny may include instances when:
    i. the controlled act is judged by the delegator to present significant risks,
    ii. the controlled act has the potential for adverse effects to the study participants,
    iii. the delegate has never performed the controlled act previously (e.g., student researcher),
    iv. there is no available arm's length training or certification available for the delegate, or
    v. the study procedure is new or novel and has never been performed in a clinical setting or for research purposes.

- A delegator can deem the delegate suitable by verifying in a supervisory plan that:
    i. the delegate, by virtue of their education, possess the relevant skills, training and credentials to perform the controlled act or the delegate has completed the appropriate training or certification outlined by one of the regulated health profession Colleges, and
    ii. the delegator assesses the competency of the delegate to be equivalent to that of a regulated health professional who is authorized to perform the act.

b) Medical Directive with Indirect Supervision

- A directive with indirect supervision involves a delegator authorizing a delegate to perform a specific controlled act on study participants who meet the criteria set out in the directive without direct supervision by the delegator.
- This directive gives authority to the delegate to carry out the procedure(s) that are specified in the directive, provided that certain conditions and circumstances exist (e.g., completion of specific training, ongoing monitoring for performing the act, study participants meet specific inclusion/exclusion criteria, etc.)
- Situations requiring this lower level of supervision may include instances when:
    i. the delegate has completed the appropriate training or certification outlined by one of the regulated health profession Colleges,
    ii. the delegate has performed the controlled act a significant number of times such that the delegator assesses the competency to be equivalent to that of a regulated health professional who is authorized to perform the act,
    iii. there have been no previous adverse events as a result of the delegate performing the controlled act or similar controlled acts, and
    iv. the delegate, by virtue of their previous or ongoing education, possesses the relevant skills, training and credentials to perform the controlled act.

22. Several members of my staff have many years of experience and are qualified individuals in performing certain controlled acts but they are not regulated health professionals. What do I need to do to seek ethics clearance for them to perform a controlled act for my research?

The following steps are to be followed:

i. Write a standard operating procedure (SOP) detailing the process to be undertaken for delegating the controlled act including details outlining the specific procedures and equipment to be used to perform the controlled act,
ii. Collaborate with a regulated health professional who is licensed to perform the controlled act and is willing to delegate the act to a non-regulated health professional,
iii. Ensure the delegator assesses the adequacy and sufficiency of the credentials, skills, and training of the person who will perform the controlled act (i.e., delegate) and make a determination if direct or indirect supervision is required,
iv. Complete the Delegation of a Controlled Act and Medical Directive form, and
v. Submit a research ethics application (Form 101).

The procedures section in the research ethics application (Form 101) needs to outline the controlled act(s) to be performed and which member of the research team will be performing the act(s). The accompanying Standard Operating Procedure (SOP) and Delegation of a Controlled Act and Medical Directive form is to be submitted with the Form 101. A SOP is needed to detail

the steps that will be taken by the staff members (i.e., delegate) to perform the controlled act. The date the SOP was created must be clearly stated along with the name of the individual(s) who prepared the SOP and the date when it will be next reviewed to ensure it is current and complete. An SOP template is available.

If the proposed research will be using a SOP from a study that has already received ethics clearance from the Clinical Research Ethics Committee it is fine to reference the ORE number and clearance date in the Procedures section of the Form 101 in all future applications. Copies of the SOPs that have already received ethics clearance will be maintained in a file by the ORE and made available to the Clinical Research Ethics Committee for their review upon request.

23. What must my potential study participants know about my research and the use of a controlled act?

The principal investigator/faculty supervisor, in collaboration with the delegate and delegator, must ensure that study participants provide informed consent for the performance of a controlled act. This includes providing the study participant with appropriate information about the person who will perform the controlled act (i.e., the delegate) and the person delegating the act (i.e., the delegator). The participant must be provided information about how the delegate has obtained authorization to perform the controlled act. The participant's consent must be documented in writing. Researchers are recommended to review the sample information-consent letters available on the ORE website. The suggested wording may aid in creating your own letter.

24. What do I need to include with my research ethics application that involves use of a controlled act?

A. Identify the name of the delegator in the Collaborator section on the research ethics application (Form 101).

B. The methods/procedures section in the research ethics application (Form 101) must clearly detail:
    a) the type of delegation directive being given (i.e., medical directive with direct supervision or indirect supervision) or if the acts are being performed through a negotiated agreement with hospital or medical laboratory; and
    b) if a medical directive, the name(s) of the delegator and delegate(s).

C. The attachments/appendices may include one of more of the following:

    a) Delegation of Controlled Act and Medical Directive Form
        i. Each delegate performing the controlled act must be listed on the form.

    b) Standard Operating Procedure (SOP)
        i. A SOP is to be prepared detailing the steps that will be undertaken by a delegate(s) to perform the controlled act(s).
        ii. The date the SOP was created must be clearly stated along with the name of the individual(s) who prepared the SOP and the date for when it will be next reviewed to ensure it is current and complete.
        iii. A copy of the SOP is to be submitted with the Form 101. If the study will be using a SOP from a previous study a reference to the ORE number and clearance date in the Procedures section of Form 101 will suffice.

c) Health and Safety Hazard Analysis Form
   i. If equipment will be used to perform the controlled act(s), a health and safety hazard analysis must be completed in conjunction with the University of Waterloo Safety Office when the equipment is first installed.
   ii. A copy of the current health and safety hazard analysis report must be submitted with each Form 101.
   iii. It is at the discretion of the Clinical Research Ethics Committee (CREC) to request the health and safety hazard analysis be updated if the vulnerability of participants changes over time or if other risk or hazard considerations arise.

d) Agreement/Statement of Work with Clinic or Laboratory
   i. The agreement/statement of work should identify if it is for a single participant or for a group of participants who meet specific inclusion or exclusion criteria.
   ii. A copy of the agreement/statement of work is not required as part of the Form 101 submissions however a copy needs to be made available for review by the CREC, if requested.

Appendix A

List of Controlled Acts as outlined in the Regulated Health Professions Act of Ontario, 1991

A controlled act is any one of the following done with respect to an individual:

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.

2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.

3. Setting or casting a fracture of a bone or a dislocation of a joint.

4. Moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust.

5. Administering a substance by injection or inhalation.

6. Putting an instrument, hand or finger,

i. beyond the external ear canal,
ii. beyond the point in the nasal passages where they normally narrow,
iii. beyond the larynx,
iv. beyond the opening of the urethra,
v. beyond the labia majora,
vi. beyond the anal verge, or
vii. into an artificial opening into the body.

7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.

8. Prescribing, dispensing, selling or compounding a drug as defined in the *Drug and Pharmacies Regulation Act*, or supervising the part of a pharmacy where such drugs are kept.

9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.

10. Prescribing a hearing aid for a hearing impaired person.

11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning. *(Note: Physicians are not authorized to perform this controlled act nor delegate it.)*

12. Managing labour or conducting the delivery of a baby.

13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.

14. Treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning. *(Note: Physicians are not permitted to delegate this controlled act.)*

Appendix B

These web links will take you to the Regulated Health Profession College websites and to the Regulated Health Professions Act (RHPA) for the 21 regulated health professions in Ontario.

Although the various RHPA outlines the scope of practice and authorized acts that may be performed by individuals licensed through a health profession college, do not only review the RHPA; also review the College information as to what controlled acts the profession can perform. There may be situations where the RHPA states a profession can perform a certain controlled act however the government may not have formally approved for that profession to perform the act as of yet.

Health Profession College	Regulated Health Professions Act (RHPA)
College of Audiologists and Speech-Language Pathologists of Ontario	Audiology and Speech-Language Pathology Act
College of Chiropodists of Ontario	Chiropody Act (also regulates podiatrists)
College of Chiropractors of Ontario	Chiropractic Act
College of Dental Hygienists of Ontario	Dental Hygiene Act
College of Dental Technologists of Ontario	Dental Technology Act
Royal College of Dental Surgeons of Ontario	Dentistry Act
College of Denturists of Ontario	Denturism Act
College of Dietitians of Ontario	Dietetics Act
College of Massage Therapists of Ontario	Massage Therapy Act
College of Medical Laboratory Technologists of Ontario	Medical Laboratory Technology Act
College of Medical Radiation Technologists of Ontario	Medical Radiation Technology Act
College of Physicians and Surgeons of Ontario	Medicine Act (regulates physicians and surgeons)
College of Midwives of Ontario	Midwifery Act
College of Nurses of Ontario	Nursing Act
College of Occupational Therapists of Ontario	Occupational Therapy Act
College of Opticians of Ontario	Opticianry Act
College of Optometrists of Ontario	Optometry Act
Ontario College of Pharmacists	Pharmacy Act
College of Physiotherapists of Ontario	Physiotherapy Act
College of Psychologists of Ontario	Psychology Act
College of Respiratory Therapists of Ontario	Respiratory Therapy Act

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