Navigating Ethical Practices for Human Participant Research

A guidebook from the Queen's University Research Ethics Boards

Queen's UNIVERSITY RESEARCH

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Queen's University is situated on **traditional Anishinaabe and Haudenosaunee Territory**.

Preface

This guidebook is primarily intended for those who will be conducting human participant research, including primary investigators, research students, and research staff.

Research ethics is a critical element of academic studies and research activities. It ensures that a researcher conducts their work in a manner that respects the autonomy, dignity, rights, and well-being of those affected by the research process. This includes participants, collaborators, research staff, institutions, communities, and the public. It ensures that researchers adhere to ethical standards and procedures.

Research ethics considers the following 6 elements:

- Assessing potential risks associated with a study.
- Informed consent is obtained.
- Ensuring proper safeguards are in place.
- Adequate protection for confidential information is provided.
- All data collected during a study is accurate and reliable.
- Determining what level of review is required for approval.

By adhering to these elements, researchers can ensure that their studies are conducted ethically and responsibly.

This guidebook will provide you with:

1. An overview of the importance of research ethics and the principles outlined in the Canadian ethical guiding document – the Tri-Council Policy Statement version 2 (TCPS 2).
2. An overview of the processes that direct the research review process at Queen's University and its affiliated hospitals.

Contents

Key Terminology

Abbreviations	Definitions
CIA	Centre Initial Application
CIH	Canadian Institutes of Health Research
DTA	Data Transfer Agreements
GREB	General Research Ethics Board
HC	Health Canada
HDH	Hotel Dieu Hospital
HSREB	Health Sciences and Affiliated Teaching Hospitals Research Ethics Board
KGH	Kingston Health Sciences Centre
KGHRI	Kingston General Hospital Research Institute
KHSC	Kingston Health Sciences Centre
LOI	Letter of Information
MTA	Materials Transfer Agreements
NOL	No Objection Letter
NSERC	Canadian Institutes of Health Research
PCC	Providence Care Centre
PDSA	Plan, Do, Study, Act
PE	Program Evaluation
PHI	Personal Health Information
PHIPA	Personal Health Information Protection Act

Abbreviations	Definitions
PI	Principal Investigator
PIA	Provincial Initial Application
QA	Quality Assurance
QI	Quality Improvement
REBs	Research Ethics Boards
REO	Research Ethics Office
SSHRC	Social Sciences and Humanities Research Council
SWOT	Strength, Weakness, Opportunities or Threats
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
VPR	Vice-Principal Research

1 Tri-Council Policy Statement 2 (TCPS 2)

The Tri-Council Policy Statement: **Ethical Conduct for Research Involving Humans** (TCPS 2) is a set of ethical guidelines for research involving humans in Canada. The policy was adopted, in 1998, by the three Canadian Research Councils:

- Canadian Institutes of Health Research (CIHR)
- Natural Sciences and Engineering Research Council of Canada (NSERC)
- Social Sciences and Humanities Research Council (SSHRC)

The TCPS 2 outlines the framework for ethical conduct of research with humans, offering guidance to researchers in the design, conduct, reporting, and assessment of research. The TCPS 2 helps institutions and research ethics boards (REBs) to evaluate research proposals and monitor research activities.

The TCPS 2 builds upon 3 core principles:

- Respect for Persons
- Concern for Welfare
- Justice

Research involving human participants taking place at Queen's University and its affiliated hospitals are expected to adhere to the TCPS 2 guidelines.

1.1 Respect for Persons

Respect for Persons is a cornerstone of ethical research and should be reflected in all research design and implementation aspects. The TCPS 2, Article 1.1 refers to the need for researchers to treat research participants respectfully and maintain their dignity and autonomy. Respect for Persons includes considering the ethical, legal, and cultural issues that can influence the design and implementation of research projects, particularly when working with vulnerable or marginalized populations.

The TCPS 2 outlines aspects of Respect for Persons, including:

- The right of participants to make informed decisions about their participation in research.
- The right to refuse or withdraw participation.
- The right to withdraw tissues, biospecimens and data.

Researchers must: Respect participants' privacy, autonomy, dignity, and well-being.

- Take all necessary steps to protect participants' privacy and maintain confidentiality.
- Provide adequate disclosure to participants as to why the research is being conducted, their role in the research, and the potential risks associated with their participation.
- Use techniques appropriate for their research population.

- Strive to create a welcoming, safe, and respectful environment for participants.

Respectful research should also consider participants' cultural backgrounds and be respectful of cultural practices and beliefs. These responsible practices can help to ensure that participants feel respected and valued throughout the research process.

1.2 Concern for Welfare

Concern for Welfare is an integral concept in TCPS 2 and requires that a researcher obtain informed consent for participation in research activities.

Concern for Welfare also requires that researchers:

- Respect the decisions, choices, and preferences of individual participants.
- Provide all potential participants with accurate and comprehensive information about the project.
- Ensure that consent is given voluntarily.
- Respect the final decision of participants to withdraw their involvement from the research project.
- Observe professional guidelines and ethical standards for research involving human participants.
- Respect participants' expressed opinions, feelings, and values and provide them with a safe and comfortable environment through which to express their research-related opinions.
- Respect the privacy and confidentiality of research participants.

Concern for Welfare also applies to those who may be unable to provide informed consent for their participation in research activities.

1.3 Justice

The principle of justice requires that research participants are treated fairly and equitably. This should be considered in the selection of participants and the allocation of risks and benefits.

Research participants should be selected based on relevant factors such as the research question and objectives and not on arbitrary factors such as gender, race, ethnicity, or socio-economic status. It is important to consider potential risks and benefits associated with the research and to ensure that benefits are fairly distributed among participants and are not restricted to certain individuals or groups.

Whenever possible, the TCPS 2 encourages researchers to involve representatives from traditionally underrepresented groups in the design and conduct of their research.

Researchers are to provide comprehensive and understandable information to participants and realistic options for withdrawing from the research or revise consent at any time.

The TCPS 2 also outlines requirements for ensuring the safety and privacy of research participants, such as protecting participant data.

2 Responsibilities of the Principal Investigator (PI)

The Principal Investigator (PI) has a crucial role in research ethics submissions. The PI is primarily responsible for ensuring the ethical conduct of research and compliance with applicable ethical guidelines and legal standards. This includes preparing and submitting the necessary documentation for ethical review, consisting of:

- Research protocol
- Consent forms
- Recruitment materials
- Participant facing documents

The PI also has the task of responding to any queries or concerns raised during the review process and ensuring all research staff are adequately trained in ethical research practices.

While a PI may enlist the aid of a project manager/research assistant, etc. The overall responsibility for all items related to the ethics submission belongs with the PI. It is crucial to ensure that any delegated responsibilities are adequately documented, and that appropriate training is obtained (and documented).

Important note: That while the PI is integral to maintaining ethical standards, certain elements are not ethical considerations and as such, these documents are the responsibility of the PI to obtain but are not required for submission to the REB. If the PI does not retain these documents, prior to the study start, the PI may be found non-compliant.

Documents not required for ethical submission, but which must be obtained and retained by the PI include:

- Legal agreements (Data Transfer Agreements/Material Transfer Agreements)
- Cover Letters/Resumes
- Medical Licenses
- TCPS 2 CORE training certificates
- CITI training certificates
- NOL from Health Canada (HC)
- Notifications from HC
- Grant information
- Financial Accounts

- Pharmacy agreement(s)

Important note: Any PI and/or study may be subject to a compliance inspection at any time.

3 Recruitment

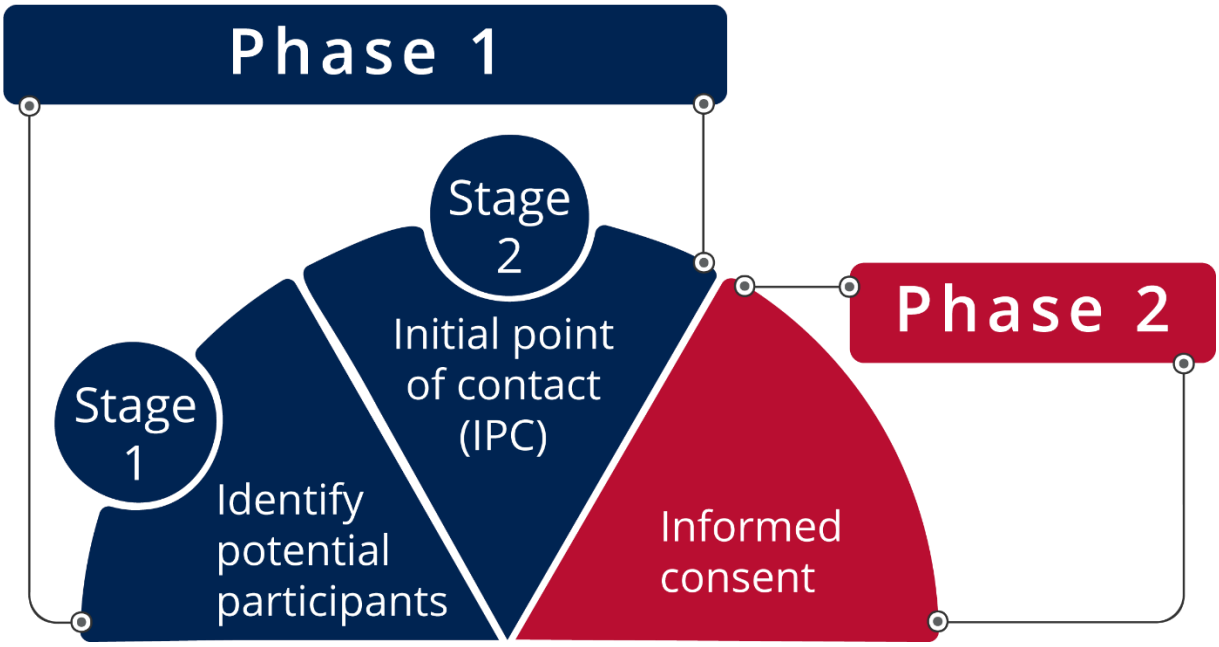
Recruitment in research ethics refers to screening and approaching potential research participants for inclusion into a study. The method of recruitment is a critical part of ethical research.

When in the recruitment phase of a study, many considerations should be considered such as:

- How and where will an individual be identified as being a potential participant.
- The approach or best method to recruit a potential participant.
- The pre-existing relationship of the person approaching the potential participant.

Efforts to minimize the power imbalance should be taken (e.g., a research study being conducted by an instructor on the students in the class may lead to the students feeling obligated to participate because the instructor has power over their academic performance and grades).

Figure 1 The 2 phases of recruitment



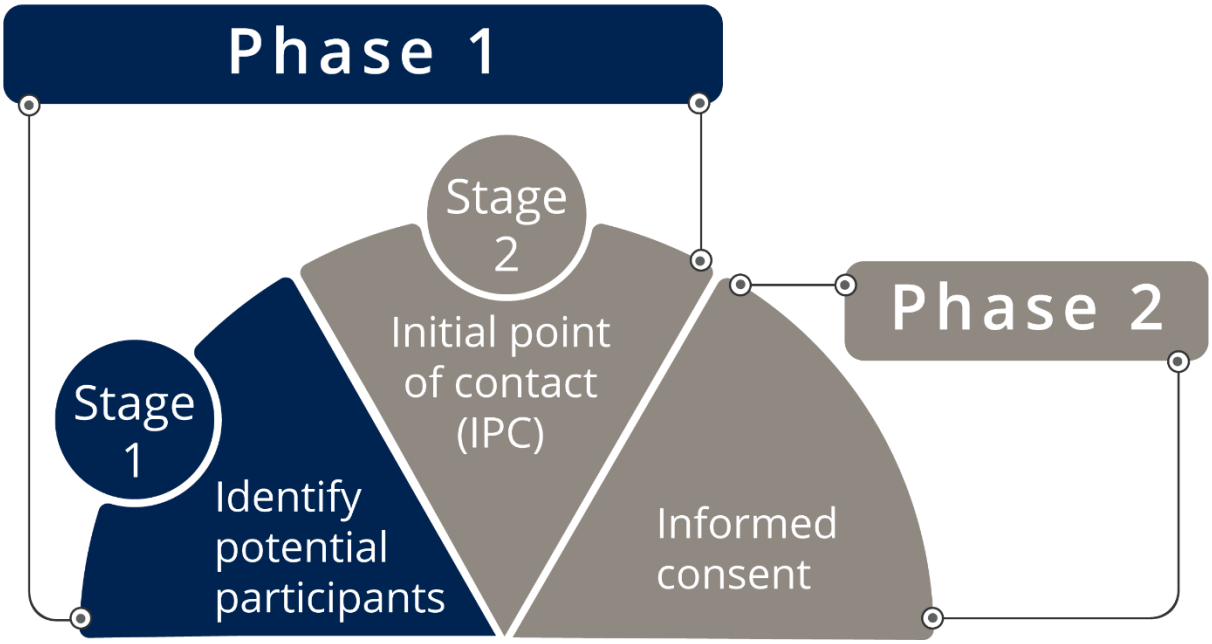
Phase 1: The recruitment phase consists of 2 stages:

1. Identification of potential participants stage (done by the researcher/study team).
2. Circle of care or its equivalent contacts potential participant stage (done by initial point of contact (IPC)). This stage includes 5 steps

Phase 2: The informed consent phase (done by the researcher/study team)

3.1 Identification of potential research participants: Phase 1, stage 1

Figure 2 Phase 1 of recruitment



The first step in the recruitment phase of a study is identifying potential participants that may be approached to assess their interest in hearing about a research study and eventually toward consent into a research study. Potential participants are targeted for potential enrollment based on study eligibility criteria. For example, a male would not be targeted for inclusion into breast cancer research. Or a high school student would not be targeted for basics of learning models in an elementary classroom. Knowing the community that you are targeting is key to identifying potential research participants.

Community engagement and environmental scans are important and encouraged by the REB. Identifying communities, sectors of the population of interest or groups of people within an industry or geographical location is important. You must identify the individuals who you would like to contact to proceed in the recruitment phase.

Other methods of identification of a potential research participants include allowing participants to self-identify using recruitment posters, brochures or social media posts.

3.1.1 Identification of potential research participants: Phase 1, stage 1 at KHSC

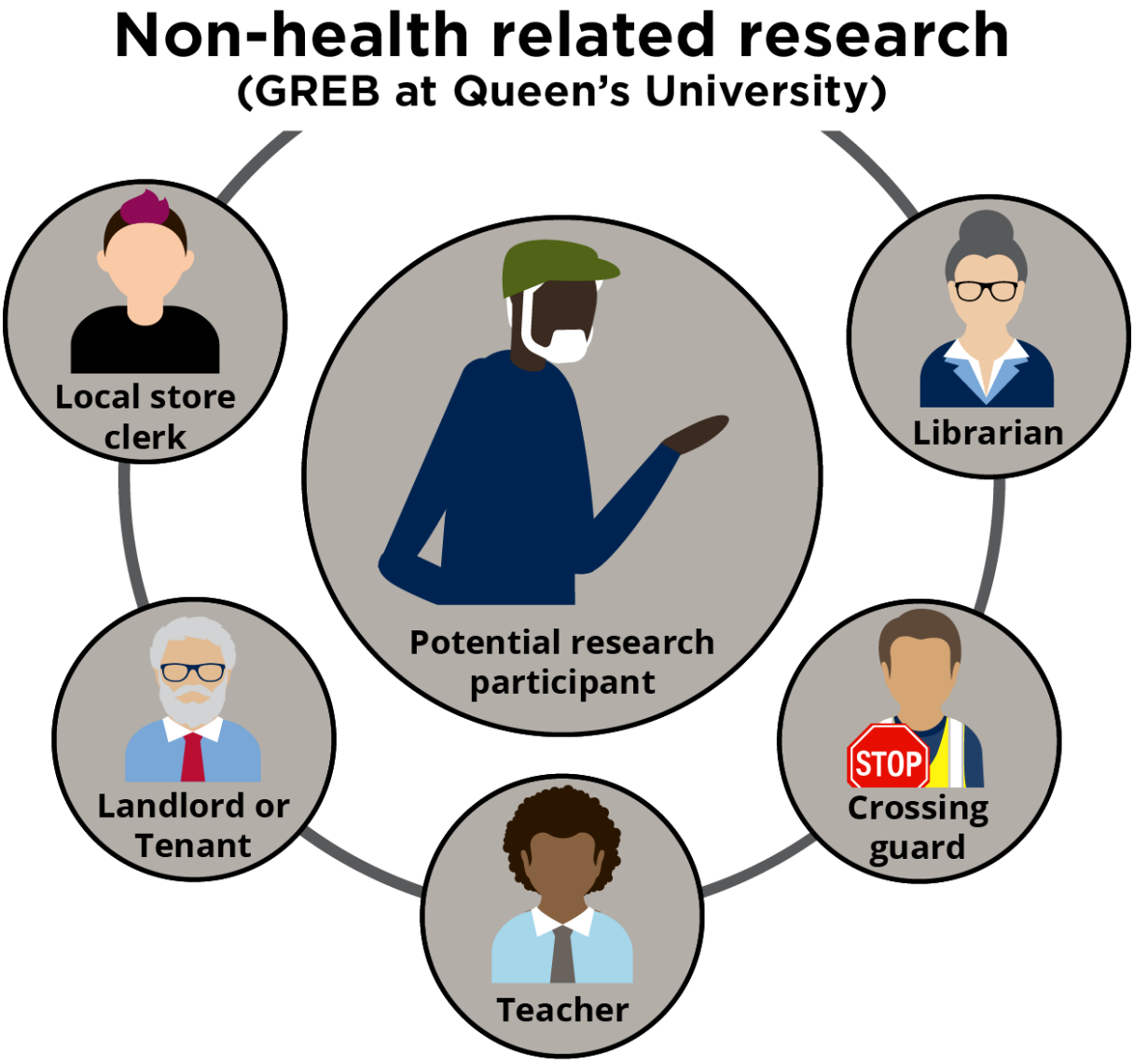
An implied consent model is used at Kingston Health Sciences Centre (KHSC). This means, a patient of the KHSC is automatically included into a system where their information can be used for chart review research and/or patients can be contacted for participation into a research study. Patients may opt-out of the use of their information or to be contacted for a research study at any time. Withdrawal of information or request for no contact for research studies is documented within individual medical records and must be respected by the researchers and research study teams within the hospital.

3.2 The initial point of contact (IPC), "Circle of care" or its equivalent contacts potential participant: Phase 1, stage 2

Once an individual has been identified as potential participant in the recruitment phase, the next step is the initial point of contact (IPC). The IPC for potential participants in research studies should occur through someone who is a part of the circle of care (for HSREB studies) or someone who is known to the participant (for GREB studies) (i.e., someone the potential participant would have had contact with regardless of a research study). Unless self-identification through exposure of a poster/recruitment brochure is the chosen method. The IPC will ask if the individual would like to hear about a research study they may be eligible for.

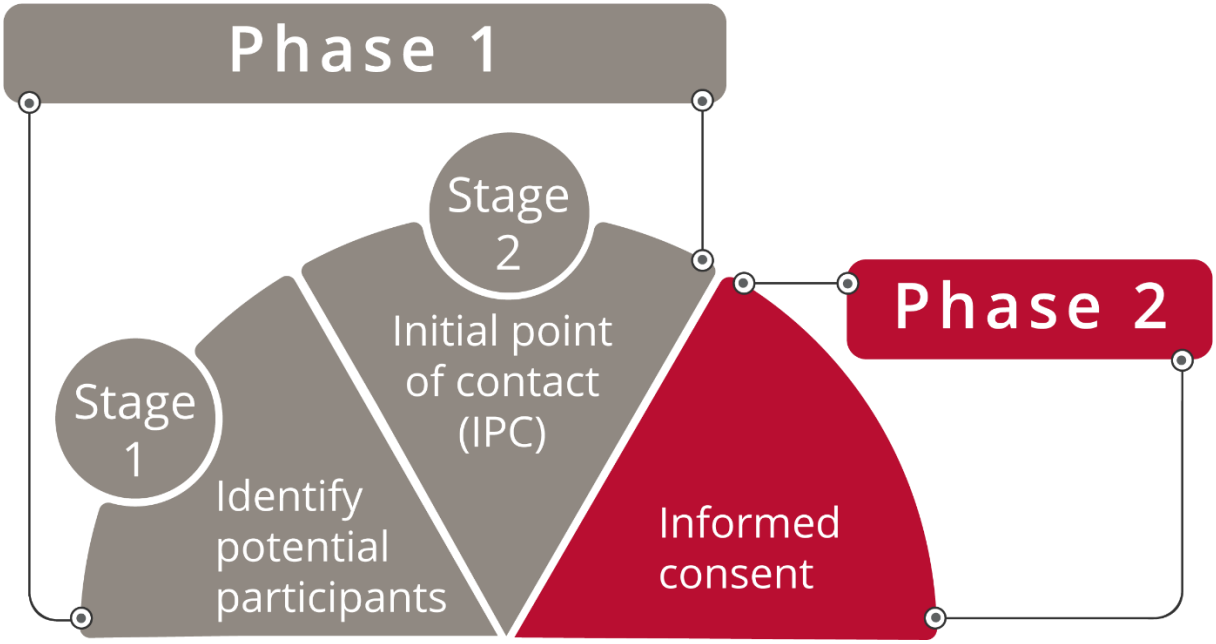
Figure 3 Initial contact made by a person from the individuals “circle of care” for health-related research (HSREB at Queen’s University)

Figure 4 Initial contacts from the potential participant's “Circle of care” or its equivalent for non-health related research (GREB at Queen's University)



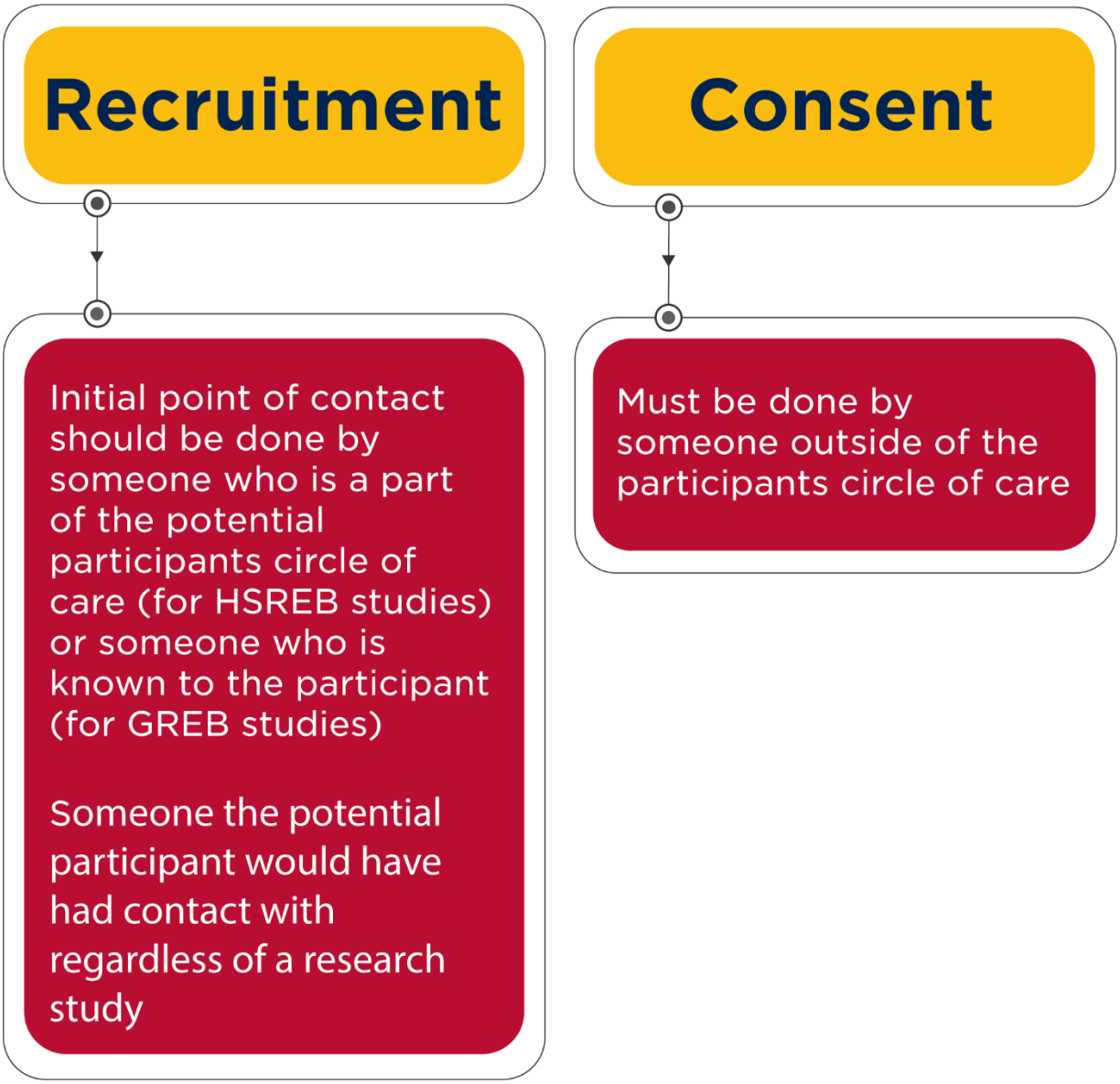
3.2.1 Informed consent: Phase 2

Figure 5 Phase 2 of the recruitment process



Once the IPC has confirmed the potential participant would like to hear more about the study, the IPC can then hand off the agreement to the research team. The research team member can then perform the informed consent procedure (Phase 2 of the recruitment process). Note, the IPC is different than the person who is performing the informed consent procedures. The IPC is known to the potential participant, whereas the person performing the consent procedures is not known to the potential participant.

Figure 6 Recruitment vs. consent



The TCPS 2, Article 3.2, states that consent is not considered informed unless potential participants receive clear, concise, and relevant information about the objectives of the research, selection criteria, risks and benefits, and methodology associated with the study. Additionally, a researcher must also provide information to potential participants about confidentiality terms, withdrawal rights, and other pertinent information. The individual must be provided with adequate time and opportunity to ask questions and make an informed decision about their involvement in the study

3.3 Possible methods of recruitment for research participants

When recruiting participants for research studies, it is important to follow the ethical guidelines outlined in the TCPS 2 and to use appropriate and fair recruitment methods that avoid undue influence and manipulation. The TCPS 2, Article 3.1 specifically emphasizes the importance of preventing recruitment by individuals in positions of authority, as it may result in power imbalances.

Acceptable recruitment methods include:

- In person (direct) contact
- Verbal (over the phone) contact
- Introductory letters
- Introductory emails
- Snowball sampling
- Self-identification
- Study advertisements (i.e., posters, brochures, social media)

3.3.1 In person (direct) contact

Once a potential participant has consented to be contacted by a member of the research team regarding a proposed research study, a research team member (who is not a part of the circle of care) will contact the potential participant to perform the informed consent procedures. The consent discussion should be documented.

Figure 7 Researcher contacting potential participant directly and in person

3.3.2 Verbal (over the phone) contact

If face-to-face contact is not feasible, potential participants may be recruited via the phone. However, cold calling potential participants is not allowed (ensure that prior initial point of contact procedures have been adhered to). If recruitment occurs via the phone, a researcher should include a recruitment script to the REB for review. This script would cover the same level of information as the written consent form.

Figure 8 Researcher verbally contacting potential participant over the phone

3.3.3 Introductory letters and emails

Many study teams prefer to contact potential participants about a study via introductory letters and emails. Introductory letters inform potential participants about a study and provide them with a way to contact the study team for more information, to indicate interest. It should be sent by someone inside the circle of care, or someone known to the participant (i.e., the potential participant is familiar with this person outside of the context of research).

Email is considered a non-secure form of communication as it may be accessed by unauthorized third parties. As a result, consent to be contacted about a research study should be obtained prior to sending out study information in an email. When consenting to contact, the potential participant should be informed that email communications are not secure, and that personal information may be included in the email. This consent should be documented in the study files.

Figure 9 Introductory letter and email sent to potential participant

When using email for recruitment of study participants, the following guidelines need to be followed:

3.3.3.1 Include in a recruitment letter/email:

Initial and follow-up communications

- Include when/who/how potential participants will be contacted again.
- Please wait 15 days before following up with participant, with a maximum of 2 follow up attempts. If no contact is made by the participant after 3 attempts, the participant can be considered as refusing to consent.

No further contact

- A participant should be given the option to opt out of a study/further contact. Therefore, included in an introductory letter/email should be contact information for the individual that can be contacted to opt-out.
- Multiple methods are preferred to be offered to the participant (i.e., a self-addressed, stamped envelope that can be mailed back to the study team, an opt-out card, email address or phone number). No Personal Health Information (PHI) should be included in this material.

Next steps

- If a participant chooses to continue in the study, then information regarding when/who/how contact will proceed. This should include details about the follow-up meetings for the study team, next visit, next steps etc.

Important notes on recruitment letters/emails:

- The sender's email address should be a professional one (i.e., Queen's University email account or Kingston Health Sciences Centre email account).
- Do not use mass emails.
- Do not send emails with Personal Health Information (PHI).

Important note: The recruitment letter/email are not considered the consent process and therefore, a detailed consenting process/script/form must be devised. All participant facing materials (i.e., introductory letters, recruitment scripts, posters, brochures) must be submitted to the REB for review and approval.

3.3.4 Using List Servs for email addresses

Some considerations when using a list serv for contact purposes of recruitment:

- Information about the source of the email list (how is the applicant obtaining the email addresses)?

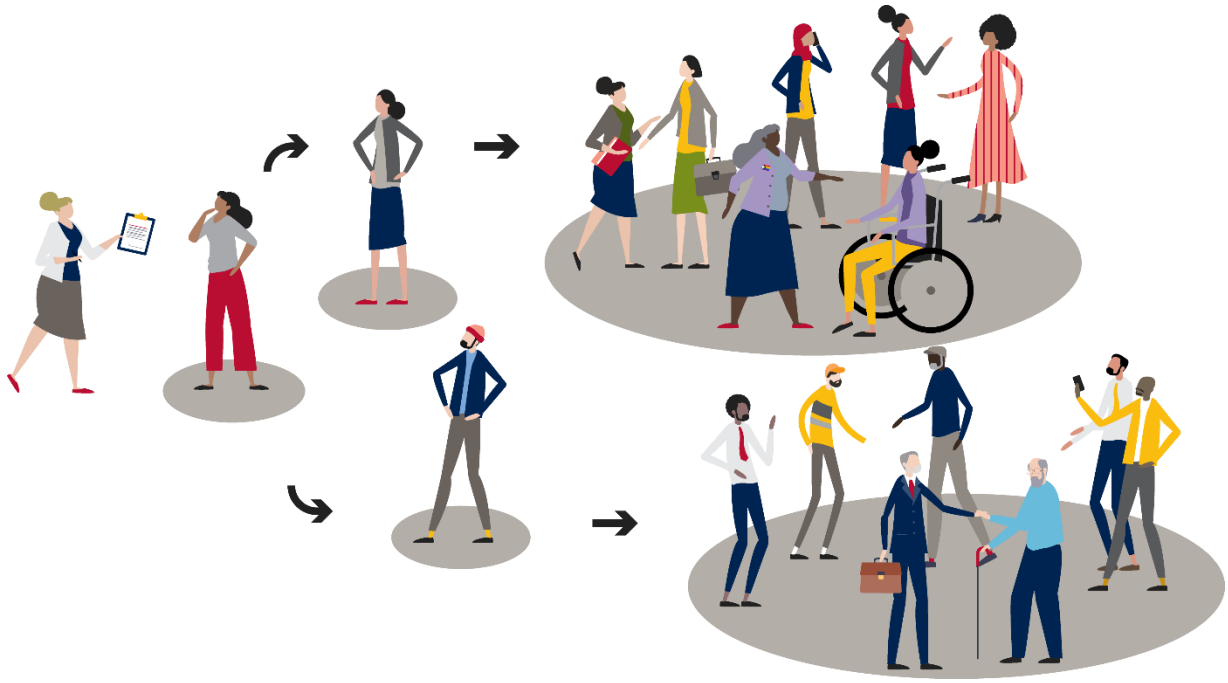
- Has consent has been provided to be contacted by email from those on the list serv for purposes such as research?

3.3.5 Snowball sampling

Snowball sampling (also known as chain-referral sampling) is a situation when initial participants are identified and recruited, and then those participants assist in referring additional participants who meet the desired criteria for the study.

This sampling technique is particularly useful when studying populations that are difficult to access or identify (e.g., individuals with rare diseases or marginalized communities).

Figure 10 Example of snowball sampling



Limitations of snowball sampling include the potential to introduce a bias as the study population may be skewed and not representative of the overall population.

3.3.6 Self-identification

Study participants may self-identify by responding to promotional materials (e.g., posters, flyers, social media posts). Even though a potential participant may self-identify, they will still need to undergo consent to be able to be fully informed of the study and study procedures.

Figure 11 Participant calling research team to take part

3.3.7 Study advertisements

Study advertisements include:

- Study posters
- Study flyers
- Study brochures
- Media advertisements
- Internet/social media posts

Recruitment material should include the following:

- Queen's University/Institutional/Departmental Logo (see **Visual Identity Guide**) and a version date.
- Ethics approval statement:
    - "This study has received ethical approval by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board."

  OR
    - "This study has received ethical approval by the Queen's University General Research Ethics Board."
- Study title – simplified as appropriate (i.e., abbreviated, or lay-person language).
- Purpose of the research study.
- Target population.
- Basic explanation of tasks and time commitment expected and location of research (e.g., lab, online, KHSC).
- State if compensation is provided (but not necessarily how much). Do not overemphasize incentives (i.e., do not use bold or large print).
- Study contact information/Principal Investigator's name and/or QR code.

3.4 Follow-up contact of participants

As research is viewed as a voluntary undertaking, it is within the best interests of a researcher to contact the participants within a defined period. Please wait 15 days before following up, with a maximum of 2 follow ups. If no contact is made after 3 attempts (initial contact and 2 follow ups), the participant can be considered as refusing to consent.

3.5 Third-party recruitment

Third party recruitment involves individuals or agencies acting on behalf of a researcher to recruit a participant into a study. In situations where there is appropriate justification, third party recruitment will be taken into consideration (e.g., research on genetic or hereditary conditions which may occur in families).

In other cases, participants may be recruited using third-party organizations, listservs etc. In these situations, a poster or study information is usually provided to participants and participants can then self-identify thereafter.

When third party recruitment is utilized by the study team, the REB will require information on how third-party recruitment will be undertaken. All materials distributed to third parties will need to be submitted for review and approval. Also, the data that the third party will retain of potential participants must be explained to the REB.

3.6 Unacceptable recruitment methods

The REB does not accept the following recruitment methods:

Cold calling

Unless the potential participant has previously consented to be contacted for future research, the use of "cold calls" to recruit participants to research studies is not allowed. Initial point of contact must be done via an individual from their circle of care, an individual known to the research participant (outside of the context of research) or the Health Information Custodian (HIC).

Finder's fees

Queen's REBs do not allow the use of finder fees for recruitment/enrollment of participants.

4 Consent

Obtaining informed consent from participants is a fundamental ethical requirement. Informed consent ensures that participants understand the research, including all foreseeable risks and benefits. Article 3.2 in the TCPS 2 specifies that "researchers shall provide to a prospective participant, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project." Informed consent must be given voluntarily and can be withdrawn at any time. If a participant withdraws consent to participate, they may also request the withdrawal of their data or human biological materials (as applicable).

4.1 Informed Consent Information

For potential participants to give true free and informed consent, they must be provided with all the information required to make the decision to participate in the research project. The research study/data collection should begin only after a participant, or their authorized third party, have provided consent. There are exceptions to this requirement, as outlined in the TCPS 2, Articles 3.7A, 3.8, 5.5A and 5.5B. Refer to the Guidelines on Waiver of Consent and Guidelines on Alterations to Standard Consenting Procedures, found on the Queen's Research Ethic's website for more information: **https://www.queensu.ca/vpr/ethics/guidelines-policies**. Researchers shall provide potential participants with the following information, as applicable for their research (Note: Other information maybe required based on regulations or policies of the institution):

- Purpose of the study
- Study procedures
- Risks/Benefits
- Participant responsibilities when enrolled in the study
- Withdrawal from the study
- Confidentiality
- Reimbursement/Incentives

Participants should be given enough time to understand the information provided in the consent process and should have the ability to ask questions. The key to true free and full informed consent is that the participant understands the information being presented to them about the research study. Researchers should ensure that simple language is used when providing this information. It should also be presented in a language that the participant can understand. See below for steps in the consenting process.

4.2 Voluntary Consent and Withdrawal of Consent

Per TCPS 2: "The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes."

There are three factors that could impact the voluntariness of consent:

1. **Undue Influence:** this can occur when potential participants are recruited by an individual in a position of authority, thus creating an imbalance in power. For example, employer and employee, teacher and student, or treating doctor and patient. The researcher should identify if there is any potential undue influence in their recruitment methods and try to eliminate these as much as possible. Participants' previous entitlement to care, education and other services should not be impacted or prejudiced by their decision to participate in a research study.

2. **Coercion:** This is a more extreme version of undue influence and involves a threat of harm or punishment for failure to participate and would thus negate the voluntariness of informed consent. Researchers should ensure all recruitment methods and materials eliminate any elements of potential coercion.
3. **Incentives:** Incentives are anything offered to participants, monetary or other, for participation in a research study. Incentives are often used to encourage participation in research and therefore have the potential to impact voluntariness of participation. Incentives should not be so large as to influence participants to disregard risks associated with participation. The researcher should justify the use of incentives to the Research Ethics Board (REB), who will consider the possibility of undue influence. If a participant does not have the ability to make decisions for themselves, then their authorized third parties should not receive an incentive but may accept incentives on behalf of that participant. In some cases, if an incentive is offered, the researcher must find an alternative to receive the incentive and still not participate in the study. (i.e. course work).

To maintain the element of voluntariness, participants must be free to withdraw their consent to participate in the research at any time and should not suffer any disadvantage when withdrawing. Any payment due prior to the point of withdrawal should not be withheld. If the study has a payment schedule, then participants should be paid in proportion to their participation prior to withdrawal. The informed consent form/process should outline any circumstances that would not allow withdrawal of data or human biological materials (e.g., anonymous survey submission). Researchers must provide the REB with a rationale for these circumstances. Participants should also be informed that their data/results can not be withdrawn once they are published.

4.3 Evaluate decision making ability

According to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), there is no age of consent and therefore researchers should evaluate the decision-making ability of participant to consent. This is determined by an individual's ability to comprehend the information provided and make a voluntary choice. Decision making ability is typically based on both a cognitive and emotional capability to make decisions about participating. Ideally, a regulated healthcare professional, a member of a professional community (i.e., teacher) or an authorized third party will assess their ability to make a decision and thereby consent/assent.

Important note: If an individual has assented previously, but then develops the ability to consent, consent must be obtained immediately.

4.4 Comprehension of consent

Comprehension refers to understanding the research study, while the decision-making ability refers to the ability to make an informed decision about participating in the research study. Comprehension involves understanding the research purpose, risks and benefits, and the ability to reason and make decisions about participating in the research. To assess a participant's comprehension of a research study, a researcher could use the "Teach-Back method". (http://teachback.org) The teach-back method (sometimes called "talk-back" or "show-me" method) asks the participant a series of questions related to the study.

4.5 Decision-making ability

Determining whether a participant has the ability to make decisions is paramount to determining if a participant is giving informed consent. Researchers must determine an individual's ability to make decisions while performing the informed consent procedures/discussion. There is no age of consent in Ontario, and it is up to the researchers to determine an individual's ability to understand all the information presented to them about the study, especially the risks and benefits. The determination of decision-making ability is not static and may change during the course of a research study. It may also be determined by the nature and complexity of the research study. For example, an individual may have the decision-making ability to participate in a study that is asking about the food they consumed today but not for a complex clinical trial involving a drug.

Individuals who lack decision-making ability on their own should not be unfairly excluded from the benefits of research participation nor should it be used to inappropriately include them in research. Authorized third parties should be asked to make a consent decision on behalf of a potential participant who lacks decision-making ability, these individuals should be aware of the legal responsibilities when providing this consent.

Researchers and the REB should determine the ethical considerations regarding individuals who lack decision-making ability. The REB should determine the following conditions are met:

- Participants who lack decision-making ability are allowed to the greatest extent possible to decide to participate in research. Participants may be capable of verbally or physically assenting, or dissenting, to participation in the research study. This assent may not be sufficient to be true informed free consent however their expression of assent or dissent must be respected.
- Initial and ongoing consent is sought from an authorized third party, who is not a member of the study team.
- The research being conducted will provide direct benefits to the participants (or another person in the same category). If there are no direct benefits to the participants, then the research should pose minimal risk and burden.

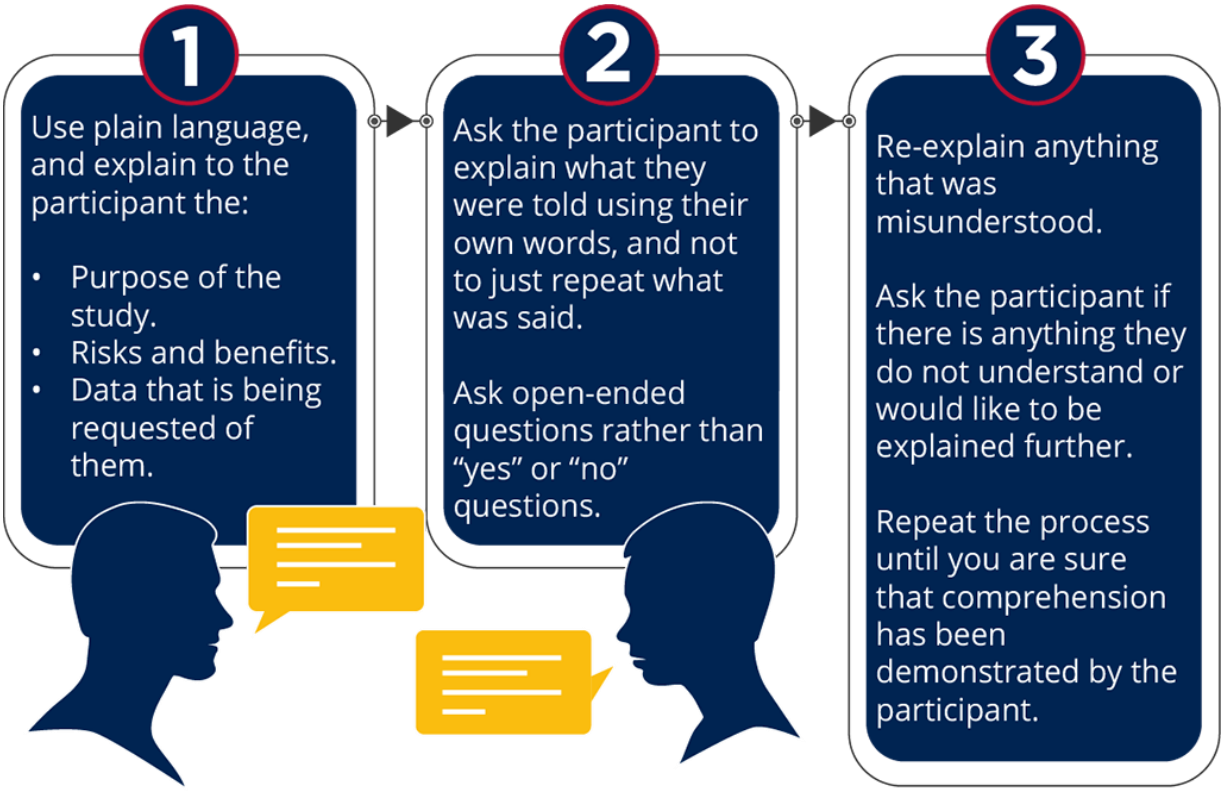
- The researcher will promptly seek the participant's consent if they regain or attain decision-making ability during the course of the research study.
- When individuals have signed a research directive about future research in the event of lost capacity or death, the REB, researchers and authorized third parties should be guided by these directives.

Important note: If an individual has assented previously, but then develops the ability to consent, consent must be obtained immediately.

4.6 Using teach-back to evaluate understanding

Teach-back is a process that a researcher can use to aid in evaluating a potential participant's understanding of a research study. The teach-back method (sometimes called "talk-back" or "show-me" method) asks the participant a series of questions related to the study. It involves asking potential research participants to explain back what you have just told them in their own words, not simply repeating your words. Any misunderstandings are then clarified by re-phrasing details if the potential participant does not understand. The potential participants' understanding is checked again. You can repeat the process until you are sure that the participant has demonstrated comprehension. It is an effective way of checking you've explained information clearly and that your potential participant understands the research study they may choose to consent to. (Teach-back, 2018)

Figure 12 The teach-back method



4.6.1 Steps for conducting the teach-back method

1. Use plain language, in a caring tone of voice and attitude. Ensure comfortable body language and make eye contact when explaining to the participant the plain language, and explain to the participant the:
    - Purpose of the study.
    - Risks and benefits.
    - Data that is being requested of them.
2. Ask the participant to explain what they were told using their own words, and not to just repeat what was said.
    - Ensure the participant does not feel this is a "test" of their abilities but more a "test'" of how well you explained the study.
    - Use non-shaming, open-ended questions (i.e., do not simply ask "yes" or "no" questions).
3. Re-explain anything that was misunderstood.
    - Ask the participant if there is anything they do not understand or would like to be explained further.
    - Repeat the process until you are sure that comprehension has been demonstrated by the participant.
    - Document use of, and the participant response to, teach-back.

Depending on the complexity of the study, a researcher should dig deep and ask more in-depth questions to evaluate the participant's understanding of the study.

4.7 Types of informed consent

In research ethics, there are various definitions surrounding the types of consent received to ensure that individuals understand and agree to participate in studies, these include:

- Written informed consent
- Verbal consent
- Implied consent
- Waiver of consent
- Broad consent
- Assent
- Opt-out consent

To provide full and informed consent, the types of informed consent listed above may include the ability for a participant to consent to certain portions of a study, while declining participation in other portions of a study. This may be presented to participants in the form of:

- Opt-in consent

4.7.1 Written informed consent

This is the most common type of consent. Research participants must be provided with a written explanation of the research study, including purpose, procedures, benefits, risks, and alternative procedures or courses of treatment. Research participants must indicate that they understand the proposed research and their rights in participating. Participants may be given the ability to participate in some portion of the study, while simultaneously declining participation in other aspects of the study. This can be presented to a research participant in the written informed consent document as an “opt-in” function.

Figure 13 Participant about to complete a written consent form

4.7.1.1 Opt-in consent when obtaining written consent

Opt-in consent requires research participants to actively choose to participate in a study by taking affirmative action, such as selecting a checkbox or signing a form. For example, a research participant may choose to enroll in the main study and would like to opt-in for the sub-study that is also presented in the written informed consent.

Figure 14 Participant checks an opt-in box and signs the consent form

4.7.2 Verbal consent

Verbal consent refers to a form of consent in which the individual participating in the research project provides their consent verbally instead of through a written document. In verbal consent, a researcher reads or explains a verbal version of the consent form, often referred to as a Letter of Information (LOI) sheet, to the participant. The participant then verbally consents, indicating their agreement to participate in the research project. Participants may be given the ability to participate in some portion of the study, while simultaneously declining participation in other

aspects of the study. This can be presented to a research participant during the verbal consent process as an 'opt-in' function.

If verbal consent is sought, a researcher must keep a verbal consent log to demonstrate that the consenting process has occurred.

Figure 15 Participant being verbally consented, and a log is maintained

4.7.2.1 Opt-in consent when obtaining verbal consent

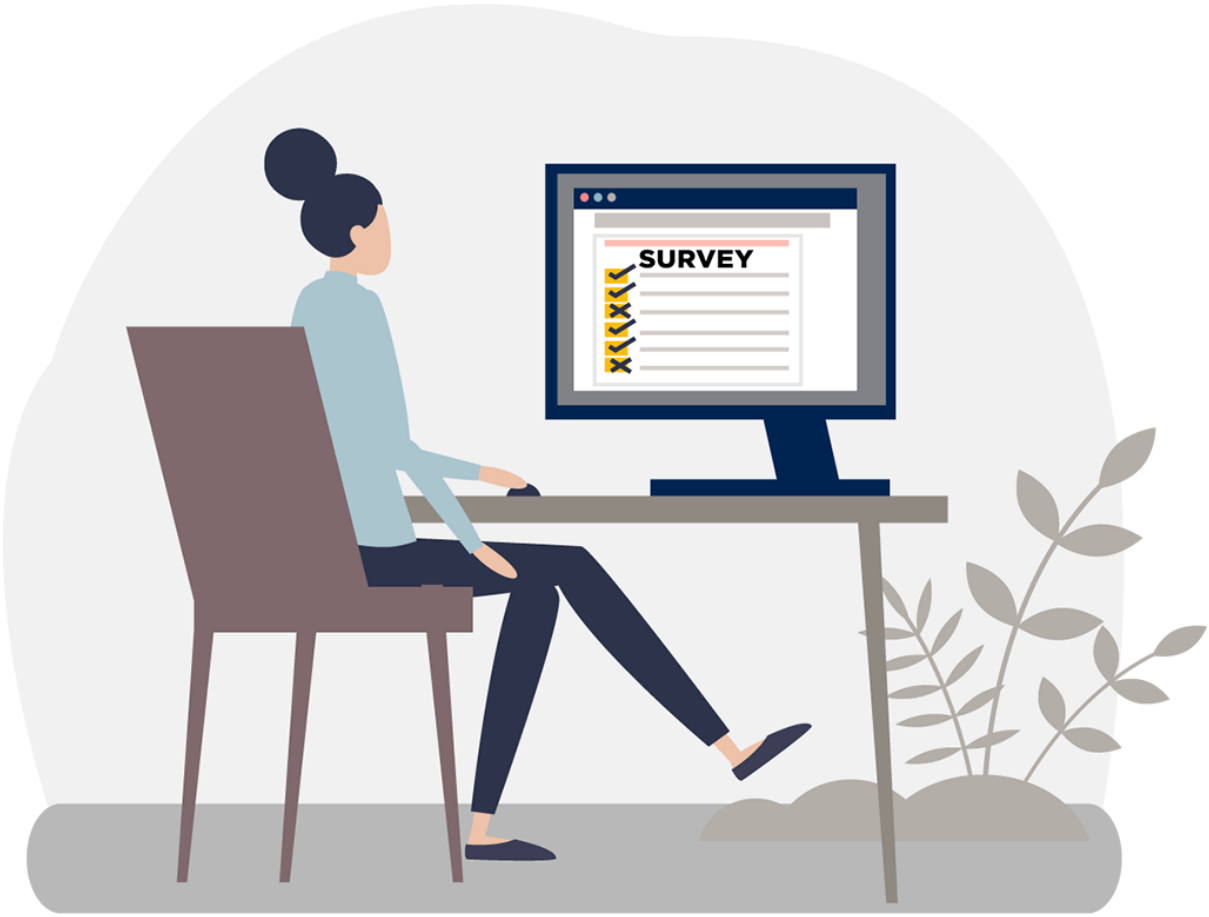
Opt-in consent requires research participants to verbally confirm they are choosing to participate in a study. For example, a research participant may choose to enroll in the main study and would like to opt-in for the sub-study that is also presented in the verbal consent.

Important note: In verbal consent, participants should still be given the opportunity to ask questions and be provided with a copy of the information sheet.

4.7.3 Implied consent

Implied consent occurs when individuals do not explicitly provide consent, but their actions imply agreement to participate. It is often assumed when participants take actions that demonstrate tacit agreement, such as showing up for an appointment or completing survey questions.

Figure 16 Individual completing an online survey



4.7.4 Waiver of consent

In some cases, it may not be possible or practical to obtain consent from individuals, such as when researching a large database of medical records. In these situations, researchers may request a waiver of consent from the REB to allow them to proceed without seeking consent. TCPS 2, Article 10.2 and 11.2. If a waiver of consent is sought for a study, the research still requires an ethical review by HSREB or GREB and justification for the waiver must be provided.

4.7.4.1 Considerations for waiver of consent

A waiver of consent may be given in accordance with TCPS 2, Article 3.7a and the following criteria are met (NOTE: the researcher must demonstrate how each criteria is met to the REB in order to obtain an waiver of consent approval):

- Research is safe and low risk (i.e. is minimal risk to the participants).
- Not obtaining consent will not harm participants.
- It would be impossible or very difficult to conduct the research and answer the research question properly if participants' consent is required beforehand.
- If a change is suggested, the exact details and extent of the change are clearly explained.
- The plan for debriefing (if applicable) will allow participants to refuse consent, withdraw their data, or remove human biological materials, following Article 3.7B.

4.7.5 Broad consent

Broad consent is an alternative to study-specific consent however, this is not considered a waiver of consent. Broad consent allows a researcher to obtain data and/or biospecimens collected within the parameters of the current study which could prove to be useful in future unknown research without having to re-consent the research participant.

Broad consent applies both to the general retention, use, and storage of data/biospecimens, as well as to the retention of contact information to recontact individuals for future unknown research projects.

Other considerations include:

- The type of information (and level of detail that will be stored in the re-contact database).
- The retention period of the database.
- The type and amount of data/biospecimens being collected.
- Storage and potential reuse purposes.
- Who will have access to the database.
- How a participant could withdraw consent from data/biospecimens retention.
- The limitations of withdrawal of consent (i.e., in the case of anonymized data).
- The risks and potential benefits of storing data and human biological materials, and their use in future unspecified research, including areas of uncertainty where risks cannot be estimated.

- The plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with TCPS 2, Article 3.7B.

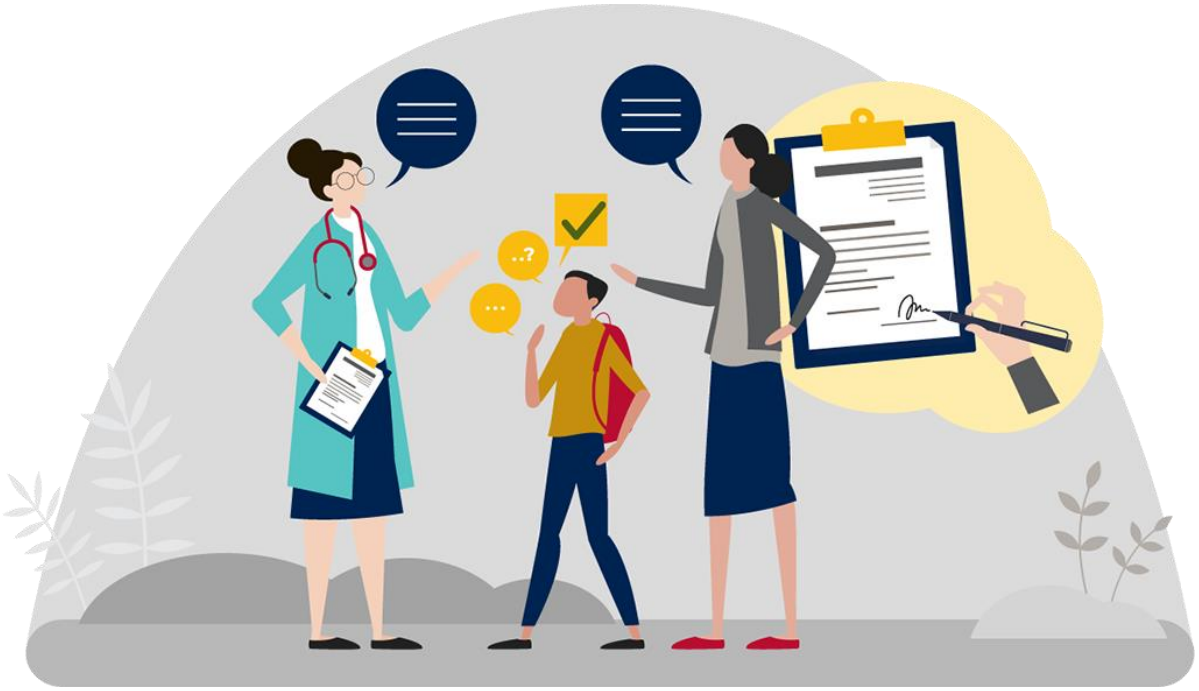
If using broad consent, there should be a clear option for the participants to either opt-in or opt-out of this optional portion of the study.

4.7.6 Assent

Assent refers to the agreement obtained from minors or individuals with cognitive impairment or those who do not have the ability to provide informed consent. Assent involves explaining the study's purpose and procedures in straightforward terms that are appropriate for the individual's age and comprehension level.

Assent allows participants who may not be able to provide informed consent, such as minors or those with cognitive impairments, to still participate in research, which is important in upholding the core principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2).

Figure 17 Assent and guardian consent being obtained



Participants who provide assent must also have a parent or legal guardian provide written consent. The TCPS 2 does not specify an age of assent/consent. The ability to consent to a study should be determined through a documented method clearly described in the ethics application (see section on: “Assessing ability to consent”). In the case that assent is not granted, the decision

of the individual assenting must be respected, and this decision supersedes the consent of the parent, legal guardian or authorized third-party.

4.7.7 Opt-out consent

Opt-out consent assumes that individuals agree to participate in the study unless they take action to decline participation. This type of consent may be used in situations where participation poses minimal risk and minimal impact on privacy, such as collecting data from email subscribers.

Figure 18 Opt-out consent

Each type of consent listed has its strengths and weaknesses, and the selection of the type of consent used will depend on the specific study and circumstances involved. Regardless of the type of consent used, it is crucial to ensure that individuals have a clear understanding of what they are agreeing to and that the appropriate measures are taken to protect their privacy, welfare, and rights.

4.8 Ongoing consent

Informed consent is obtained prior to a participant being enrolled in a research study, but consent is an ongoing process that continues until the end of a participant's involvement in the study. The researcher must bring to the participant's attention any information or changes to the research project that may affect them and their free and informed consent to continue in the research study. Another important element of ongoing consent is potential changes in participants' decision-making ability during the research study. If applicable, researchers should have a mechanism in place to evaluate participants decision-making ability to provide informed consent throughout the study.

Figure 19 Assent was established, consent is now obtained

4.9 Consent form

The consent form must include separate options for consenting participants for the general retention, use and storage of their data/biospecimens as well as recontact for future unknown research projects.

Other considerations to include:

- The type of information (and level of detail that will be stored in the re-contact database).
- The retention period of the database.
- The type and amount of data/biospecimens being collected.
- Storage and potential reuse purposes.
- Who will have access to the database?
- How a participant could withdraw consent from data/biospecimens retention.
- The limitations of withdrawal of consent (e.g., in the case of anonymized data).
- The risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated.

4.10 Incidental Findings

An incidental finding occurs when, during the course of research, a discovery is made about a research participant that is outside the purpose of the research study. For example, the discovery of an unrelated disease on a test done as part of the research study. An incidental finding is considered to be a material finding if it is determined to have significant welfare implications for the participant or potential participants. Researchers should determine if an incidental finding is material. If the researchers do not have the expertise to evaluate any incidental findings, they should seek expertise. The initial consent process should outline the likelihood of material incidental findings and provide information on plans to disclose such findings to participants.

For research where material incidental findings are not foreseeable but are discovered during the course of the research, the researcher should report the discovery to the REB. Disclosure of material incidental findings to participants should occur when participants have consented to receive this information. Where the researchers have outlined that these will not be disclosed, and a finding is discovered, researchers should consult their REB to determine whether there is sufficient ethical basis to disclose the finding(s) to the participants, and how to do so. In some cases, incidental findings may trigger legal reporting obligations. The possibility of this should be outlined in the initial consent process. In some instances, disclosure of incidental findings may not be possible. If this is the case, the researcher should provide justification to the REB.

4.11 Documentation of consent

According to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), documentation of obtaining consent is an essential step in research ethics. Researchers are required to maintain accurate and comprehensive records of the consent process and the consent obtained from participants. When documenting the process of obtaining consent, researchers should include key details such as the date and time of the consent and the method used, such as written, verbal, or electronics.

5 The right to withdraw

Participants maintain the right to opt out of research at any point. This can be done formally, in writing, or through verbal communication. This includes the ability to request the disposal of their provided data and/or biological samples and the ability to withdraw from participation in the study altogether.

It is the responsibility of a researchers to guarantee participants are well informed of this right and provide convenient ways for them to action it, ensuring they have control over future usage, destruction, or the potential removal of their samples or data. The consent form must stipulate this right and any possible restrictions, such as data anonymization, aggregation, or publication.

Informed consent forms must include the following:

- The process by which participants may retract their samples.
- The circumstances under which withdrawal of samples is not possible, for example, when samples have already been utilized for research.
- Whether it's possible to retract provided research data.

Despite donating their biospecimens and data, participants retain ownership of these contributions. This information must be relayed during the consent discussion and again in the consent form.

6 Reimbursement/Incentives

In research involving human participants, reimbursement and incentives play different roles in the ethical conduct of a study. Reimbursement refers to compensating participants for expenses incurred as a result of their participation, such as travel, meals, or child care costs. Reimbursement is not considered a form of influence but rather a means to ensure that participants are not financially disadvantaged by their involvement in the research. Incentives, on the other hand, are additional forms of compensation that may encourage participation, such as monetary payments, gift cards, or other benefits. The use of incentives requires careful ethical

consideration to ensure they do not unduly influence participants or compromise voluntary consent. If incentives are being offered for course work credit, the researcher must ensure that the course credit amount is reasonable (i.e. it is recommended a max of 2-3% is offered). In addition, if a participant does not want to participate in the research study, but would still like to be eligible for the incentive, an alternative pathway to receive the incentive must be provided to them (i.e. through an additional assignment). If monetary amounts are being offered to participants that are $500 or more in one calendar year, financial services recommends that SIN numbers are collected upfront for T4 issuances. It is the responsibility of the researcher to track the amount paid to participants and to notify financial services if the amount is $500 plus.

Both reimbursement and incentives should be clearly outlined in the consent process to ensure transparency and avoid any perceived coercion or pressure on participants to take part in the study.

7 Types of research needing additional considerations

7.1 Health Canada approval for drugs/medical devices

Health Canada (HC) approval is required for research involving an investigational drug or device that is being used “off label” (i.e., for purposes other than its approved/intended use). The principal investigator must ensure that HC approval is received and a No Objection Letter (NOL) is obtained.

7.2 Research involving deception/incomplete information

Studies involving false or incorrect details, scenarios, social circumstances, or research objectives to participants fall under the category of “deceptive research”. The issue with deceptive research is that it directly contradicts the principle of informed consent. The REB may approve this type of research if:

- There is little to no risk posed to participants.
- It's not feasible to conduct the research without employing deception and modifying the consent process.
- Any proposed changes to the consent process must be expressly outlined in the ethics application.
- Participants should retain the right to withdraw, consent and/or opt out of the study at any point in time. Including after the research is completed.
- A plan for debriefing the participants about the full nature of the study at appropriate times.

7.3 Focus groups

Executing research within a focus group environment can challenge the research team's capacity to ensure the privacy and confidentiality of research actions. Each participant's expectations in the focus group must be comprehensively defined before initiating the group discussion.

7.4 Research involving video and/or audio-recording

Should the research endeavors incorporate video/audio documentation of the participants, the necessary particulars to be clarified include the following:

- Is the video/audio documentation a compulsory component of the research? If yes, for what reason is it mandatory?
- Will some or all of the video/audio be de-identified? If yes, how (e.g., voice augmentation, blurred faces, etc.).
- To whom will the video/audio documentation be accessible, and what will be their need for access?
- Where will these video/audio records be stored, and when is their destruction scheduled?
- How can the participants initiate removing their video/audio documentation?

7.5 Biospecimens

If biological specimen collection is mandatory for study procedures, consent must be obtained. The reasons for collecting biospecimens in research are:

- Certain biological specimens may be collected to address a specific research question. Occasionally, optional biological samples may also be collected. Yet, these will solely be employed to meet the objectives outlined in the main protocol and cannot be utilized for other purposes.
- Biospecimens preserved in biobanks could be beneficial for future research.
- In trials that could be therapeutic, the optional banking of biological samples for future indeterminate research or research not related to the current study is a prerequisite. This is considered broad consent. Please see the section regarding broad consent.

8 Research occurring outside Queen's University

A Queen's University faculty member or researcher may conduct research outside of Queen's University and its affiliated hospitals; and/or outside Canada that may still require REB approval from the Queen's Research Ethics Board (REB). The following criteria outline the specific requirements and if REB approval is necessary:

Table 1 Research requiring REB review when occurring outside of Queen's University

Criteria	Queen's University REB Approval Required?	Application Type
Queen's University and/or its affiliated hospitals will be involved in active recruitment/participation	YES	Application-for-Prospective-Research-with-Human-Participants
Queen's University and/or its affiliated hospitals logo will be listed on any participant facing documents and/or referenced in the participant facing documents	YES	Application for Prospective Research with Human Participants OR Application for Streamlined Multi-Jurisdictional-Review*
Researcher/student is affiliated with Queen's University and/or its affiliated hospitals will only be receiving study data for analysis and/or storage on Queen's University and/or hospital servers.	YES	Application for Streamlined Multi-Jurisdictional-Review*
Researcher/student is affiliated with Queen's University and/or its affiliated hospitals, and only data analysis is occurring at Queen's University and/or its affiliated hospitals. (i.e. there is no recruitment, consent, or data collection occurring at Queen's University and/or its affiliated hospitals AND no	NO	

Queen's University and/or hospital resources are being used for the study)		
Researcher/student is affiliated with Queen's University and/or its affiliated hospitals but is acting as a consultant on the study using a different, non-Queen's affiliation. Plus, no study tasks (such as recruitment, consent, or data collection) are being performed at Queen's nor are any Queen's resources (such as servers or emails) being used for the study"	NO	

*Application for Streamlined Multi-Jurisdictional Review can only be completed if ethics approval has already been obtained from another Canadian institution (adhering to the Tri-Agency Funding requirements). Note: this form can only be used if the local researcher is responsible only for receiving funding and/or data and/or samples for analysis (i.e., without local active recruitment or participant interaction).

It is recommended that you reach out to the Research Ethics Office at **researchethics@queensu.ca** before you begin preparing a streamlined multi-jurisdictional REB application, to discuss which institutional REB you must seek approval from first, as it may not be your home institution.

9 Research ethics boards (REBs) at Queen's University

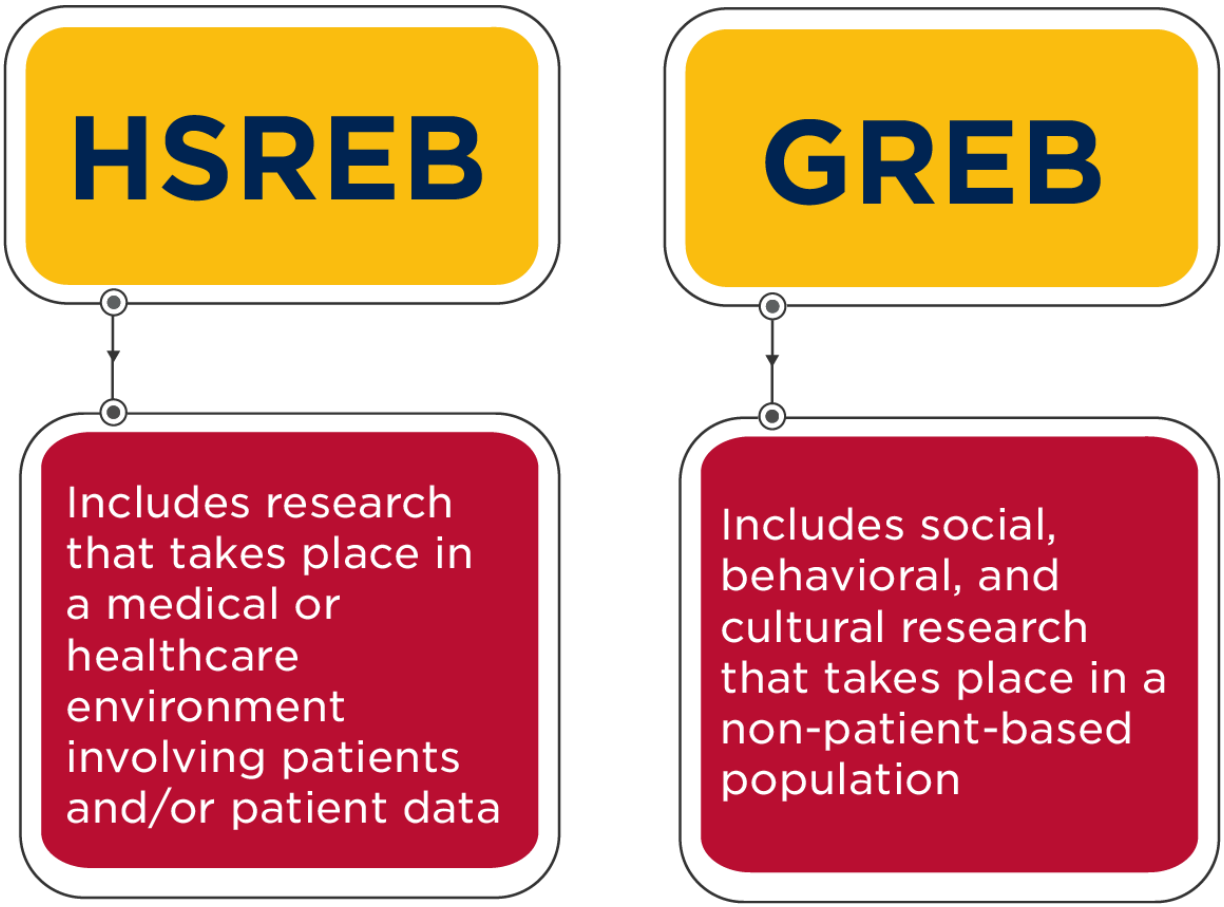
Queen's University has 2 research ethics boards (REBs):

- The Health Sciences and Affiliated Teaching Hospital Research Ethics Board (HSREB)
- The General Research Ethics Board (GREB)

At Queen's University these 2 REBs protect the rights of research participants and ensure ethical conduct of research. HSREB and GREB review research proposals to ensure that projects meet ethical conduct standards and comply with applicable regulations and laws, including the TCPS 2.

9.1 HSREB and GREB

Figure 20 HSREB and GREB responsibilities



HSREB includes research that takes place in a medical or healthcare environment that involves patients and/or patient data.

GREB includes social, behavioural, and cultural research that takes place in a non-clinical, non-patient-based population.

9.2 Submitting to HSREB vs. GREB

If your study includes **one or more** of the following elements, you must obtain a review from the HSREB:

- Participants from any of the Affiliated Teaching Hospitals or in other health care clinics or medical settings at any point during the research.
- Conducting research or recruiting participants from any of the Affiliated Teaching Hospitals (Kingston Health Sciences Centre (KGH and HDH Sites), Kingston General Health

Research Institute (KGHRI), Hotel Dieu Hospital Research Institute (HDHRI), Providence Care Centre (PCC) and Ongwanada) or in other healthcare, clinic, or medical settings.
- Pharmaceutical device, drug, or natural product(s) clinical trials.
- Medical or physical interventions, treatments, therapies, or surgeries.
- New medical techniques or technologies, deviations from standard of care.
- Using human biological material from living or deceased participants; physical exertion (beyond walking/normal daily activities).
- Medical or dental patients, doctors, nurses, dentists, or any other health care professionals, and rehabilitation therapy.
- Accessing health or medical records.
- Using X-rays, CT scan, PET Scan, MRIs, ultrasounds, EKG or other medical tests or scans.
- Administering or ingesting any substance.
- Biobanks and large databases.

If none from the list above are applicable to your study, you must obtain a review from the GREB.

9.3 Hospital-based research: Opt-out research policy at KHSC

Kingston Health Sciences Centre and/or Hotel Dieu Hospital (KGH and/or HDH Sites) all conduct research using human participants and/or their data.

The current policy of Queen's University-affiliated hospitals at KHSC is that all patients, and their data, are available for research purposes. For patients who do not want their data available, there is an 'opt-out' research policy. Hospitals display posters in different hospital areas and on the website that informs patients they have a right to opt out of the research. Personal Health Information (PHI) that is contained in the medical records for all patients of KGH and/or HDH Sites is allowed to be used for research purposes **unless** patients have opted out by completing and submitting the "Withdrawal of Consent Form" found on the "My Healthcare Information" webpage on the KHSC website. Researchers, research staff, students, and trainees must verify within each medical record that consent for research has not been withdrawn by a patient if extracting patient data for research purposes.

All researchers must check the electronic medical record to ensure participants have not opted out of research before using any personal health information for research purposes. For instructions, refer to the Kingston General Hospital Research Institute (KGHRI) website, and navigate to the web page **For researcher, staff & trainees**. There you will locate the pdf document titled **"Accessing Medical Records for Research"** under the heading Research Roadmaps: Navigating the halls of Kingston Health Sciences Centre.

The study team must take this action to verify consent for research, and these steps must be documented in the REB application form.

9.4 Research that requires REB review approval

Research that involves interacting with human participants in any capacity requires REB review according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Article 2.1, includes:

- Collecting data from human participants.
- Analyzing human data.
- Research involving:
    - Psychological and behavioural interventions, Socio-cultural interaction.
    - Surveys, interviews, questionnaires, focus groups, observation.
    - Collection of biological material from human participants.
    - Clinical trials involving the use or administration, of drugs or medical procedures.
    - Some quality improvement/assurance studies and program evaluations which address a research question.
- Queen's University staff (including clinicians at affiliated Queen's Hospitals who fall under the mandate of HSREB) conducting research at another site (TCPS 2, Article 6.1).

9.5 Research exempt from REB review

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), provides several cases in which REB exemption can be granted for a research project. Currently, the following types of research typically **do not** require REB approval under TCPS 2:

- Research involving the observation of people who are in public view and where it is not anticipated that the recording of data will generate identifiable information.
- Research that relies exclusively on publicly available information where the information is legally accessible to the public and where individuals will not be identified.
- Research that involves using certain documents or records for which the individual's consent has already been provided.
- Quality assurance and quality improvement (QA/QI) studies, program evaluation activities, performance reviews, or testing within normal educational requirements. Note: Some QA/QI projects may require REB approval.
- Creative practice activities in arts, writing, and other related fields only require REB approval if it does not involve significant participant engagement in data gathering and doesn't intend to test a particular research question.

Important note: A researcher should consult with the REB in cases of uncertainties about the requirement for REB approval.

10 Types of REB review

10.1 Full Board review

Full Board Review is the full and comprehensive review of a research protocol and all relevant documents conducted by a majority of the members of the REB present at the meeting. A full board review is considered necessary for studies that are more than minimal risk, considering the vulnerability of the participant population. This includes reviewing the consent form(s), recruitment materials, protocols, recruitment processes, and other research documents. It also includes an open discussion among the REB members to ensure the research adheres to the highest standards of ethics and respect for human participants.

10.2 Delegated review

Delegated Review is a type of review conducted by delegated members of the REB for studies considered to be of minimal or no risk to research participants, considering the vulnerability of the participant population. This review typically involves a single, qualified member of the REB and a delegated staff member of the Research Ethics Office (REO). The primary purpose of this review is to provide the principal investigator with an efficient review process by eliminating the need for a full board review for certain studies.

11 Risk level of project

There are risks to participants being studied in research.

11.1 Minimal risk

Minimal risk means that the probability and degree of harm or discomfort anticipated in the research are not greater than those encountered daily or during routine physical or psychological examinations or tests. Interventions, such as surveys, questionnaires, interviews, and focus groups might be considered minimal risk.

11.2 More than minimal risk

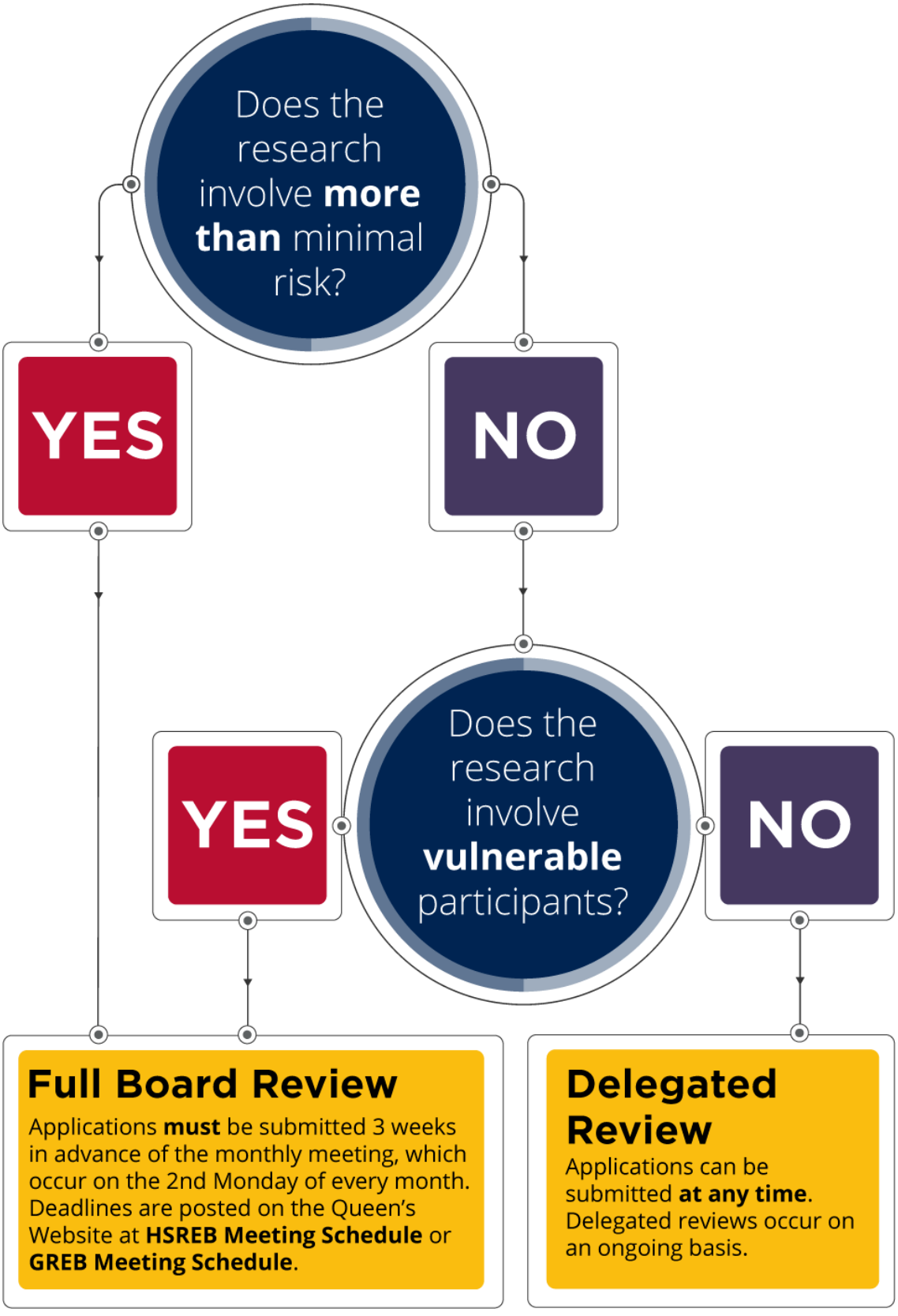
More than minimal risk involves a potentially higher risk level than that experienced in daily life or during routine examinations or tests. Interventions, such as testing new drugs/interventions, procedures that are not part of standard of care, and research about emotional trauma would be considered more than minimal risk.

11.3 Vulnerable groups

Vulnerable groups have historically included children, the elderly, students, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Vulnerability is often caused by limited decision-making capacity, or limited access to social goods.

Queen's University adheres to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), concerning the principle of proportionate review; that is, the higher the level of risk, the higher the level of scrutiny in the review process by the REBs. The risk matrix below will determine if a study receives a full board or a delegated review.

Figure 21 Risk level and the required REB review



11.4 Risk matrix

The risk matrix presents the relationship between the degree of a participant's vulnerability (low, medium, high) verses the degree of research risk (low, medium, high). The level of risk and vulnerability will determine the level of review required (i.e., delegated review or full board review).

Figure 22 Risk matrix: Participant vulnerability compared to research risk

When the participants vulnerability level is **low**, **medium,** or **high** and the research risk level is any combination of **low**, **medium,** or **high** a **full board review is needed**.

When the participants vulnerability level is **medium** and the research level is **low** a **delegated review is needed**, however, if the research risk level is **medium** or **high** then a **full board review is needed**.

When the participants vulnerability level is **low** and the research risk level is **low** or **medium** a **delegated review is needed**, however, if the research risk level is **high** then a **full board review is needed**.

11.5 Risk types

There are 5 types of risk associated with human participant research.

11.5.1 Physical risk

There is a chance that participants may be put in harm's way or suffer physical harm from participation in a study. This includes risks from obtaining samples or administering medications.

11.5.2 Psychological risk

Includes the potential for psychological harm or discomfort resulting from taking part in a study. This includes using touch, questions about intimate subjects, or exposure to distressing material.

11.5.3 Privacy risk

Research studies might require collecting data that is of a sensitive or confidential nature. In such cases, there is a risk that the information collected could be shared or disclosed without the participants' permission or knowledge.

11.5.4 Breach of confidentiality

Participants in research studies provide confidential information to a researcher. If a researcher divulges this information, it can lead to a breach of confidentiality and legal liability.

11.5.5 Loss of autonomy

A participant has the right to make their own decisions without being influenced by others, but in a research setting, they must follow the instructions of a researcher or risk ending their participation. This can lead to a sense of loss of autonomy.

12 Review cycle and process

The review cycle is a process by which the REB reviews and approves research protocols. This process begins with submitting the research application to the REB for review.

A research application includes:

- A protocol.
- Consent forms/letter of intent (if applicable).
- Recruitment materials (if applicable).
- Completed application form questions.

Based on this documentation, the risk level of the application is decided, and the review continues through to the approval or rejection of the protocol/study. The review cycle is completed when the REB has issued a decision to the investigator on the status of their application.

The review cycle in research ethics is made up of several steps:

1. Beginning with the principal investigator (PI) or applicant submitting an application for review. The proposal should include any pertinent information about the research project, including the research question, objectives, methods, timeline, and resources to be used.
2. The research application undergoes a preliminary review by the Research Ethics Office (REO). Once a preliminary review is conducted, the application may be returned to the PI or applicant for clarifications, edits, or modifications.
3. Once complete, the ethics submission is typically sent to the REB (or a subset of the REB, depending on the review level being conducted). The REB members are composed of a diverse group of experts in various fields who are responsible for ensuring that the ethical principles of research involving human participants are upheld. The reviewers must assess the research risks, including potential harms that participants may experience and any conflicts of interest that may unduly affect the research or its results.
4. The REB decides on whether to approve, reject, or suggest modifications for the research project. A detailed explanation of the rationale for the decision is made available to the PI or applicant.

12.1 Possible decisions of a research ethics submission post-review.

12.1.1 Approved

Allows the PI or applicant to ethically start the research project. It is the responsibility of the PI/applicant to ensure that other aspects such as: training (i.e., Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 CORE)) has been obtained by all research team members, CVs are on file, Data Transfer Agreements (DTAs) or Material Transfer Agreements (MTAs) are in place.

12.1.2 Approved with Modifications Required

The PI or applicant will modify the application/submission/documents, which must be re-submitted to the REB for further review. The application may undergo one or more review cycles between the PI or applicant and the REB before approval is obtained.

12.1.3 Deferred/Rejected

The PI or applicant cannot conduct research as ethics approval has yet to be obtained or has been rejected. If rejected, the PI or applicant will be able to appeal the decision.

Figure 23 Flow chart for the review cycle and process, part 1

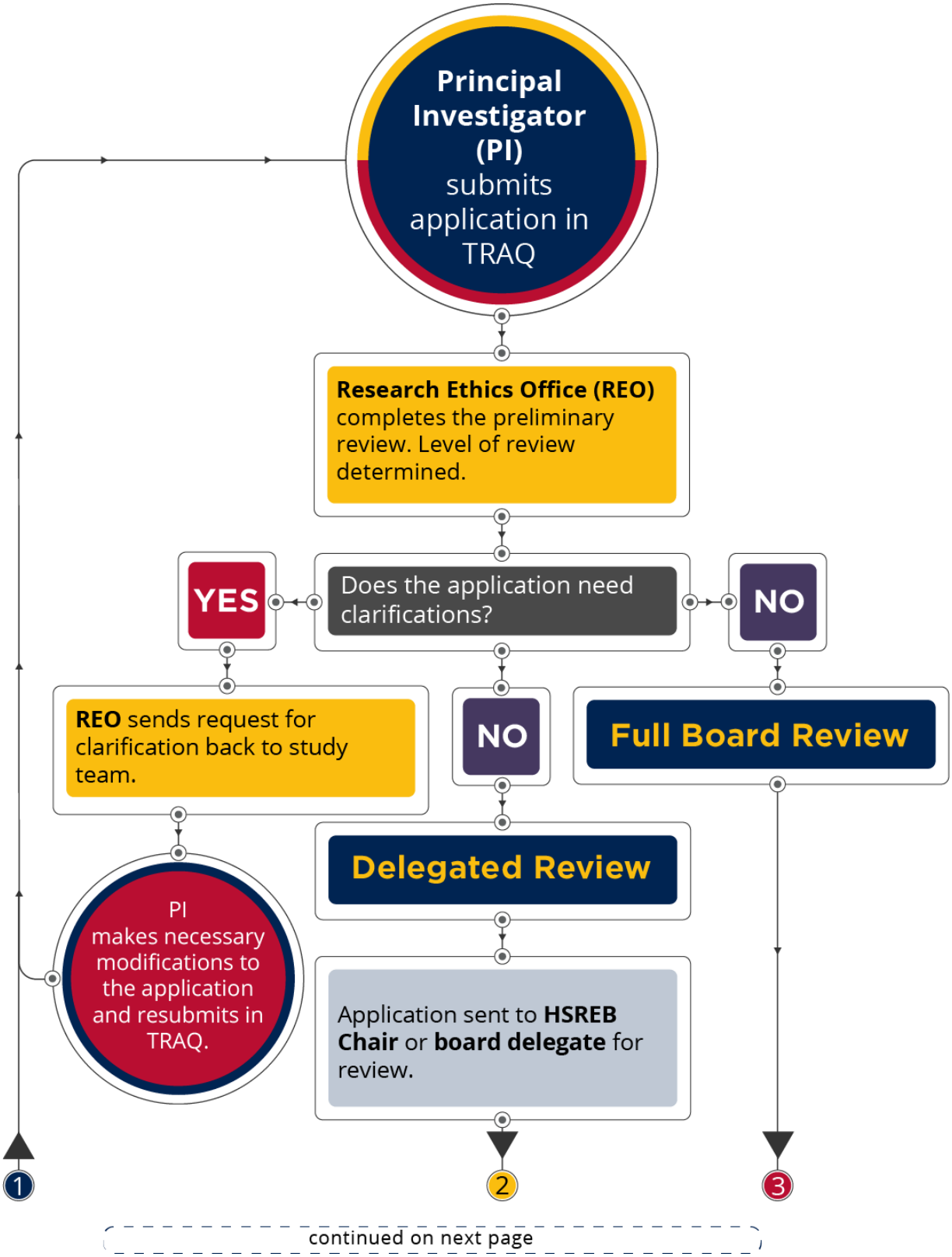


Figure 24 Flow chart for the review cycle and process, part 2

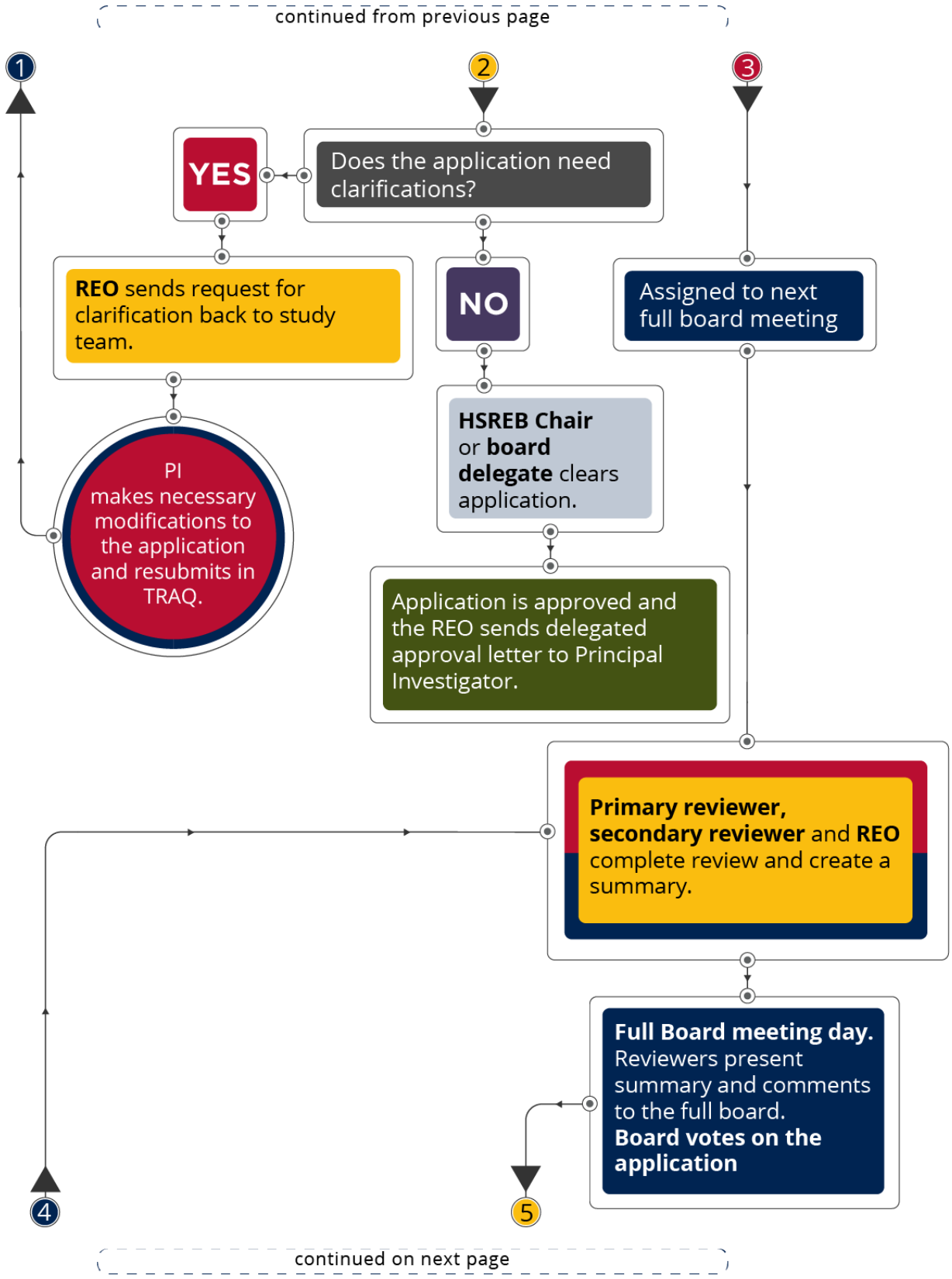
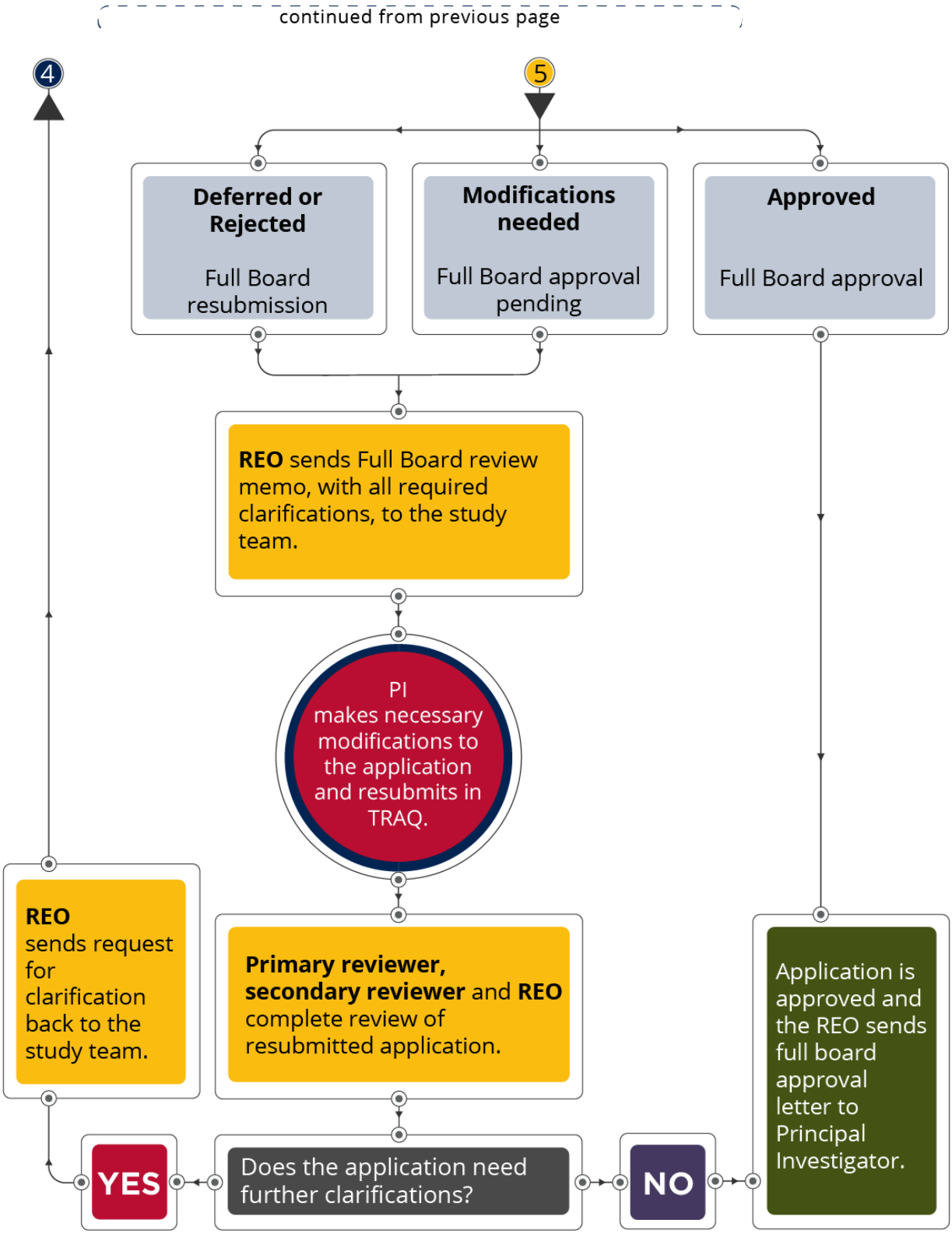


Figure 25 Flow chart for the review cycle and process, part 3



12.2 Research Ethics Board process and review cycle steps described

1. The Principal Investigator submits application in TRAQ.
2. The Research Ethics Office (REO) completes a preliminary review. Level of review determined.

Does the application need clarifications?

Yes, the application needs clarifications:

1. The REO sends a request for clarification back to the study team.
2. The Principal Investigator makes the necessary modifications to the application and resubmits in TRAQ.

No, the application does not need clarifications: A delegated review is decided.

1. The application is sent to HSREB Chair or board delegate for review.
2. The HSREB Chair or board delegate complete review.

Does the application need clarifications?

Yes, the application needs clarifications:

1. The REO sends a request for clarification back to the study team.
2. The Principal Investigator makes necessary modifications to the application and resubmits in TRAQ.

No, the application does not need clarifications:

1. The HSREB Chair or board delegate clears the application.
2. The application is approved, and the REO sends a delegated approval letter to Principal Investigator. The PI is now able to start the research project.

If an application is determined to need a Full Board review:

1. The application is assigned to the next full board meeting.
2. The primary reviewer, secondary reviewer, and REO complete the application review and create a summary.
3. On Full Board meeting day, the reviewers and REO present summary and comments to the Full Board. The board votes on the application.

The board **approves the application**:

- The application is approved, and the REO sends a full board approval letter to the Principal Investigator.

The board **deferrers/rejects the application** (full board resubmission) or decides that **modifications are needed** (full board approval pending):

1. The REO sends a full board review letter, with all clarifications, to the study team.
2. The Principal Investigator makes necessary modifications to the application and resubmits in TRAQ.
3. The primary reviewer, secondary reviewer, and REO complete review of resubmitted application.

Does the application need further clarifications?

Yes, the application needs clarifications:

1. The REO sends a request for clarification back to the study team.
2. The primary reviewer, secondary reviewer, and REO complete review of resubmitted application.
3. On Full Board meeting day, the reviewers and REO present revised summary and comments to the Full Board. The board votes on the resubmitted application.

No, the application does not need clarifications:

- The application is approved, and the REO sends a full board approval letter to the Principal Investigator.

13 Important submission deadlines

Studies deemed a higher risk, requiring a full board review, will have different submission deadlines than those deemed a lower risk, requiring a delegated review. **Not every study submitted to the REBs will receive a full board review.**

13.1 Full Board review

Full Board review: More than minimal risk (i.e., high risk studies based on risk type and vulnerability).
A Full Board meeting occurs on the 2nd Monday of every month. Ethics applications are due 3 weeks in advance of the monthly meeting. Meeting dates and submission deadlines are posted on the Queen's University Website at **HSREB Meeting Schedule** or **GREB Meeting Schedule**.

13.2 Delegated review

Delegated review: Minimal risk (i.e., low risk studies based on risk type and vulnerability). Ethics applications are reviewed on an ongoing basis.
There is no submission deadline. Applications can be submitted at any time.

14 Secondary use review (review of retrospective data collection)

The secondary use of data and/or biospecimens refers to the use of existing data, tissues or other biospecimens for purposes of research according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Article 5.4. That is, the proposed data and/or biospecimens were originally collected for another research purpose. Secondary use of data or biospecimens involves re-analyzing, re-examining, or repurposing data or biospecimens. Secondary use of data for research purposes requires REB approval. Suppose a study has been determined to be minimal risk and uses secondary data/tissues only. In that case, the study will undergo a secondary use, delegated review process.

Secondary use of data or biospecimens is becoming increasingly popular as biobanks and data repositories become more available. It is essential to ensure that the secondary use of data and/or biospecimens is conducted ethically.

When considering the secondary use of data or tissues in research ethics, there are several important factors to consider:

- **Informed consent**
  Determine whether the original consent obtained from participants or donors explicitly permitted secondary use. If not, consider seeking additional consent. Established biobanks and data repositories should have documents advising on the consent that has been given. However, it is the responsibility of the PI to ensure proper consent has been obtained.
- **Privacy and confidentiality**
  Ensure that appropriate measures are in place to protect the privacy and confidentiality of individuals whose data or biospecimens are being used.
- **Ethical approval**
  Review the ethical guidelines and obtain proper approval from the REB to ensure compliance with ethical standards.
- **Purpose and benefit**
  Clearly articulate the purpose of the secondary use and assess its potential benefits. Evaluate whether these advancements in knowledge or potential benefits outweigh any potential risks or harm to participants.
- **Use of identifiable information**
  Assess the necessity and justification for using identifiable information. Whenever possible, use de-identified or anonymized data or biospecimens to protect the privacy and confidentiality of individuals.
- **Data governance and handling**
  Establish clear data management, storage, and handling protocols. Implement appropriate security measures to prevent unauthorized access, loss, or misuse of data.

- **Transparency and accountability**
  Communicate transparently with participants, stakeholders, and relevant authorities about the secondary use of data or tissues. Ensure accountability in the use, storage, and sharing of data.

By considering these factors, researchers can navigate the ethical complexities associated with the secondary use of data or tissues, ensuring that studies are conducted with respect for individuals' rights and well-being.

15 Case report forms (CRFs)

For HSREB, a case report study/series is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient/person.

For GREB, a case report is a detailed report of the situation, events, and intervention or support provided in a person's file.

Certain types of case report studies require REB approval.

15.1 Research case reports requiring REB approval

Research case report studies will be reviewed under the TCPS 2, Article 2.1. A research case report satisfies the following:

- Includes a research objective and/or question (i.e., What, how, or why).
- Makes a conceptual and theoretical contribution to the discipline.
- This could include the development of a research instrument.
- It could have theoretical propositions.
- It will be submitted to an external publication or conference.

15.2 Teaching case reports do not require REB approval

Teaching cases are exempt from ethics review based on the TCPS2, Article 2.5. The ‘intent or purpose’ of a teaching case report study is for educational or learning purposes rather than research and, therefore, does not fall under the scope of the TCPS 2. A teaching case report will satisfy the following:

- It would be written as a “story.”
- It would be written to support problem-based learning.
- It would require teaching notes.

- It would value practical implications more than theoretical knowledge.

An applicant can submit to the REB for a teaching case report exemption letter if required.

16 Questionnaires

Questionnaires provide a way for researchers to collect data from participants in a structured and efficient manner. They can also be used to ensure that participants are not asked questions that make them uncomfortable by allowing them to skip over those questions. This will enable researchers to collect accurate data while respecting their participants' autonomy.

17 Quality assurance (QA), quality improvement (QI), and program evaluation (PE)

QA, QI and PE studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI projects are conducted internally and for operational and/or administrative purposes. QA is a process used to ensure services are meeting quality standards. QI is a continuous improvement process focused on processes and systems. PE is an evaluation of a program focused on weaknesses, strengths and room for growth or improvement.

QA/QI/PE studies do not require REB Review Per **TCPS 2 2022 Article 2.5**:

“Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.”

In order to determine whether your study qualifies as QA/QI/PE refer to the **ARECCI (Alberta Research Ethics Community Consensus Initiative) guidelines and screening tool.** The ARECCI Screening tool helps to determine the level of risk of your project, the types of ethical risks and the appropriate type of ethics review. You will be given a score: Yellow (score 0-7), Orange (score 8-46) and Red (score greater than 47).

There are exceptions to that rule where a QA/QI project may need an ethics submission and will receive an exemption letter from the REB:

- An explicit requirement by a funding agreement or by a prospective publication.
- The key purpose of QA/QI activities is research (i.e., to answer a research question).

- There is a plan to disseminate findings outside of the institution (e.g., conferences, journals).
- Personally identifiable information will be collected.
- Research associated with QA/QI poses more than minimal risk.
- The dual role of practitioner/researcher can be perceived as posing a conflict of interest.

Table 2 The differences between QA/QI/PE and Research

	Quality Assurance, Quality Improvement, and Program Evaluation	**Research**
Purpose	To improve internal processes, practices, costs, or productivity for a specific intervention (e.g., to decide how this intervention affected this participant in this setting)	To generate new knowledge that is generalizable to the wider population.
Will the result be generalizable	Results are (usually) not generalizable and are relevant only to the institution.	Results are generalizable and can be applied elsewhere. Generalizable knowledge consists of facts, theories, principles, or relationships of the accumulation of information on which they are based and that can be corroborated by accepted scientific methods of observation and inference.
Will participants be placed at risk?	There will be no risks beyond the usual intervention (e.g., to improve usual care and not place participants at risk)	There may be some risk incurred by participants (e.g., physical, emotional, privacy risks, or harm because of change in the usual standard of care/intervention)

	Quality Assurance, Quality Improvement, and Program Evaluation	Research
The TCPS 2	Article 2.5 – "Quality assurance and quality improvement studies, program evaluations activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this policy, and do not fall within the scope of REB review."	Article 2.1 – "research is defined as an undertaking to extend knowledge through a disciplined inquiry or systematic investigation."

18 Community engagement

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) recognizes the importance and value of community engagement in research. It is believed that community involvement strengthens the quality and impact of research, consequently facilitating research that is not only relevant but also respectful of the communities it intends to serve.

Community engagement under the TCPS 2 framework highlights the necessity for a meaningful collaboration between researchers and the community, promoting mutual respect, understanding, and shared responsibility. As such, participatory engagement models are advocated, where community members are actively involved in various stages of the research process, from planning and design to execution and interpretation of results. This approach makes research more contextual, localized, and ethically sound by directly considering and addressing the community's needs and concerns.

Figure 26 A diverse group of individuals working together

TCPS 2 also encourages mechanisms for continued engagement and feedback, fostering an ongoing dialogue and ensuring that results benefit the community.

Five considerations should be kept central to performing community engagement initiatives:

- Consultation
- Respect
- Interpretation
- Dissemination
- Benefits

Communities should be consulted to support transparency and an open dialogue. This will ensure that the research benefits the community. Interpretation of the research will be accurate as communication will be maintained.

Some community engagement efforts, according to the TCPS 2, Article 6.11, do not require REB approval unless they involve research. It extends to activities such as town hall meetings, public

consultations, and volunteer initiatives aimed at improving community wellbeing. However, if these activities are used as a platform to collect data for research purposes, then REB approval would be necessary. However, informing the REB at the time of submission about community engagement efforts is required.

Overall, the TCPS 2 emphasizes that only endeavours intended to contribute to a greater understanding or knowledge that follow a defined methodology fall under the purview of "research" and potentially require REB approval.

Several methods of engagement can be used:

- Obtaining consent from community leaders.
- Joint planning with a responsible party.
- Sealing the collaboration through a research agreement.
- Having discussions with an expert advisory group acquainted with the required information.

The engagement can range from merely sharing information to active collaboration and possibly sharing authority in the research project. However, the community may also choose to just recognize the initiative without any active engagement or objections.

18.1 Indigenous research

We acknowledge that this guidebook currently lacks comprehensive information on Indigenous content/research. The TCPS 2 is being updated to encompass additional guidance in this area. We warmly invite individuals who are interested in Indigenous research and have any queries or concerns to contact us directly at **researchethics@queensu.ca**.

19 Incidental findings

Incidental findings refer to unexpected results or findings that are not directly related to the research question or objective (e.g., a research study may call for a blood test and a CT scan to test for a blood clot and clotting agents. However, when the study results are returned, the CT scan reveals a growth. The growth was not an intended finding of the study however, now that the growth has been found it is termed an incidental finding). These findings can arise during data collection or analysis and may have ethical implications.

It is crucial to devise a plan and present it to the REB to appropriately handle incidental findings. This plan should involve clear guidelines on how to:

- Identify and manage incidental findings.
- Ensure that participants' rights and well-being are prioritized.

The plan should also involve obtaining informed consent from participants about the potential for incidental findings and how they will be handled. Additionally, it is important to have a framework in place to determine the significance and potential impact of these findings, as well as procedures for disclosure and follow-up if necessary.

By implementing a solid plan for incidental findings, researchers can promote transparency, respect participants' autonomy, and uphold the integrity of their studies.

Figure 27 Researcher speaking to participant and executing incidental findings plan

20 Translation documents

Translation certificates and documents are documents to certify or attest that a research study's text/documents have been accurately translated from one language to another. These documents often provide vital context and background information to the intended audience, ensuring that the original meaning of the text is conveyed.

Important note: The version date should not change from the English document to the translated document as the content of the approved English document has not changed.

20.1 Translation company

If a research team is using a translation company a translation certificate must be produced with details containing: the name of the document (not the electronic file name), the version date of the English document that has been translated and the stamp/signature of authenticity from the translation company certifying this as a true translation without content changes.

20.2 Independent translator (study team member)

If a research team is using a study team member or equivalent to translate a document then a translation attestation must be provided to the REB with details containing: the name of the document (not the electronic file name), the version date of the English document that has been translated and a signature to attest that this is a true translation without content changes.

21 Conflict of interest

Conflicts of interest in research refer to situations where financial, professional, or other personal considerations can improperly influence a researcher's decision making about conducting, designing, or reporting empirical findings of an investigation.

According to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2),Article 7.4, a conflict of interest is a conflicting situation that arises when the personal interests of a researcher, and/or associated persons, come into conflict with the duty of a researcher to the public, the research participants, the research sponsors, and/or the research funding body.

The TCPS 2 also states that conflicts of interest must be managed, reduced, or eliminated to ensure that the research is conducted ethically and with integrity. Any actual, potential, or perceived conflict of interest that can be pre-emptively predicted must be presented on the informed consent form and described in the ethics application.

22 Data management

Data management plays a critical role in research as it involves the responsible handling, storage, and protection of research data throughout the entire research process.

Ethical considerations in data management include:

- Protecting participant confidentiality.

- Ensuring data integrity.
- Adhering to relevant privacy regulations and policies.

Researchers must establish a data management plan that includes:

- Clear data collection.
- Storage protocols.
- Analysis protocols.
- Procedures for securely obtaining informed consent.
- Strategies for anonymizing or de-identifying data.
- Appropriate measures for securely sharing and transmitting data, if applicable.

Data management plans should address:

- How data will be stored.
- Who will have access to it.
- How long it will be retained.
- Consider factors such as privacy, security, and the potential for data sharing.

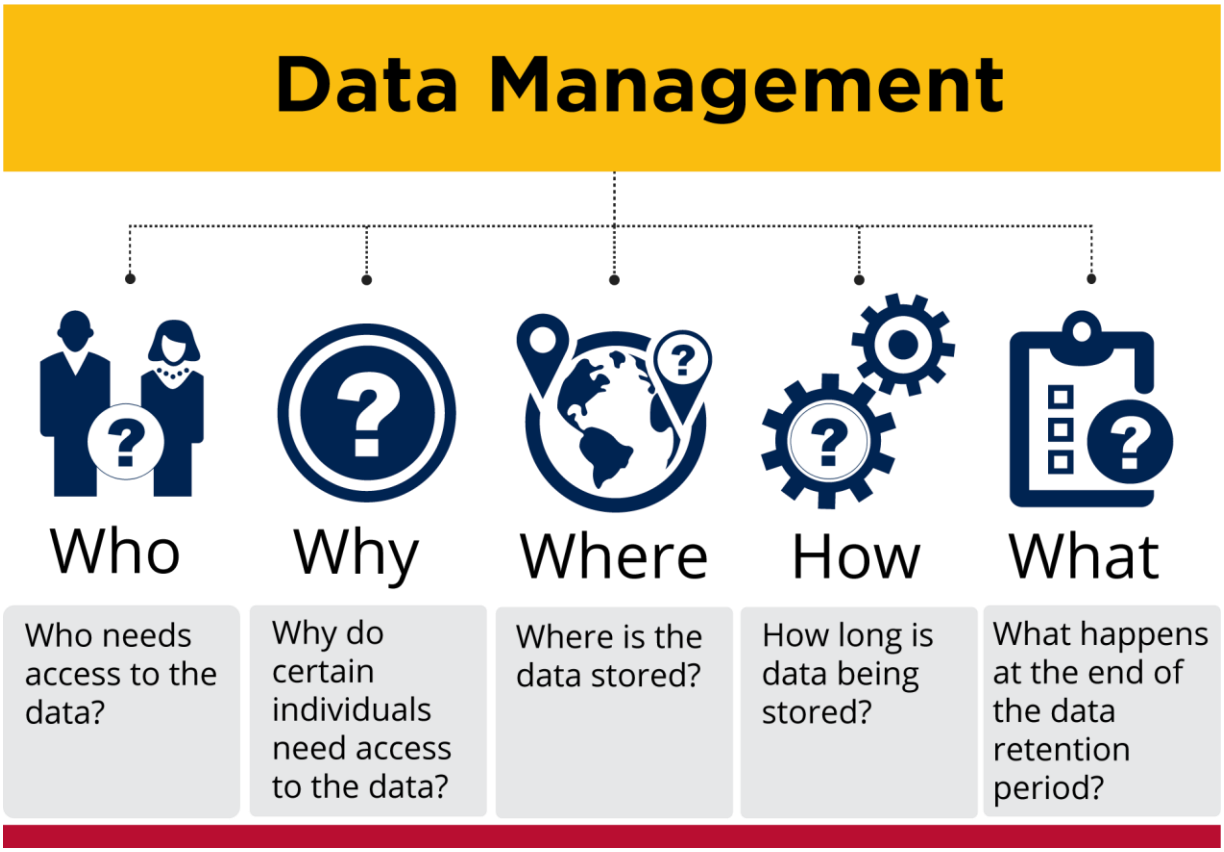
By implementing robust data management practices, researchers can safeguard the rights and welfare of participants, maintain data accuracy and integrity, and promote transparency and accountability in their research endeavors.

Things to consider for the development of a data management plan are:

- Plans for access.
- Plans for storage.
- Plans for retention.
- Plans for disposal of data.

These items can be considered by asking who, why, where, how and what.

Figure 28 The who, why, where, how and what questions of data management



Who and why

Who needs access to the data and why?

- Especially with identifiable data (e.g., DOB, video files).
- Is it necessary? What is the risk of re-identification?

Where

Where is the data stored?

- The preferred method for storage is Queen's OneDrive.
- Secure department drive.
- Portable device that can be encrypted and destroyed (e.g., USB).
- **Not** personal laptops.

How and what

How long is data being stored?

- Study teams should specify storage/retention

What happens at the end of the retention period?

- Disposal plans for identifiable data.

23 Privacy and confidentiality

Privacy and confidentiality are fundamental principles in research ethics and data management. Respecting privacy means protecting individuals' right to control the access and use of their personal information. At the same time, confidentiality ensures that the information shared by participants remains confidential and is not disclosed without their consent.

Researchers have an ethical obligation to manage personal and sensitive data with the utmost care, implementing measures to safeguard participants' identities and maintaining strict confidentiality protocols, including:

- Obtaining informed consent from participants.
- Storing data securely.
- Using anonymization or de-identification techniques to protect identities.
- Limiting access to the data to authorized personnel only.

Researchers must also adhere to relevant privacy laws and regulations, ensuring that participant information is not shared or used for purposes beyond the scope of the study. By prioritizing privacy and maintaining confidentiality, researchers can foster trust, honor the rights of participants, and uphold the ethical principles of research.

24 Personal Health Information Protection Act (PHIPA) and personal health information (PHI)

The Personal Health Information Protection Act (PHIPA) is legislation in Ontario, Canada that governs the collection, use, and disclosure of personal health information (PHI).

In research ethics, PHI is any individually identifiable health information about an individual which details:

- Past, present and/or future physical and mental health conditions.
- Health care payment information.
- Demographic information.

Examples of PHI include medical records, lab results, test results, insurance records, and any other individually identifiable health information.

PHIPA plays a crucial role in safeguarding the privacy and confidentiality of research study participants. Researchers must obtain informed consent from participants and ensure that their PHI is protected throughout the research process. PHIPA also outlines the responsibilities of researchers in securely storing and sharing PHI, as well as the rights of individuals to access and

correct their health information. Adhering to PHIPA guidelines ensures that research studies are conducted ethically and respects participants' privacy.

Queen's University REBs will request that PHI collection is limited to that necessary to fulfil the research objectives. The justification should be presented when the collection of any PHI will occur for research purposes.

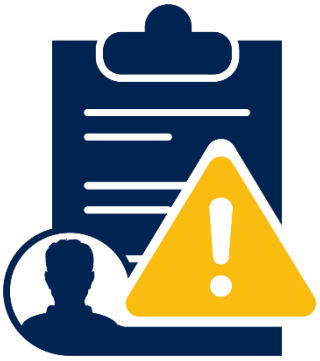
25 Classification of data

Study data can be classified through various methods, such as personally identifiable, de-identified, anonymized, and anonymous. These terms are not interchangeable.

25.1 Personally identifiable data

Personally identifiable data is any information that allows for the identity of an individual (i.e., directly identifies an individual). For example, full name, date of birth, health card number.

25.2 De-identified data



De-identified data involves the removal of direct identifiers, but it may still be possible to re-identify individuals using indirect information or via a linking log. For example, deleting or masking personal identifiers, such as participant name, with the use of a participant specific code.

25.3 Anonymized data

Anonymization removes or alters identifiable information from datasets, ensuring that individuals cannot be directly identified or re-identified. For example, data that has phone number and name would be removed. There would be no way to re-identify the individuals.

25.4 Anonymous data

Anonymous data refers to information that has never been associated with any identifiers. For example, filling out a survey online without providing any identifiers like email, phone number or name. Thus, there is absolutely no way to determine which response is associated with a particular individual.

25.5 Indirect identifying data

Indirect identifying information is not enough to confirm someone's identity. However, when combined with other information, it could indirectly identify someone. For example, gender, age, postal code, geographical area, or additional information.

The classification of data into these categories helps to protect privacy while still allowing for analysis and research.

26 Collection of data

Using a unique study identifier or code only as the unique identifier is considered best practice. The unique study identifier/study code must not include any Personal Health Information (PHI) of research participants, such as name, initials, full date of birth (DOB), and medical record number (MRN).

26.1 Master linking log vs. data collection tools

A master linking log is a document that allows researchers to link participants with a unique ID code to de- and re-identify them. It also links different data sources or records while maintaining confidentiality. These logs generally contain two columns: one for identifiable participant information (e.g., name, MRN) and one for the participant ID.

On the other hand, a data collection tool is a device or instrument used to collect data during a research study. It can be a questionnaire, survey, interview protocol, or any other tool that gathers information from participants. Participants are identified only by their participant ID or pseudonym on these documents.

The difference between a master linking log and a data collection tool in research ethics is that the master linking log focuses on maintaining participant confidentiality and privacy. It is a reference point to connect various data elements without directly identifying individuals. In contrast, a data collection tool is designed to collect specific information directly from the participants. It is used to systematically gather standardized data based on the research objectives.

Figure 29 Example of a master list

Master list

Participant ID	Hospital chart number
1.	
2.	

Figure 30 Example of a data collection tool

Data collection tool

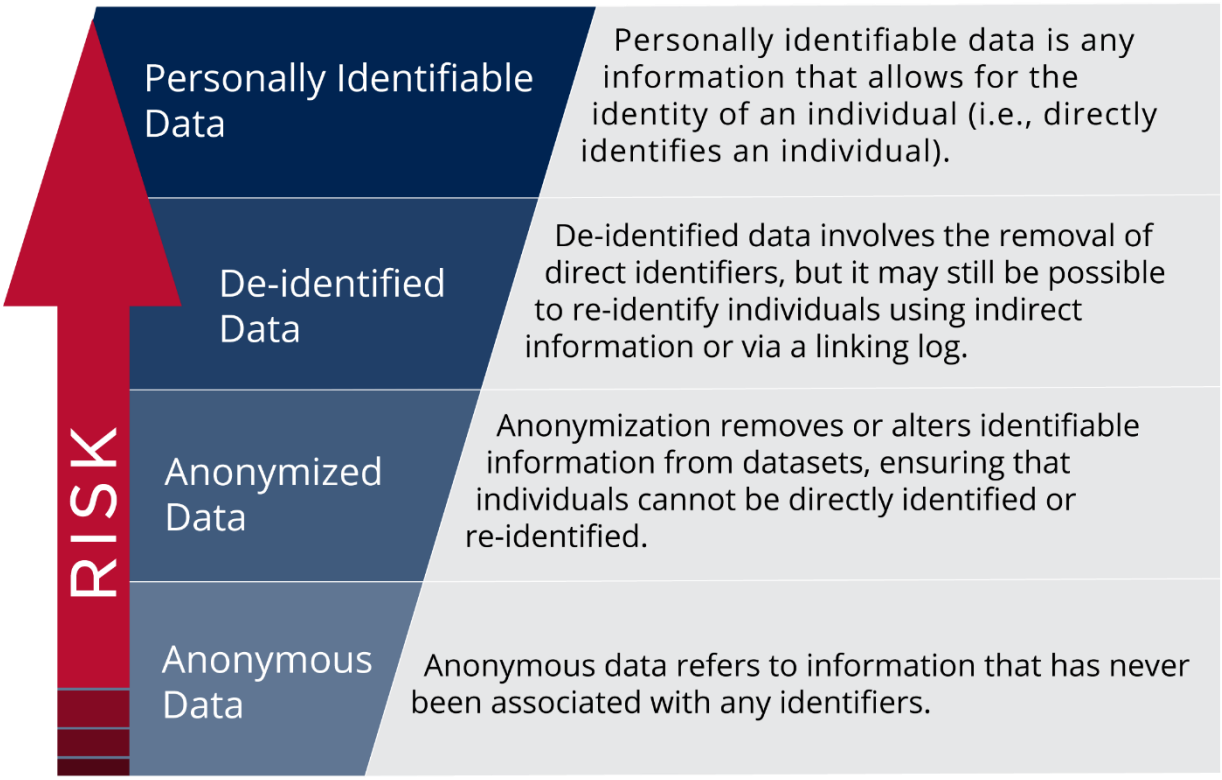
Participant ID	Age	Date of Dx	Test result 1	Test result 2

In summary, while a master linking log is concerned with the management of participant data and maintaining confidentiality, a data collection tool is focused on gathering data directly from participants during a research study.

26.2 Risk according to data classification

As the collection of identifiable data increases or the possibility of re-identification of data increases, the risk level of the study also increases.

Figure 31 Personally identifiable data increases risk



26.3 Data governance

Data managers or custodians are responsible for data governance with respect to monitoring, use of data and access to the data within ethical guidelines.

26.4 Access and permissions

Data managers/custodians are responsible for deciding who can access the data and how they can access the data. Access and permission rules must be created to ensure that data is only used in accordance with its intended purposes, and to limit potential data misuse.

26.5 Maintenance

Research data must be regularly checked and maintained to ensure accuracy and reliability. Data managers/custodians should establish and monitor processes to keep the data secure and up to date.

26.6 Risk management

With data come risks, and data managers/custodians must be responsible for managing and mitigating data-related risks. They should also have effective processes to detect, respond and deal with data security breaches.

26.7 Data managers/custodians

Data managers and custodians are responsible for monitoring the use of data, including preparing reports on data usage and analysis. They must also regularly review and update reports to go on in identifying any unusual usage or trends.

26.8 Version-control and file/document names

Version control and version dates on research documents is extremely critical. Version control serves as an effective tool in tracking modifications made to these documents, ensuring a clear audit trail of changes, justifying who made what alterations and when. This process safeguards the integrity of the research by avoiding potential duplications or discrepancies.

Equally important are version dates, which provide certain timestamps indicating when the changes occurred. They function as markers for the progress and development of the research over time, contributing to transparency and accountability in the research process. Together, version control and version dates in research documents uphold ethical research standards, boosting reliability and confidence in findings.

Files should be stored under a meaningful folder structure representing the study conducted and each file will have a relevant title and file name. Document names should reflect the contents of that document.

For example, the recommended format for a consent form is: ICF-Part A_v1_15Jul2023.

Important note: At a minimum, the file name should contain the document's name, version number, and date. Each time a change in a document is made, update the version number and date.

26.9 Storage of data

Queen's University follows a strict data storage policy to ensure that all sensitive data is kept safe and secure. This policy applies to any records containing personal information that are stored in any form, such as paper records, electronic records, voice recordings, and/or images.

Queen's University data storage policy requires that all records and personal information must be stored securely, with access limited to authorized staff only. Non-sensitive electronic information can be stored on-site or on the cloud, but all highly sensitive data must be stored on an approved secure network or protected servers.

All electronic information must be:

- Password-protected
- Encrypted
- Stored on secure servers with firewalls and anti-virus software (to protect from malicious attacks)

Data must be stored by researchers for 5 years post publication or study closure (but can be destroyed earlier if feasible), or 15 years from end of study in the case of Health Canada regulated studies.

Details of how data will be destroyed, if applicable, should also be provided to the REB. If data will not be destroyed, this should also be clearly described in the ethics application, along with the proposed data storage/retention plan. If indefinite storage is proposed, this must be justified, and a long-term data storage/security plan must be outlined. The data management plan must be disclosed to the participants during the consenting process.

It is recommended to store data behind 2 physical safeguards, 2 administrative safeguards and 2 technical safeguards.

26.9.1 Physical safeguards

These include locked office, locked storage unit, biometric authentication, cipher/coded locks, access cards, etc.

26.9.2 Administrative safeguards

These include developing and enforcing organizational rules about who has access to personal information about participants (e.g., computer passwords only with study team, designated person responsible for controlling who has access to data, etc.)

26.9.3 Technical safeguards

These include use of computer passwords, firewalls, anti-virus software, network drive, encrypted computer, encrypted USB, etc.

26.10 Data management IT platforms

Queen's University has robust and advanced information technology resources, effectively promoting e-learning and safe communication within its community. The institution endorses various IT platforms to ensure efficient functionality and security. These IT platforms have been thoroughly vetted and deemed appropriate for use by Queen's University staff, students, and faculty.

Queen's ITS partners with Microsoft Office 365 for document management and collaboration, enabling students and staff to access emails, word processing, and presentation tools remotely. The university's online Learning Management System (LMS), onQ, supports e-learning through web conferencing, course content, assessments, and discussions. The institution utilizes Zoom and Microsoft Teams for meetings and webinars to foster seamless remote collaboration. For data analysis and visualizations, the approved platform is Tableau. For every approved platform, the university offers thorough training and user support, reinforcing the commitment to safe and efficient usage of IT resources in its academic ecosystem.

If a researcher plans to use a non-ITS Queen's approved platform, the following questions should be considered, with appropriate responses included with the REB submission:

- Description of the privacy and security of the app.
- How is data shared?
- How is data stored?
- Who has access to the data?

When using external applications:

- Provide a plain language description of the privacy and security of the app.
- Describe how the app meets Queen's ITS standards.
- Explain how data will be shared (e.g., for transcription purposes).
- Indicate if the data will remain on the platform after the end of the study.
- Identify who owns the data and who has access to it.

When using mobile apps:

- Indicate if participants need to download apps or can a study device be provided.
- If the app is installed on a participant's phone, identify what data is being collected outside of study data (e.g., location data, IP address, contact information, camera and/or microphone access).
- Explain who has access to non-study data and for what purpose.

26.11 Protection during data/materials transfer

Should there be a transfer of data or materials to or from Queen's University, it is critical to explain to the REB what measures for protection and safeguarding will be implemented during the interaction with external sites. It is of the utmost importance that no identifiable information departs from Queen's University. In instances where there is an exchange of data or materials with another site, a data or materials transfer agreement (DTA or MTA) may be required.

Important note: A DTA/MTA may be required if information/data is being transferred to or from Queen's University to its affiliate hospitals, as these are considered independent entities.

Important note: A DTA may be required if information/data is being transferred to and received from a transcription service.

For guidance on the prerequisites of a transfer agreement, please reach out to the **Legal Department** at Queen's University.

26.12 Borealis

Queen's University has a data repository, Borealis. The Queen's Collection within Borealis is designed to store research data that is intended to be shared with other researchers and reused in future research studies.

If you do not intend to share your research data with other researchers, depositing that data into Borealis is unnecessary. In this case, you can simply keep the data in OneDrive and delete it after the 5-year retention period.

Important note: To protect the privacy of your participants, you can delete the linking file when you no longer need it for analysis purposes. You do not have to wait 5 years to delete this file.

If you do intend to share your research data with other researchers, then you should deposit your anonymized data into Borealis immediately upon completion of your project. (Using Borealis as your storage platform would satisfy the minimum 5-year retention requirement of the Senate's Policy on the Integrity of Research.)

If you intend to share your data with other researchers, the intent for indefinite storage and data sharing should be included in the consent process.

27 Serious adverse events (SAEs), adverse events (AEs), and protocol deviations (PDs)

Serious adverse events (SAEs), adverse events (AEs), and protocol deviations (PDs) are critical aspects of any research study that must be carefully monitored and reported to ensure the integrity and safety of participants.

27.1 Serious adverse events (SAEs)

SAEs refer to any unexpected occurrence during a study that results in death, hospitalization, disability, or any other life-threatening or significant event. SAEs are to be reported to the REB within 5 calendar days.

27.2 Adverse events (AEs)

AEs encompass any unfavorable occurrence in a participant, even if it does not have a direct causal relationship with the intervention being investigated. AEs are to be reported to the REB within 15 calendar days of the PI becoming aware of them.

27.3 Protocol deviations (PDs)

PDs involve any departure from the research plan or protocol, including deviations in the administration of interventions or the collection of data. PDs should be reported to the REB within 3 months of the PD occurring.

It is crucial to promptly report SAEs, AEs, and PDs to the research ethics committee to uphold ethical standards and protect participants. This reporting process allows for the continual monitoring and evaluation of the risks and benefits of the study, leading to appropriate interventions or modifications to the protocol, if necessary.

Overall, transparent, and diligent reporting of these events contributes to advancing scientific knowledge and the well-being of research participants.

28 Non-Compliance

Research ethics are pivotal in maintaining integrity, validity, and credibility in any research project. However, non-compliance has been found to yield catastrophic effects on the research community and society.

Non-compliance with research ethics can encompass many forms, including:

- Data fabrication
- Plagiarism
- Protocol deviations
- Unethical experimentation on human subjects

Such non-compliance compromises the research outputs' reliability and undermines public trust in scientific research. Research ethics, therefore, serve as the bedrock foundation for maintaining ethical behavior, promoting the honest interpretation of results, and fostering responsible conduct among researchers. Furthermore, they protect participants and ensure the appropriate use of scientific methods, thereby upholding the sanctity of scholarly investigation and safeguarding the reputation of the research community. The role of ethics in research is integral and inalienable, as it builds an accountable and respectful environment where non-compliance is discouraged and penalized.

If non-compliance is found, the following actions may be taken:

- Disallowance of data, publication, presentation.
- Hold/Suspension of the research.
- Termination of the research.
- Involvement of the Queen's University Compliance Team.
- Loss of ability to obtain Tri-Agency funding.

Compliance inspections of studies performed under the auspices of Queen's University may be undertaken at any time. Study teams should always manage and maintain study documentation in line with REB approval to avoid being found non-compliant.

The VPR compliance team will work with the REBs, ethics office, and study team to ensure studies are brought back into alignment with approved processes, as needed. More information can be found on the **VPR website**.

29 Initial applications and post approval applications

Submissions to the REB can largely be categorized into two types:

- Initial submissions
- Post approval submissions

Initial applications are the preliminary proposals researchers submit for ethical consideration. For example, studies that have not received ethics approval and have not yet started. These encompass the purpose, methodology, and potential impact of the intended research and include details about participant consent and protection, anticipated results, and risk-benefit analysis. These submissions can be reviewed via the full board or delegated review method.

Post approval submissions represent subsequent submissions to the file put forth after initial approval has been granted, and may include:

- Requests for amendments to the original plan.
- Continuation or renewal of projects.
- Deviations in the research plan.
- Reporting unexpected occurrences:
    - Protocol deviations
    - SAEs, AEs
    - DSMB
    - Privacy breaches
- Study closures

This allows the REB to monitor ongoing research and ensure adherence to ethical guidelines.

30 Queen's Application Systems

30.1 Tools for Research at Queen's (TRAQ) and Clinical Trial Ontario (CTO)

Queen's university uses two application platforms:

- Tools for Research at Queen's (TRAQ)
- Clinical Trial Ontario (CTO)

Both platforms significantly differ in their roles and functions at Queen's University. TRAQ is an internally focused research management system, providing a unified platform for all Queen's research proposal submissions to REB, tracking and storing data regarding the project. This

includes ethics review, financial details, and project outcomes. Submissions to either GREB or HSREB can be submitted via TRAQ.

On the other hand, CTO works at a broader scale, focusing on streamlining the approval process of clinical trials across the province. Unlike TRAQ, however, CTO is not limited to a sole institution but works to improve and enhance the quality of the research environment across Ontario. Only submissions to HSREB can be submitted via CTO.

30.1.1 TRAQ - HSREB and GREB

- Used for all single centre studies being run at Queen's University.
- Used for multi-centre studies where the lead site is not using CTO (i.e., could be outside Ontario/international).

30.1.2 CTO - HSREB

- Used for multi-site research studies in Ontario.
- Streamlined ethics review.
- One board of record for all centres in Ontario.
- Initial application is provincial and then each centre will submit a centre application based on the initial provincial application.
- CTO has its own consent templates.

31 TRAQ Applications and Events

HSREB and GREB both have application processes in the TRAQ system. Once the appropriate board for submission is determined, the type of application/event will be selected. Below is a summary of the applications/events available and when to use them.

31.1 HSREB applications available and when to use them

Table 3 HSREB applications available and when to use them

Application Name	Description

HSREB - Application for Prospective Research with Human Participants	Complete this form if you wish to start a new prospective research study involving human participants. Prospective research evaluates the effects of one or more health-related interventions on health outcomes. Investigations include, but are not restricted to, drug administration, surgical procedures, radiologic procedures, devices, genetic therapies, cells and other biological products, radiopharmaceuticals, natural health products (NHPs), preventive care, manual therapies, psychotherapies, as well as prospectively collecting data/biological specimens, or interventions and physical interventions, interviews, surveys, questionnaires, focus groups/sharing circles, biological sample collection, creation of a database, etc. Refer to SOP 101.
HSREB - Application for Multi-Jurisdictional Review	Complete this form if ethics approval has already been obtained from another Canadian institution (adhering to the Tri-Agency Funding requirements). Note: this form can only be used if the local researcher is responsible only for receiving funding and/or data and/or samples for analysis (i.e., without local active recruitment or participant interaction). Please note that determining which institutional REB is the one that you must seek approval from first (it is not necessarily your home institution first) may need to be discussed. Before you begin preparing the multi-jurisdictional REB application, it is recommended that you reach out to the Research Ethics Office at **researchethics@queensu.ca**. Refer to SOP 408.
HSREB - Application for Secondary Data Use	Complete this form if you are conducting research involving secondary use of data (other than chart reviews) or secondary use of biological samples (i.e., data or samples that have been initially collected for a different purpose), and that does NOT involve recruitment of participants or interventions.

	Review by a research ethics board is required for all research that relies exclusively on secondary use of information unless the information is publicly available. NOTE: To use this data, you will have to demonstrate that consent (i.e., broad consent) was obtained by the participants in the initial data collection study or describe how your proposed use of the data satisfies the TCPS 2 Article 5.5A and/or 5.5B. Refer to SOP 102.
HSREB – Application for Chart Review	Complete this form if you are conducting a study that solely involves Chart Review(s). If your study involves any other methodologies alongside the chart reviews, you must use the appropriate alternative application form. A chart review is an evaluation or analysis of a patient's medical record. As the information contained in medical records was originally collected for another purpose (e.g., clinical treatment), when used for research purposes, chart reviews are considered "secondary use of identifiable information for research purposes." Refer to SOP 102.
HSREB - Application for Case Study/Series	Complete this form for case report study/series. Case reports are unique accounts of individual cases noted during regular practice. These reports are not initiated as inquiry/investigation, nor are these cases meant to be generalizable. If your case report study/series has a research objective, you will require approval by HSREB. prior to beginning your case report study/series. If your case report study/series is a teaching series, you can obtain an exemption from the HSREB. Refer to SOP 102.
HSREB – Application for Quality Assurance/Quality	Complete this form if your research is a Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (QA/QI/PE) study.

Improvement/Program Evaluation (QA/QI/PE)	QA/QI/PE studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI/PE projects are conducted internally and for operational and/or administrative purposes per TCPS 2 Article 2.5. QA/QI/PE projects will be granted a formal exemption by the REB. Please refer to SOP 102.

31.2 HSREB events available and when to use them

Table 5 HSREB events available and when to use them

Event:	**Description**
HSREB Adverse Event and Serious Adverse Event Form	Complete this form to submit adverse events or serious adverse events which satisfy the reporting criteria. The Researcher is responsible for reporting to the REB any information about the conduct of the research that could affect the rights, safety, and well-being of research participants, including information about any serious or continuing noncompliance. Refer to SOP 404.
HSREB Amendment Event Form	Complete this form to make any changes to the initial REB-approved research. Researchers may only implement changes to their study once the amendment has been reviewed and approved by the REB. If the change is necessary to eliminate an immediate hazard to a participant, the change can be implemented prior to REB review; however, the REB must be immediately notified, and the modification submitted for consideration immediately thereafter. Refer to SOP 404.
HSREB Change to Project Team Event Form	Complete this form to request changes (additions or removals) to the study team members who have or require TRAQ access.

	NOTE: You do not need to submit this form for a study team member change involving personnel who do NOT require access in TRAQ. If study team members require access to the files/correspondence in TRAQ, they must be listed as a study team member within the study files.
HSREB Protocol Deviation Event Form	Complete this form to submit a protocol deviation (PD) report. PDs are changes to the study that have not undergone ethics review and received approval. These are normally unanticipated or unintentional changes. Refer to SOP 102 and 404.
HSREB Privacy Breach Event Form	Complete this form to submit a privacy breach report. Privacy breaches occur when there is unauthorized access to, or collection, use, or disclosure of, personal information. Refer to SOP 404.
HSREB Renewal Event Form	Complete this form to submit a study renewal. Renewals are required for research that will continue beyond the stated approval expiry date. Renewal dates are usually on the anniversary date of the initial REB approval, but not always, so please check the expiry date on the approval letter. It is the responsibility of the researcher to submit the renewal according to Queen's SOPs. Refer to SOP 405.
HSREB Study Closure Event Form	Complete this form to submit a study closure. Study closures should be submitted when: there is no further participant involvement at the site; there will be no new data collected from the study participants; databases are "locked" and queries have been resolved; sponsor closeout activities have been completed (if applicable). Refer to SOP 405 and 406.

31.3 GREB applications available and when to use them

Table 6 GREB applications available and when to use them

Application Name	Description
GREB - Application for Prospective Research with Human Participants	Complete this form if you wish to start a new prospective research study involving human participants. Use this form if the research study looks at the relationship between people and their surroundings, including how people interact with each other, their communities, and institutional systems. They include psychological phenomena such as emotions, biases, and motivations. Psychological therapy and counselling studies fall under behavioural research. Emergent design and community-based studies are considered social science and behavioural research unless a clinical intervention is involved. Common methods include, but are not limited to, interviews, focus groups, surveys, questionnaires, behavioural therapy workshops, experimental coaching, and observations. Refer to SOP 101.
GREB - Application for Multi-Jurisdictional Review	Complete this form if ethics approval has already been obtained from another Canadian institution (adhering to the Tri-Agency Funding requirements). Note: this form can only be used if the local researcher is responsible only for receiving funding and/or data and/or samples for analysis (i.e., without local active recruitment or participant interaction). Please note that determining which institutional REB is the one that you must seek approval from first (it is not necessarily your home institution first) may need to be discussed. Before you begin preparing the multi-jurisdictional REB application, it is recommended that you reach out to the Research Ethics Office at **researchethics@queensu.ca.** Refer to SOP 408.

GREB – Application for Secondary Data Use	Complete this form if you are conducting research involving secondary use of data (i.e., data that have been initially collected for a different purpose), and that does NOT involve recruitment of participants or interventions. Review by a research ethics board is required for all research that relies exclusively on secondary use of information unless the information is publicly available. NOTE: to use this data, you will have to demonstrate that consent (i.e., broad consent) was obtained by the participants in the initial data collection study or describe how your proposed use of the data satisfies the TCPS 2 Article 5.5A and/or 5.5B. Refer to SOP 102.
GREB - Application for Chart Review	Complete this form if you are conducting a study that solely involves Chart Review(s). If your study involves any other methodologies alongside the chart reviews, you must use the appropriate alternative application form. A chart review is an evaluation or analysis of an individual's record. As the information contained in the records was originally collected for another purpose (e.g., court proceedings or probation orders), when used for research purposes, chart reviews are considered "secondary use of identifiable information for research purposes." Refer to SOP 102.
GREB - Application for Case Study/Series	Complete this form for case report study/series. Case reports are unique accounts of individual cases noted during regular practice. These reports are not initiated as inquiry/investigation, nor are these cases meant to be generalizable. If your case report study/series has a research objective, you will need to obtain approval by GREB before beginning your case report study/series. If your case report study/series is a teaching series, you can obtain an exemption by GSREB.

	Refer to SOP 102.
GREB – Application for Quality Assurance/Quality Improvement/Program Evaluation (QA/QI/PE)	Complete this form if your research is a Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (PE) study. QA/QI/PE studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI/PE projects are conducted internally and for operational and/or administrative purposes per TCPS 2 Article 2.5. QA/QI/PE projects will be granted a formal exemption by the REB. Refer to SOP 102.
GREB – Application for Instructor Course-Based Research Assignment	Complete this form if you are an instructor and you wish to oversee the conduct of course-based student research assignments. Review of course based research is required due to participants encountering similar risks and experiences in these course assignments as they would in research studies, even if the assignments are primarily learning experiences for students. This includes, for example, asking students to conduct interviews to collect data to be used in a course assignment, or to practice interviewing techniques. Participants in the activities may be exposed to risks (normally minimal risk) as a result of their participation and may not distinguish these activities from others that meet the definition of research in TCPS 2.
GREB – Application for Self Study	Complete this form for research where self-study is the only type of research being conducted. Self-study research is an approach to understand one's own practice and one's self-concept, means that individuals look critically at their own professional values, work towards a better self-understanding, and have a moral purpose.

31.4 GREB events available and when to use them

Table 7 GREB applications available and when to use them

Event:	**Description**
GREB Adverse Event (AE) Form	Complete this form to submit adverse events which satisfy the requirements of submission criteria. The Researcher is responsible for reporting to the REB any information about the conduct of the research that could affect the rights, safety, and well-being of research participants, including information about any serious or continuing noncompliance. Refer to SOP 404.
GREB Amendment Event Form	Complete this form to make any changes to the initial REB-approved research. Researchers may only implement changes to their study once the amendment has been reviewed and approved by the REB. Refer to SOP 404.
GREB Change to Project Team Event Form	Complete this form to request changes (additions or removals) to the study team members who have or require TRAQ access. NOTE: You do not need to submit this form for a study team member change involving personnel who do NOT require access in TRAQ. If study team members require access to the files/correspondence in TRAQ, they must be listed as a study team member within the study files.
GREB Protocol Deviation Event Form	Complete this form to submit a protocol deviation (PD) report. PDs are changes to the study that have not undergone ethics review and received approval. These are normally unanticipated or unintentional changes. Refer to SOP 102 and 404.
GREB Privacy Breach Event Form	Complete this form to submit a privacy breach report. Privacy breaches occur when there is unauthorized access to, or collection, use, or disclosure of, personal information.

	Refer to SOP 404.
GREB Renewal Event Form	Complete this form to submit a study renewal. Renewals are required for research that will continue beyond the stated approval expiry date. Renewal dates are usually on the anniversary date of the initial REB approval, but not always, so please check the expiry date on the approval letter. It is the responsibility of the researcher to submit the renewal according to Queen's SOPs. Refer to SOP 405.
GREB Study Closure Event Form	Complete this form to submit a study closure. Study closures should be submitted when: There is no further participant involvement at the site; there will be no new data collected from the study participants; databases are "locked" and queries have been resolved; sponsor closeout activities have been completed (if applicable). Refer to SOP 405 and 406.

32 Clinical Trials Ontario Applications

32.1 Provincial Initial Application (PIA) vs. Centre Initial Application (CIA)

In the Clinical Trials Ontario system, two types of initial applications are available:

- Provincial Initial Application (PIA)
- Centre Initial Application (CIA)

The main difference between these two types of applications is in the scope of their coverage.

A Provincial Initial Application (PIA) covers multiple sites within a specific province, allowing researchers to submit a single application for all the sites involved in the clinical trial.

This application acts like a master trial file, containing the:

- Protocol
- Consent forms
- Participant facing documents
- CRFs
- Questionnaires
- Recruitment documents
- Patient facing documents

The PIA must be submitted and approved by HSREB before any CIA is approved. Once the PIA is approved, a Centre Initial Application (CIA) can be submitted.

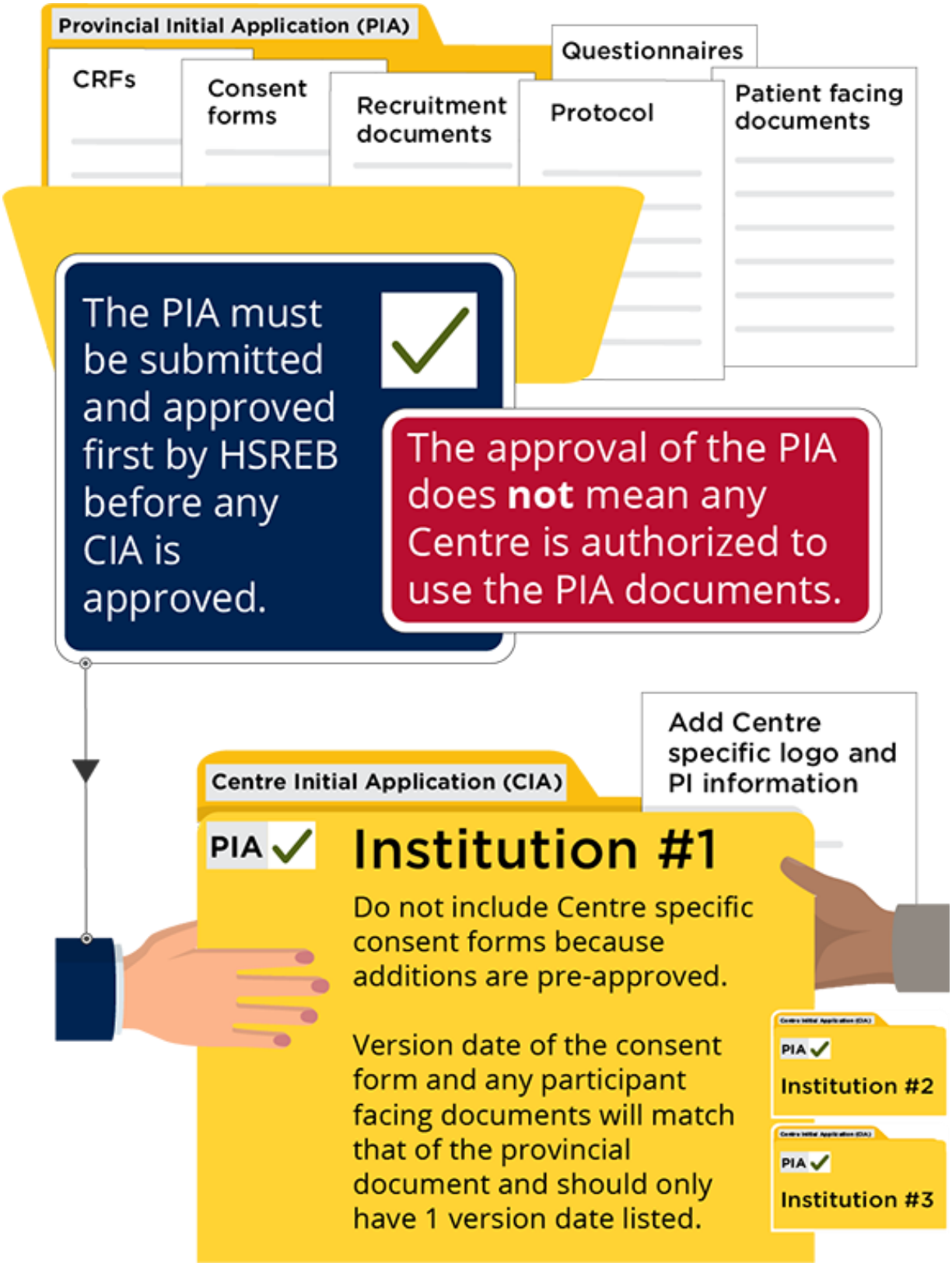
Important note: The approval of the PIA does not mean any Centre is authorized to use the PIA documents.

A CIA is specific to a single site, providing a more focused approach for researchers who are conducting trials at a single location. The CIA must include Centre specific logo and PI information.

Important note: Version date of the consent form and any participant facing documents will match that of the provincial document and should only have 1 version date listed.

A provincial applicant (who submits the PIA) will also have to submit a CIA if their site will be participating.

Figure 32 Provincial initial application, related documents, and CIA requirements



Conclusion

This guidebook provides an overview of the principles of research ethics and a guide on the processes that direct the research review method with HSREB and GREB at Queen's University.

The goal of HSREB, GREB and the REO is to ensure that research is conducted ethically and responsibly. Research ethics is essential for conducting any study or research activity ethically and responsibly. It involves assessing potential risks, determining the level of review required for approval, obtaining informed consent, providing adequate protection for confidential information, and ensuring accuracy and reliability of data. This is important to ensure that the autonomy, dignity, rights, and well-being of those involved in the research process, including participants, collaborators, research staff, institutions, communities, and the public, are respected.

Resources

Kingston General Hospital Research Institute (KGHRI) document titled “Accessing Medical Records for Research” is found at **For researcher, staff & trainees**.

Microsoft’s **instructions for assessing reading level** to determine if a document is at a grade 8 or lower reading level.

Queen’s **Off-Campus Activity Safety Policy** (OCSAP)

Stephanie Glen explains snowball sampling in the video, **Snowball Sampling: Definition, Advantages and Disadvantages**,

Tri-Council Policy Statement: **Ethical Conduct for Research Involving Humans** (TCPS 2)

Citations

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022. https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf, Retrieved on August 31, 2023.

Glen, S. (2022, December 12). Snowball sampling: Definition, advantages, and disadvantages. Statistics How To. https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/snowball-sampling/

Teach Back. (2022, November 24). *Teach-back*. Retrieved October 19, 2020, from http://teachback.org/

Contacts

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Vice-Principal Research for all other questions, please email **research@queensu.ca**