Section 1: Study Overview

1.4) * Is this a multi-site research study? (select all that apply):

If the study is conducted at more than one research site in Ontario, you should submit using the Clinical Trials Ontario (CTO) Streamlined Research Ethics Review System or to the Ontario Cancer Research Ethics Board (OCREB). OCREB is an expert central oncology REB that reviews multi-centre clinical cancer trials for almost every hospital in Ontario. CTO and OCREB's centralized models mean that once a study has received ethical clearance, participating study sites can receive a delegated ethics review. "This streamlines the review process, minimizes redundancy, ensures harmonization and consistency, and saves the time and cost of having the study reviewed by an REB at every participating institution (study site)" (OCREB).

Yes

No

1.10) * This study will involve the following (select all that apply):

Pharmacokinetics (PK) characterizes the absorption, distribution, metabolism, and elimination properties of a drug. Pharmacodynamics (PD) defines the physiological and biological response to the administered drug. The term 'disinfectant' includes bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants, or combinations of these. A disinfectant without specific target organisms indicated on the product label is regarded only as a bactericide.

Drugs, Biologics (including vaccines), Genetic Therapies, or Radiopharmaceuticals

Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))

Medical Devices

Biological specimen collection for research purposes (e.g., blood/tissue for PK/PD, biomarker, biobanking, genetic testing, etc., excluding specimens taken as part of normal care or for safety)

Imaging/Radiation (including tests involving exposure to radiation)

Surveys/Questionnaires/Interviews/Focus Groups

Audio/Video Recording

Registry

Observation

Other (specify below)

1.11) If 'other' selected above, specify:

1.12) * Does this study require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)? (select all that apply):

Yes - A Clinical Trial Application under the Food and Drugs Act

Yes - A Clinical Trial Application under the Natural Health Products Regulations

Yes - A Clinical Trial Application under the Medical Device Regulations

No

1.13) * Is this study funded or supported by the United States Federal Government or is your study subject to the Code of Federal Regulations Title 21 Food Drug Administration and/or Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects?

'Federally supported' is defined as the U.S. Government providing any funding or other support including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes and/or the conduct of the research involving U.S. Government employees. Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within 107.28 Tm [(limi)-6.6 (te)-26-2 (r)2 re ff 72 87.42

(FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP). Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46) provides protection for human subjects in research carried out or supported by most federal departments and agencies.

- Yes
- No

1.14) * If this study has been or will be submitted to the US Food and Drug Administration (FDA) under an Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application, provide the US IND/IDE number:

If not applicable, enter 'N/A'. Some pharmaceutical trials may be conducted in Canada under a US Food and Drug Administration (FDA) Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application. In such instances, U.S. FDA regulations may apply to drug trials conducted in Canada.

1.15) * Is this study subject to the General Data Protection Regulation (GDPR) mandated by the European Union (EU)?

The GDPR implementation date is 2018MAY25. This may impact researchers working in and/or

Select the level of research that applies to the Principal Investigator (PI). NOTE: if you are applying as a Queen's employee, hospital employee or as an external applicant, you may be asked to include the name of a local investigator or faculty member as a supervisor on your ethics application

- Undergraduate*
- Master's*
- Doctoral*
- Medical Student*
- Medical Resident*
- Postdoctoral Fellow*
- Clinical Fellow*

for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external

KFL&A Public Health
St. Lawrence College
Other (specify below)

2.7) Describe any other study participant visits or procedures that will take place outside of the sites listed in 2.6 (e.g., local doctor's office). If 'other' selected above, specify and describe:

Do not include external testing or imaging (e.g., Lifelabs, Kingston MRI, KMI X-ray & Ultrasound).

2.8) * Does your research need to comply with Queen's University's Off Campus Activity Safety Policy (OCASP)?

All members of the Queen's community involved in off-campus activities must register their trip/activity in the Off-Campus Activity Safety Policy On-line Planning Tool. The Policy applies to not only all Students, but also all Faculty and Staff, who are undertaking studies, doing research, or carrying out any other work that takes place off-campus and is under the purview of the University. Refer to the OCASP website if you will be conducting your research off

Research Institute); 5. Research involves extracting patient data from hospital

Canada

Investigational

4.9) Describe how the Health Product will be used in the study outside of the parameters of the conditions of use approved by Health Canada:

4.10) Indicate the status of the above Health Canada Clinical Trial Application (CTA):

If your NOA is pending, ensure this is submitted in the form of an amendment as soon as it has been obtained.

- Notice of Authorization attached
- Notice of Authorization pending

4.11) If using medical devices, name all device components, parts, and/or accessories as per the product label for devices covered under the Investigational Testing Application (ITA) with Health Canada:

Research involving the testing of a medical device is subject to the Medical Devices Regulations and may require the submission of an Investigational Testing Application (ITA) to Health Canada

4.12) Indicate the statu

be conducting genetic testing, refer to the HSREB's guidance document titled, "Statements for HSREB Informed Consent Forms" (ICFs) that is posted on HSREB's website under 'Resources' and ensure that you include the appropriate language as applicable in the ICF.

5.13) Where will the associated data be located (e.g., name & address, including country)?

Ultrasound

Surveys
Questionnaires
Interviews
Focus Groups
Cognitive Behavioural Therapy (CBT)
Surgery
Exercise
Observation
Registry
Retrospective Chart Review
Prospective Chart Review
Audio/Video Recordings
Conducting, administering or supervising tests that require professional credentials
Delegation of a “controlled act” as specified in the Regulated Health Professions Act, 1991 (RHPA)
Other (specify below)
N/A, skip the rest of this section

7.2)

you are seeking participants throughout multiple phases/stages of your study, indicate the number of participants required for each phase/stage.

People in palliative care*

People in long-term care*

Less than 6 participants (increased risk of identification/re-identification)*

Ethno-cultural minorities*

Data bank/registry

Other, specify below

8.5) * If you have selected participant populations with an asterisk (*) above, justify the inclusion of all applicable participant populations. If you have selected 'Other,' specify the participant population and justify the inclusion of the participant population:

If not applicable, enter 'N/A'. Historically, researchers have not sufficiently considered the ethical rights of certain populations. For additional guidance, see TCPS 2 (2018) Chapter 4.

KHSC – KGH Site
KHSC – HDH Site
PCC
Other (specify below)
N/A

8.9) If 'other' selected above, specify:

8.10) * Will participants be hospital inpatients?

- Yes
- No

8.11) * Will participants be hospital clinic patients?

- Yes
- No

8.12) * If participants designated incompetent, why do you consider the participants incompetent?

If not applicable, enter 'N/A'.

8.13) * Provide the inclusion criteria:

If not applicable, enter 'N/A'.

8.14) * Provide the exclusion criteria:

If not applicable, enter 'N/A'.

8.15) * What is the accepted local standard of care for this/these population(s)?

If not applicable, enter 'N/A'.

person, but rather implicitly granted through a person's actions. Assent is the expression of approval or agreement. For additional guidance on alterations to consent, refer to TCPS 2 (2018) Chapter 3.

Written Informed Consent Form (active consent)
Written Letter of Information with separate written Consent Form (active consent)
Written Letter of Information with survey completion representing consent
Written Assent Form
Expression of assent (e.g., nodding of head)
Verbal consent*
Implied consent*
Participant unable to provide consent*
Substitute decision maker
Other (specify below)

10.2) If 'other' selected above, specify:

10.3)

If not applicable, enter 'N/A'. The healthcare provider should not be the individual obtaining the signature during the informed consent process. How, when, and where participants are approached, and who recruits them, are important elements in assuring (or undermining) voluntariness (TCPS 2 (2018) Chapter 3).

10.6) * If there are procedures in place for participants who may have communication difficulties (e.g., who may need translation, who are illiterate, who have trouble understanding or producing speech and require special support including the use of assistive devices), explain the procedures. If not, explain why not:

If not applicable, enter 'N/A'. Participants should be made aware that if they do need to contact the HSREB for ethics concerns, they may need translation services, as the Ethics Office can only communicate to participants in English.

10.11) * Attach clean copies of all Letters of Information/Consent Forms/Assent Forms to the ethics application and any other materials that will be distributed to study participants (e.g., diaries, wallet cards):

with local standard of care do not need to be included. Only include those expenses that are directly related to study participation.

Section 12: Risks and Benefits

12.1) * Select all risks to participants (real or potential) associated with participation (select all that apply):

Research would be classified as 'Minimal risk' if the probability and magnitude of possible harms, related to participating in the research, is no greater than that which would be encountered in aspects of everyday life. Anything greater than minimal risk needs to be communicated to participants. For additional guidance, see: TCPS 2 (2018), an26be

12.3) * Describe your plan to mitigate risks to participants, and how you will provide support to
nts in the context of these risks:

ble, enter 'N/A'. Ensure that you have included a plan to mitigate risks for all participant populations as

are different degrees of risk for different participant populations, ensure that all risk mitigation

ed in your response.

Include all information required for research purposes and you will need to explain your request to collect this

[redacted] individual that may

identify an individual; that could be used or manipulated to identify an individual; or information that could be linked

13.3) * If Personal Information (PI), Personal Health Information (PHI) or sensitive information, including demographic information is required, explain why you need this information and how you will be using it for research purposes as selected above. If 'other' selected above, specify and explain:

The collection of full dates of birth / death, admission dates, discharge dates and full postal code increased the risk for potential re-identification. The Board prefers only

Information transferred outside your research group should not contain any personal identifiers (e.g., full date of birth, hospital numbers, initials, and names must be removed). This must be communicated on the ICF. Queen's supports the use of OneDrive for Business as a secure method for file sharing with external users. Queen's supports Windows File Service for internal users.

Fax

Electronic data collection (EDC)

Private courier

Canada post registered mail (priority or other secure shipping method3 0 cr6133f.184.06 -1208.057 32.999 2

13.20) * What will happen to the data at the end of the study (e.g., anonymized, destroyed)?

All Tri-Agency funded research is subject to the Tri-Agency Open Access Policy on Publications. For additional information, refer to the Open Access Policy. All National Institutes of Health (NIH) funded studies must abide by the NIH Access Policy. This policy dictates that you will be required to deposit the final manuscript of your journal articles in PubMed Central (PMC), and ensure their free availability (open access) within 12 months of publication.

14.3) * Is there an agreement between the investigator and the sponsor regarding use, publication, or disposal of the data?

- Yes
- No
- N/A

14.4) * If ‘yes’ to above, describe any restrictions the funding agency or sponsoring company has placed on the publication of findings or on the reporting of interim results?

Indicate ‘N/A’ if not applicable. All Tri-Agency funded research is subject to the Tri-Agency Open Access Policy on Publications. For additional information, refer to the Open Access Policy. All National Institutes -Al pn8t-8(to5118 88 80.1 0.66

15.4) Describe if there are mechanisms in place to provide ongoing access to the investigational agent post-

15.11) Describe the process for return of study drugs from the patients and for disposal of returned or unused study drugs at the study site:

15.12) Describe the records that will be maintained for all study drugs and outline who is responsible for maintaining these records:

Section 16: Safety and Monitoring

16.1) * Will you be implementing a safety/monitoring component for your study?

ICH GCP E6, as adopted by Health Canada; 5.18.1 Purpose, states that the purposes of trial monitoring are to verify that: a) The rights and well-being of human subjects are protected. b) The reported trial data are accurate, complete, and verifiable from source documents.c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

- Yes
- No, skip the rest of this section

16.2) Describe the procedure for safety monitoring, including during serious adverse events (SAEs).

Section 17: Study Contract

17.1)

Internal funding

19.1) * Will the investigator or sub-investigators, or anyone connected to them through their interpersonal relationships (including their partners, family members, or their former or current professional associates), receive any personal financial benefit in connection with this study?

Sources of personal financial benefit may include but are not limited to: patent or intellectual property rights; royalty income; employment; share ownership; stock options; spin-off companies in which researchers have stakes or private contract research outside of the academic realm; proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study; having any association (e.g., as a consultant, advisor, board member, employee, director, etc.) or connection with an entity that is sponsoring or otherwise interested in the outcome of the study; receiving any other incentives (e.g., honorarium, trips to conferences unrelated to this study); or any other incentives that may compromise integrity, independence, or ethical duties in the conduct of the research. For additional guidance, see HSREB SOPs 105A-C Conflicts of Interest (COI) or TCPS 2 (2018) Chapter 7.

- Yes
- No

19.2) If 'yes' above, specify [illegible]

- Yes, attached
- N/A

20.3) * Is the Principal Investigator (or their Research Supervisor, if the PI is a student, resident, or fellow) entitled to provide health care (if applicable) under the applicable laws?

- Yes
- No

20.4) * Is the Principal Investigator (or their Research Supervisor, if the PI is a student) a member in good standing with his or her respective regulatory authority?

- Yes
- No

20.5) * The Principal Investigator (or their Research Supervisor, if the PI is a student), is/are aware of and shall make all reasonable efforts to comply with the applicable laws, guidelines, policies, and professional obligations:

- Yes
- No

20.6) If 'no' selected in any question above, explain:

Section 21: Checklist

21.1) * Protocol, peer review

- Yes, attached
- N/A

21.2) * Informed Consent Form (ICF), Assent Forms

- Yes, attached
- N/A

21.3) * IBs/PMs/Device Manuals/Safety Information

- Yes, attached
- N/A

21.4) *

21.6) * Budget

- Yes, attached
- N/A

21.7) * Debriefing Materials

- Yes, attached
- N/A

21.8) * PI's/Co-PI's CVs and/or other documentation evidencing qualifications

- Yes, attached
- N/A

21.9) * CORE, GCP training, CITI Ethics training certificates

- Yes, attached
- N/A

21.10) * Data Collection forms

- Yes, attached
- N/A

21.11) * Interview, focus group scripts

- Yes, attached
- N/A

21.12) * Any other documents that the REB may need to review?

- Yes, attached
- N/A