Section 700:	**Informed Consent**
Title:	**Informed Consent Form Requirements and Documentation**
SOP Code:	**701.001**
Effective Date:	**2015MAY25**

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor	Name: Jennifer Couture	2015MAY22 Date
Approval Authority:		
Chair, HSREB	Name: Dr. Albert Clark	May 22, 2015 Date
Approval Authority:		
Director, Research Ethics Compliance	Name: Dr. Andrew Winterborn	May 22, 2015 Date

1.0 PURPOSE

This SOP describes the requirements for the informed consent form and the process for waiving or obtaining and documenting initial and ongoing informed consent.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the HSREB with a detailed description of the rationale for a consent waiver or the consent documents, a description of the consent process and the process for withdrawing consent. The Researcher also is responsible for providing a description of the recruitment methods and recruitment materials (if applicable).

When a written informed consent form is used, the Researcher, the research sponsor and the HSREB are jointly responsible for ensuring that the consent form contains all of

the basic elements of consent and the applicable additional elements of consent. The HSREB is responsible for verifying that the consent form contains the required elements.

The HSREB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate (see section 5.8).

The HSREB Chair or designee is responsible for reviewing consent forms or changes to consent forms if the changes meet the criteria for delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Researchers must provide prospective participants, or authorized third parties, with full disclosure of all of the information necessary for making a voluntary informed decision to participate in a research project.

Research participants should be able to voice their concerns, questions and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the HSREB or in the HSREB office.

5.1 HSREB Review of required Elements of Informed Consent

5.1.1 The HSREB members will review the proposed consent process for appropriateness;

5.1.2 The HSREB members will review the proposed consent form(s) for:

- general readability,
- for appropriateness of the language and content, and
- for the inclusion of the required elements (Refer to Informed Consent Required Elements for Biomedical Clinical Trials (Appendix 1) and Informed Consent Required Elements for all HSREB Research (TCPS2) (Appendix 2) for applicable consent form required elements);

5.1.3 The HSREB will ensure that the consent form indicates consent shall be given voluntarily and that the participant can withdraw consent at any time. This may also include the withdrawal of their information and biological materials;

5.1.4 The HSREB will review the proposed consent form to ensure that it contains adequate information to safeguard the privacy and confidentiality of research participants and prospective participants;

5.1.5 The HSREB will review the proposed consent form to ensure it does not contain any language that causes the participant or the

legally acceptable representative to waive or appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor or their agents from liability or for negligence;

5.1.6 The HSREB may require a separate consent form for optional procedures or sub-studies (e.g., tissue, blood, genetic testing or specimen banking);

5.1.7 Following the review, the HSREB may approve the consent form(s) as submitted or require changes;

5.1.8 When changes are required by the HSREB and are made by the Researcher, the HSREB or designee will review the consent form(s) to confirm that the required changes have been made and that the version date has been updated;

5.1.9 When the changes meet the criteria for delegated review, the revised consent will be provided to the HSREB Chair or designee for review and ethical clearance;

5.1.10 When changes do not meet the criteria for delegated review, the revised consent form will be reviewed at the next Full Board meeting.

5.2 Translation of Informed Consent Documents

5.2.1 The informed consent document should be in language understandable to the research participant (or acceptable representative);

5.2.2 When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:

- **Written consent:** The HSREB ethically cleared English version of the informed consent document is translated into the research participant's native language. The HSREB may require that translated informed consents be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the HSREB ethically cleared English informed consent. This method is preferred if it is anticipated that a significant percentage of a prospective research population is non-English speaking. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant will sign and date the translated version of the informed consent form document,
- **Oral consent:** If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets the HSREB ethically cleared English consent form to the research

participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form in addition to the research participant;

5.2.3 The HSREB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English-speaking participants. The HSREB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the HSREB ethically cleared English materials;

5.2.4 If a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent is obtained from the research participant after the informed consent document and any other written information is read and explained to the research participant. Signatures will be obtained from the research participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the research participant, and that informed consent was freely given by the research participant;

5.2.5 The HSREB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been ethically cleared (particularly if a signed translation certificate or statement is on file);

5.2.6 An interpreter should be available to the research participant throughout the research;

5.2.7 The interpreter must sign and date the consent form attesting that the research was accurately explained to, and appeared to be understood by, the research participant.

5.3 Consent Update for Ongoing and Completed Research Participants

5.3.1 The Researcher must inform research participants of any new information that might affect their willingness to continue their participation in the research or that may affect their long term health even if they have completed their participation in the research;

5.3.2 The Researcher must obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the research or risk;

5.3.3 If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the research participant sign an HSREB ethically cleared consent document containing the updated information;

5.3.4 If applicable, ongoing consent may be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue;

5.3.5 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the HSREB;

5.3.6 The Researcher must inform former research participants of any new information that may be relevant to their long term health by contacting them via phone or mail or in person, as applicable.

5.4 Recruitment Materials

5.4.1 **Researcher's Patients:** If the patient is under the care of the primary Researcher, the primary Researcher may approach the patient directly, but in such a manner that the patient does not feel pressured or obligated in any way; however the HSREB recommends that the patient is not approached initially by the primary researcher. Any exceptions to this procedure must be appropriately justified and submitted to the HSREB for review;

5.4.2 **In circumstances where the Researchers will obtain consent:** The Researcher must ensure that the consent has been obtained without undue coercion or influence and that there is no likelihood of therapeutic misconception, if applicable;

5.4.3 **Referrals:** The Researcher may send a letter to colleagues asking for referrals of potential patients. The Researcher may provide colleagues with the HSREB ethically cleared consent form or research information sheet to give to their patients. The patient will then be asked to contact the Researcher directly, or, with documented permission from the patient, the Researcher may initiate the call;

5.4.4 **Health Records Departmen**t: The Researcher may ask the Health Records Department to identify patients who appear to meet the research's eligibility criteria. The Researcher should supply Health Records with a standard letter describing the research to give the patient's physician, and asking whether the physician would be willing to approach his/her patients about participation. It is NOT acceptable for the Researcher or his/her staff to contact patients identified through hospital records, clinic charts or other databases independently by phone, unless the patient has previously agreed, or is already under the medical care of the Researcher;

5.4.5 **Registries**: If the HSREB has previously ethically cleared a patient research registry and the patient has provided permission to be contacted for potential research, the Researcher or his/her research team may contact these patients directly. The person contacting the patient should identify him/herself as associated with

the patient's clinical caregiver, and remind the patient that they have agreed to be contacted. The patient must be offered the option of having his/her name removed from the database;

5.4.6 **Advertising:** The HSREB must first review and approve the text and the use of any advertisements, notices or media messages.

5.5 Recruitment Materials

5.5.1 The HSREB reviews the recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the HSREB ethically cleared research and informed consent document(s);

5.5.2 Advertisements should be reviewed by the HSREB, as applicable, and according to HSREB requirements;

5.5.3 All recruitment materials must be ethically cleared by the HSREB and approved for use by each organization where the recruitment material will be displayed, as per local practice prior to their use.

5.6 Documentation of Informed Consent

5.6.1 The HSREB typically requires documentation of informed consent by the use of a written informed consent form ethically cleared by the HSREB and signed and dated by the research participant or the research participant's legally acceptable representative, and by the person obtaining consent;

5.6.2 As required by the Research Sponsor or if required by Queen's University and/or Affiliated Teaching Hospital policies, the Researcher must also sign and date the informed consent form for clinical trials;

5.6.3 The original informed consent should be filed in the patient's medical record or research file;

5.6.4 A copy of the signed consent form and any re-consent forms shall be provided to the research participant;

5.6.5 The Researcher or designee should document details of the consent process in the research participant's medical record or research file, according to the organization's guidelines;

5.6.6 The Researcher should inform the research participant's primary physician about the research participant's involvement in the research if the research participant agrees to the primary physician being informed;

5.6.7 The HSREB may approve a short form written consent document in cases where the research participant may lack the capacity to consent. The short form consent form contains all required elements of informed consent. A written summary of the information is presented orally to the research participant or their substitute decision maker. The short form consent document is signed by the research participant or the substitute decision maker. An impartial

witness must be present during the oral presentation. The witness must sign both the short form consent document and a copy of the written summary. The person obtaining consent must sign a copy of the written summary of the information that is presented orally;

5.6.8 The HSREB may ethically clear a process that allows the informed consent document to be delivered by regular mail, email or facsimile to the potential participant, and to conduct a consent interview by telephone when the participant can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure;

5.6.9 In some types of research, and for some groups or individuals where written signed consent may be felt by the participants as mistrust on the part of the Researcher, the HSREB may ethically clear the process of oral consent, a verbal agreement or a handshake;

5.6.10 Where consent is not documented in a signed consent form, Researchers may use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed questionnaire). The procedures used to seek consent must be documented by the Researcher and ethically cleared by the HSREB;

5.6.11 Whenever possible, the research participant should have written documentation of participation in a research project unless it may compromise their safety or confidentiality;

5.6.12 Consent must be maintained throughout the research project and all participants must be provided with information relevant to their ongoing consent to participate in the research.

5.7 Consent Monitoring

5.7.1 In considering the adequacy of informed consent procedures, the HSREB may require monitoring of the consent process by an impartial observer;

5.7.2 Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided;

5.7.3 Monitoring may also be appropriate as a corrective action when the HSREB has identified problems associated with a particular Researcher or a research project.

5.8 Waiver or Alteration of Informed Consent

5.8.1 The HSREB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that the HSREB finds and documents that:

- The regulatory and ethics guidance framework supports the waiver,
- The research involves no more than minimal risk to the participants,
- The waivered or altered consent does not involve a therapeutic intervention,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,
- The research could not practicably be carried out without the waiver or alteration,
- The precise nature and extent of the alteration is defined,
- The information is used in a matter that will ensure its confidentiality,
- Whenever appropriate, the participants will be provided with additional pertinent information after participation,
- The trial is not prohibited by law;

5.8.2 These findings and their justifications shall be clearly documented in the HSREB minutes when the HSREB exercises this waiver provision.

5.9 Consent for Research Involving Individuals who Lack Capacity

5.9.1 For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether to participate, the HSREB must ensure that at a minimum the following conditions are met:

- The Researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process,
- The Researcher seeks and maintains consent from authorized third parties,
- The authorized third party is not the Researcher or any other member of the research team,
- The Researcher demonstrates that the research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant, the Researcher shall demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research,

5.9.2 If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, the Researcher ascertains the wishes of that individual with respect to participation;

5.9.3 Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent is respected;

5.9.4 Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:

- Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing,
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and
- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment;

5.9.5 If assent for research is required, the Researcher must submit to the HSREB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the research participant. The Researcher must submit an assent form or summary of the assent process to the HSREB for review;

5.9.6 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation;

5.9.7 If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

5.10 Other Vulnerable Groups

5.10.1 The HSREB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the HSREB will take into account the risks and benefits of the research, and will consider protections afforded by Queen's University and Affiliated Teaching Hospital(s) policies, and provincial and federal law;

5.10.2 In addition, when the HSREB regularly reviews research involving a vulnerable population, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these participants this population;
Potentially vulnerable groups may include, but are not limited to:

- Children,
- The Elderly,
- Individuals with mental illness,
- Pregnant women,
- Individuals with limited language skills,
- Aboriginal individuals and communities,
- Prisoners;

5.10.3 If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the US Federal Government, the HSREB shall apply the requirements of 21 CFR 50 Sub-Part D, 45 CFR 46, including as appropriate, Sub-Parts, B, C and D.

5.11 Consent for Research in Health Emergencies

5.11.1 The HSREB establishes the criteria for the conduct of research involving medical emergencies prior to ethical clearance of the research. The Researcher must justify to the HSREB the reasons why an exception to obtaining informed consent from participants is required;

5.11.2 The HSREB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of his/her authorized third party if ALL of the following apply:

- A serious threat to the prospective participant requires immediate intervention,
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care,
- Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant,
- The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research project,
- Third-party authorization cannot be secured in sufficient time, despite diligent, and documented efforts to do so, and
- No relevant prior directive by the participant is known to exist;

5.11.3 When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

5.12 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

5.12.1 The HSREB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the Researcher is able to satisfy the following conditions:

- Identifiable information/materials is essential to the research,
- The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- The Researchers will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
- The Researchers will comply with any known preferences previously expressed by individuals about any use of their information/materials,
- It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and
- The Researchers have obtained any other necessary permission for secondary use of information/materials for research purposes;

5.12.2 In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been ethically cleared by the HSREB, if the Researcher proposes to contact individuals for additional information and/or materials, HSREB ethical clearance must be obtained prior to contact;

5.12.3 Researchers are required to obtain HSREB ethical clearance, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.

5.13 Consent for use of Personal Health Information (PHI)

5.13.1 In order to grant ethics clearance for use of Personal Health Information from a Health Information Custodian (HIC), the HSREB must consider:

- If the objectives of the research could be reasonably accomplished without using PHI,
- If adequate safeguards will be in place to protect the privacy and confidentiality of the participants,
- The public interest in conducting the research and protecting the privacy of participants,
- Whether obtaining ICF of the participants would be impractical,

- The researcher has followed all steps outlined in PHIPA (2004, c.3, Sched. A, s.44) with regards to obtaining PHI from a HIC and complies with any additional conditions requested by the HSREB;

5.13.2 A researcher who received PHI from a HIC must:

- Use the information only for the purposes outlined in the ethics application,
- Not publish the information in a manner that could lead to identification of participants or disclose the information except as required by law or to the exceptions and additional requirements, if any imposed,
- Does not make contact with participants, unless the HIC has obtained consent for the participant to be contacted,
- Notify the HIC and HSREB immediately in writing of any breeches of PHI disclosure.

5.14 Incidental Findings

5.14.1 Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research. The Researcher's plan to identify and to disclose incidental findings must be submitted to the HSREB and ethically cleared prior to implementation.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Informed Consent Required Elements for Biomedical Clinical Trials
2. Informed Consent Required Elements for all HSREB Research (TCPS2)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Informed Consent Form Requirements and Documentation	v.701.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Informed Consent Required Elements for Biomedical Clinical trials

☐ Project Title

☐ Name of the Researcher/Principal Investigator(s), Institution(s) and Sponsor(s)/Funder(s) (as applicable)

☐ Statement that the participant is being invited to participate in a research project

☐ Explanation of the research purpose of the clinical trial

☐ The participant's responsibilities

☐ Expected duration and nature of participation

☐ Description of all procedures to be used, including transparency as to which procedures are experimental and invasive

☐ Description of interventions and probability of assignment to each intervention

☐ Approximate number of research participants in the trial

☐ Inclusion/Exclusion Criteria

☐ Description of all reasonably foreseeable and unforeseeable risks and potential benefits, both to the participants (including pregnant mothers, nursing infants or to the embryo or fetus if the participant were to become pregnant) and in general, and that the research participant will be informed if there is no known clinical benefit

☐ Statement that participation in the clinical trial is voluntary and that the refusal to participate or, once agreeing to participate, may withdraw from the clinical trial at any time, with no loss of benefit to which the research participant was otherwise entitled

☐ Description of available alternative procedures or courses of treatments outside the scope of the trial and their important potential benefits or risks

☐ Statement that new findings discovered during the clinical trial which may affect the research participant's willingness to continue participation will be provided to them in a timely manner

☐ Statement that outlines process involved for withdrawal of participation and Information on the participant's right to request the withdrawal of information or specimens, and any limits on the feasibility of withdrawal

☐ Information concerning the possibility of commercialization of research findings, and the potential or perceived personal benefits and/or conflicts of interest on the part of the researcher, their organizations or the sponsor

☐ The individual(s) to contact for further information about the trial, about the rights of the research participants and in case of trial related injuries

☐ Description of type of response that will be undertaken if injury occurs to the research participant in the event of a study related injury (for example, treatment will be made available and covered by the clinical trial funding), or that no such response is planned

☐ The measures to be undertaken for dissemination/publication of research results and whether the participant's identity will remain confidential, and any limits to their confidentiality

☐ Indication about what information will be collected from participant's, the purposes of collection, description of anticipated uses of information, who may have access to the information and who may have a duty to disclose the information collected and to whom such disclosures could be made, including if personal information (including personal health information) will be sent outside of Kingston

☐ Description of how privacy and confidentiality of research records identifying the research participant will be protected, to the extent permitted by the applicable laws and/or regulations, and will not be made publically available and any limits to their confidentiality

☐ Written informed consent will be obtained and a signed and dated copy of the ICF will be given to participants

☐ Statement regarding monitors, auditors, REB and regulatory authorities will be granted direct access to the research participant's medical and research records for verification of the clinical trial data, as well as organizational officials for legitimate purposes, including quality management

☐ Information about any payments (including proration), including incentives for participants, reimbursement for participation-related expenses and compensation for injury

☐ The anticipated expenses, if any, to the participant for participating in the study

☐ Statement by consenting to the research the participant does not waive any legal rights that he or she would otherwise have but for being a research participant in a clinical trial. Any offers of compensation in the event of injury shall not limit recourse to other legal action

☐ Circumstances or reasons under which the research participant's participation in the clinical trial may be terminated, without consent, by the principal investigator and a statement identifying any other persons with the authority to modify the research participant's participation, such as the sponsor

☐ For studies subject to the US Food and Drug Administration Regulations the following statement must be included: (21 CFR 50.25c): **"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time"**

☐ For all genetic research trials please include the statement: "**If you are a First Nations person, or an indigenous person who has contact with spiritual elders you may want to talk with them before you proceed with being part of this experiment. Elders may have reservations about genetic procedures"**

☐ If data will be used for secondary analysis, indication if de-identified data will be used or if consent will be sought (if applicable)

Additional HSREB Requirements:

☐ Version controlled and on appropriate letterhead,

☐ Written in lay terminology (8th Grade reading level)

☐ Written in second person (use 'you', not 'I')

☐ Contact information for Department Head (if applicable)

Informed Consent Required Elements for all HSREB Research

Elements from TCPS 2 - 2014

☐ Project Title

☐ Name of the Researcher/Principal Investigator(s), Institution(s) and Sponsor(s)/Funder(s) (as applicable)

☐ Statement that the participant is being invited to participate in a research project

☐ Explanation of the research purpose

☐ Description of all procedures to be used/requirements of participants

☐ Expected duration of participation, including follow up

☐ Indication about what information will be collected from participants, the purposes of collection, description of anticipated uses of information

☐ Description of how privacy and confidentiality of research records identifying the research participant will be protected to the extent permitted by applicable laws/regulations for the full data life-cycle (data collection – storage - destruction), and any limits to their confidentiality

☐ Who may have access to the information and who may have a duty to disclose the information collected, and to whom such disclosures could be made, including if personal information, including personal health information, will be sent outside of Ontario (as applicable)

☐ If data will be used for secondary analysis, indication if de-identified data will be used or if consent will be sought (if applicable)

☐ Description of all reasonably foreseeable unforeseeable risks to the participant (including pregnant mothers, nursing infants or to the embryo or fetus if the participant were to become pregnant) and in general (or statement of no known risks)

☐ Statement that participation is voluntary and that the refusal to participate or, once agreeing to participate, may withdraw at any time, with no loss of benefit

☐ Process involved for withdrawal of participation and information on the participant's right to request the withdrawal of information/data, and any limits on the feasibility of withdrawal

☐ Dissemination/publication of research results and whether the participant's identity will remain confidential, and any limits to their confidentiality

☐ Description process for communicating findings to participant(s)

☐ Information about any payments (including proration), including incentives for participants, reimbursement for participation-related expenses and compensation for injury

☐ Individual(s) to contact for further information about the study, about the rights of the research participants and in case of study related injuries

☐ Potential benefits to participants or in general (if applicable)

☐ New findings discovered which may affect the research participant's willingness to continue participation will be provided to them in a timely manner (if applicable)

☐ Information concerning the possibility of commercialization of research findings, and the potential or perceived personal benefits and/or conflicts of interest on the part of the researcher, their organizations or the sponsor (if applicable)

Consent Form:

☐ Participant has read LOI and all questions have been answered

☐ Written informed consent will be obtained and a signed and dated copy of the ICF will be given to participants

☐ Specific consent is sought for audio/video/photo recordings (if applicable) and Biological Submissions/Genetic research (if applicable)

☐ By consenting, the participant does not waive any rights to legal recourse in the event of research-related harm

Additional HSREB Suggestions:

☐ Written in lay terminology (~8th Grade reading level)

☐ Version controlled and on appropriate letterhead,

☐ Written in second person (use 'you', not 'I')

☐ Contact information for Department Head (if applicable)