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| **Summary of Revisions to:**  **OHSN-REB Clinical Trial/Study Main Informed Consent Form Template** | | | |
| **Version Number** | **Effective Date** | **Current Language** | **New Language** |
| 1 | 7-Dec-2017 | Original version released  December 7th, 2017 | N/A |
| 2 | 20-Dec-2018 | **Introduction:**  Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care. | **Introduction:**  You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study *include if applicable:* *however, it may affect your future health care options. This will be discussed with you. If you have any questions about this, you can ask the study team.* *Specify any other potential areas where participants might be concerned about a potential penalty or discrimination, such as The decision will not affect your employment.* |
| **Mandatory Sample Collection:**  No existing language | **Mandatory Sample Collection:**  Even with protections in place, there is a risk that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your blood relatives. These results might contain information (e.g., an inherited genetic disease) that could result in problems for you or your relatives. There is no way to predict what effects such an information loss would have. You will be given the choice/not be given the choice to find out about genetics testing results.  *If the study includes genetic testing (mandatory or optional), include the following:*  If you are First Nations or an indigenous person you may wish to contact an Elder, before you make a decision about this research study. |
| **Tissue Collection:**  No existing language | **Tissue Collection:**  *If archived specimens are required from another institution, include the following:*  If your biopsy or surgery was completed at another institution, signing this consent form means that you are consenting to the collection of your tissue sample, together with any related personal health information, from that institution. |
| **What are the risks or harms of participating in this study?**  No existing language | **What are the risks or harms of participating in this study?**  *NOTE: If the comparison arm includes standard of care treatment/intervention alone, and the risks and side effects associated with the comparison arm should be considered against the experimental arm to assist the patient to make an informed decision, then they should be included here in place of the text above.* |
| **Radiation Risks**   1. **Greater or equal than 0.1 and under 2.7mSv:**   “The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for *insert number* months. The risk is considered to be negligible.”   1. **Greater or equal than 2.7 mSv and under 20 mSv:**   “The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for *insert number* years. The risk is considered to be minimal and there are no expected consequences associated with this exposure.”   1. **Greater or equal than 20 mSv and under or equal to 50 mSv:**   “The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for *insert number* years. The overall risk is considered to be acceptable and there are no expected consequences associated with this exposure.”   1. **Above 50 mSv:**   “The additional amount of radiation you will receive from participating in this research study is approximately *insert percentage*% of the average natural lifetime exposure in Ontario. The overall risk is considered to be acceptable and there are no expected consequences associated with this exposure.” The following statement applies only to nuclear medicine studies where nuclear substances are administered: “Doses to individual organs are listed and can be discussed with your physician.” | **Radiation Risks**  Language has been removed.  The consent template risk section instructions inform applicants to list all study related risks in the risk section.  Note, the Radiation Safety committee will inform Investigators when radiation risk must be disclosed (may provide prescribed language) in the consent form. Investigators must review their signed Radiation Safety Form prior uploading in the Notification tab, for any suggested radiation risk language to be included in the risk section of the consent form. |
| **What are the reproductive risks?**  No existing language | **What are the reproductive risks?**  *If there is a risk of sperm mutation or teratogenic risk, include the following:*  Participants should discuss these risks with sexual partners of the opposite sex. |
| **How will participant information be kept confidential?**  Your name, address or other information that may directly identify you will not be used.  No existing language | **How will participant information be kept confidential?**  Your name, address**, email** or other information that may directly identify you will not be used.  *If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:*  Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail. |
| **What is the cost to participants?**  No existing language/new bullet added | **What is the cost to participants?**  Taking part in this study may result in added costs to you. For example:   * i*nsert name(s) of product/agent/device/intervention* used in this study may not be covered by provincial insurance. You can speak with the study team about added costs. Everything possible will be done to help you access reimbursement from your insurance company or other third-party payer. |
| **Signature pages:**  Administrative changes were made to the signature pages to align with the CTO ICF template. | **Signature pages:**  Administrative changes were made to the signature pages to align with the CTO ICF template. |
| 3 | 14-Apr-2021 | **Confidentiality:**  Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared. | **Confidentiality:** Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, scientific journals, or deposited in an online repository, information that links your study data directly to you will not be shared.  If information from this study is published, shared, or presented at scientific meetings, your name and other personal information will not be used. |
| **Signature pages:**   * I understand that my family doctor/health care provider will/may be informed of study participation | **Signature pages:**  I understand that my family doctor/health care provider will/may be informed of my participation in this study by the study team, or may learn of my participation when reviewing my electronic health record. |
| 4 | February 10, 2022 | **Institutional Logos:**  TOH, OHRI, uOttawa and Heart Institute Logo | **Institutional Logos:**  uOttawa logo deleted. TOH, OHRI and Heart Institute logos updated |
| **Instruction Page:**  No existing language | **Instruction Page:**  \*\*The Summary of Informed Consent Form on page 3 of the template must only be included for studies funded or supported by a US federal funding agency. **DO NOT** include for studies not meeting this criterion. |
| **Summary of Informed Consent Form:**  No existing section | **Summary of Informed Consent Form:**  Two page “Summary of Informed Consent Form” section added to beginning of ICF |
| **Mandatory Sample Collection:**  The collection of these samples is a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold. | **Mandatory Sample Collection:**  The collection of these samples is a necessary part of this study. The samples will not be sold. |
| **Mandatory Sample Collection:**  *Specify what will happen to samples once the mandatory research has been completed. For example:*  Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed *include the following if applicable* unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign.  *Include one of the following options*  Hereditary genetic testing (to look at whether *specify condition* runs in families) will not be done on these samples.  *Or*  Hereditary genetic testing (to look at whether *specify condition* runs in families) will/may be done on these samples | **Mandatory Sample Collection:**  Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed, or destroyed at the request of the organization that provided the sample. |
| **Mandatory Sample Collection:**  *If there is a possibility that a medically relevant sample will be exhausted:*  If you participate in this study it is possible that there will not be enough of your tissue/sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.  Even with protections in place, there is a risk that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your blood relatives. These results might contain information (e.g., an inherited genetic disease) that could result in problems for you or your relatives. There is no way to predict what effects such an information loss would have. You will be given the choice/not be given the choice to find out about genetics testing results. | **Mandatory Sample Collection:**  *If there is a possibility that a medically relevant sample will be exhausted:*  If you participate in this study it is possible that there will not be enough of your tissue/sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility. |
| **Mandatory Sample Collection:**  *If the study includes genetic testing (mandatory or optional), include the following:*  If you are First Nations or an indigenous person you may wish to contact an Elder, before you make a decision about this research study. | **Mandatory Sample Collection:** If you are First Nations or an indigenous person you may want to talk to an Elder before you make a decision about this research study. |
| **Genetic Testing:**  No existing section | **Genetic Testing:**  *If the study includes genetic testing (mandatory or optional), include the following:*  Genetic Testing  This study involves genetic testing. Researchers will be looking at your genes (DNA).  Hereditary genetic testing (to look at whether *specify condition* runs in families) will not/will be done on these samples.  *Include if applicable (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen):*  The study will/may involve whole genome sequencing. Whole genome sequencing is the analysis of the complete set of genetic instructions in a cell.  Every person has their own unique set of genes or ‘genome’. Sometimes there are differences between individuals, but these differences are very small. The reason this is important is because these results might contain information (for example, an inherited genetic disease) that could impact you or your biological (blood) relatives. When you donate your genetic information or materials you are sharing information about yourself, and it can be used to identify these relatives.  Even with protections in place, there is a risk that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your relatives. There is no way to predict what effects such an information loss would have. For example, if an insurer, a current or future employer, or law enforcement were to learn your genetic code it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.  You will be given the choice/not given the choice to find out about genetics testing results.  If you are a First Nations or an indigenous person, you may want to talk to an Elder before you make a decision about this research study. |
| **Confidentiality:** If the results of this study are published your identity will remain confidential. It is expected that the information collected during this study will be *include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals*.  Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, scientific journals, or deposited in an online repository, information that links your study data directly to you will not be shared.  If information from this study is published, shared, or presented at scientific meetings, your name and other personal information will not be used. | **Confidentiality:** If the results of this study are published shared, or presented at scientific meetings, your identity will remain confidential. It is expected that the information collected during this study will be *include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals*. |
| **Other Future Research**  No existing section | Other Future Research  *If de-identified data or samples may be used or shared for future research, include the following:*  Your coded study data and/or coded samples may be used or shared with other researchers (inside and outside of Canada) for future studies.  “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the study data and/or samples.   This may include storing the coded study data and/or samples in controlled-access databases/biobanks, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database.  The goal of sharing is to make more research possible. However, the code matching your study data and samples with your name and other directly identifying study data will not be shared.  You will not be asked if you agree to take part in future research studies using your study data and/or samples. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data and/or samples.  OR, *for studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) where researchers will NOT be using specimens or information for future research (even if identifiers are removed), include the following paragraph. This paragraph is not required for non-US federally funded studies:*  Your study data and/or samples will not be used or shared with other researchers for future studies, even if the researchers remove any information that could directly identify you. |
| **Are Study Participants Paid to be in this Study?**  *If applicable (alter as needed to fit the research):*  It is possible that the research conducted using your samplesand/or study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. There are no plans to provide payment to you if this happens. | **Are Study Participants Paid to be in this Study?**  *If applicable (alter as needed to fit the research):*  It is possible that the research conducted using your samplesand/or study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products.  *If participants will not share in commercial profit:*  There are no plans to provide payment to you if this happens.  *If participants will share in commercial profits:*  If this happens, you will receive describe participant’s share in commercial profit. |