**TBRHSC REB #**

**PI:**

**Title**:

**ICF VERSION**:

|  |  |
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| **Best Contact for Project** |  |
| **Title** |  |
| **First Name** |  |
| **Last Name** |  |
| **Department Contact** |  |
| **Secondary Affiliation Contact** |  |
| **Address** |  |
| **Phone Number** |  |
| **Email Address** |  |

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| **A/ GENERAL** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 1 | ✓ |  |  |  | Appropriate letterhead. |  |  |  |
| 2 | ✓ |  |  |  | Full study title as it appears on the protocol and REB application. |  |  |  |
| 3 |  | 3.2B |  |  | The identity of the researcher, the funder or sponsor. |  |  |  |
| 4 | ✓ |  |  |  | If the study involves more than minimal risk and there is a potential for a participant to experience adverse events after regular business hours OR the study requires an emergency contact number, a 24 hour contact number. |  |  |  |
| 5 | ✓ |  |  |  | Version date of consent is visible on all pages (preferably in footer). |  |  |  |
| 6 | ✓ |  |  |  | All pages labeled as Page x of y (preferably in footer). |  |  |  |
| 7 | ✓ |  |  |  | Suitable reading level (grade 6 to 8) in lay language. Whenever possible, avoid using technical or medical terms and acronyms. However, when required, clearly define at first use. |  |  |  |
| 8 | ✓ |  |  |  | Suitable readability: Font size (12): font type (Arial or Times New Roman); bullets; adequate margins, spacing (no page breaks across sections), and headings. |  |  |  |

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| **B/ INTRODUCTION** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 9 |  | 3.2 a | X | X | Information that the individual is being invited to participate in a research study. TBRHSC language is “being asked to consider participating” in a research project. |  |  |  |
| 10 |  | X | X | X | An assurance that the prospective participants are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements |  |  |  |
| 11 | ✓ |  |  |  | For clinical trials involving an investigational agent, state that <investigational agent> has not been approved for this indication by Health Canada (for Division 5 clinical trials) although it has been allowed for use in this research study. |  |  |  |
| 12 |  |  | 4.8.10m |  | That the subject’s participation in the research project is voluntary. |  |  |  |
| 13 |  |  | 4.8.10 a |  | That the study involves research. |  |  |  |
| 14 | ✓ |  |  |  | [If applicable] An introductory statement to the patient’s Substitute Decision Maker. |  |  |  |

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| **C/ IS THERE A CONFLICT OF INTEREST?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 15 |  | 3.2 e |  |  | Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of researchers, their institutions, or the research sponsors. |  |  |  |
| 16 | ✓ |  |  |  | Indicate if their physician, PI or study doctor will receive a fee for enrolling them in the research study. |  |  |  |
| 17 |  |  |  |  | A statement concerning any personal benefits that may accrue to the researcher, if applicable and deemed necessary by the REB |  |  |  |

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| **D/ WHY IS THE STUDY BEING DONE?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 18 |  | 3.2 b |  |  | A statement of the research purpose in plain language. |  |  |  |
| 19 |  |  | 4.8.10 b |  | The purpose of the research project. |  |  |  |

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| **E/ WHAT IS THE USUAL TREATMENT?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 20 | ✓ |  |  |  | Describe the usual treatment(s), and if applicable include an explanation that the participant may not receive the usual treatment if they participate in the research study. |  |  |  |

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| **F/ WHAT OTHER CHOICES ARE THERE?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 21 |  |  | 4.8.10 i | X | A description of available alternative procedure(s) or course(s) of treatment that are available outside of the research project |  |  |  |
| 22 |  |  | 4.8.10 i |  | The alternative procedure(s) or course(s) of treatment that may be available to the subject. |  |  |  |

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| **G/ HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 23 |  |  | 4.8.10 t | X | Approximate number of subjects involved in the research project. |  |  |  |

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| **H/ WHAT WILL HAPPEN DURING THIS STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 24 |  |  | 4.8.10 c |  | The treatment(s) and the probability for random assignment to each treatment. / The probability of randomization to each intervention |  |  |  |
| 25 |  | 11.6 |  |  | Which specific elements are required for research purposes, as well as the differences between research and the standard clinical care patients might otherwise receive. |  |  |  |
| 26 |  |  | 4.8.10 d |  | The research project procedures to be followed, including all invasive procedures. |  |  |  |
| 27 |  |  | 4.8.10 f |  | Those aspects of the study that are experimental. |  |  |  |

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| **I/ WHAT IS THE STUDY INTERVENTION? WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION? WHAT ARE THE STUDY PROCEDURES?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 28 |  | 3.2 b | X | X | A description of the research intervention and procedures to be used, including clear indication of those aspects that are experimental. |  |  |  |
| 29 |  | X |  | X | The nature of participation |  |  |  |
| 30 |  | 11.2c |  |  | For studies involving a placebo control, describe any therapy that will be withdrawn or withheld for purposes of the research; and of the anticipated consequences of withdrawing or withholding the therapy. |  |  |  |

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| **J/ MANDATORY SAMPLE COLLECTION?** N/A | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 31 | ✓ |  |  |  | Note: Collection of samples/tissues for future unknown research and/or banking (i.e. where the research purpose is not yet known) must have a separate informed consent form. |  |  |  |
| 32 |  | 12.2 |  |  | The type and amount of biological materials to be taken; |  |  |  |
| 33 |  | 12.2 |  |  | The manner in which the biological materials will be taken, and the safety and invasiveness of the procedures for acquisition; |  |  |  |
| 34 |  | 12.2 |  |  | The intended uses of the biological materials including any commercial use; |  |  |  |
| 35 |  | 12.2 |  |  | The measures employed to protect the privacy and minimize risks to participants; |  |  |  |
| 36 |  | 12.2 |  |  | The length of time the biological materials will be kept, how they will be preserved, location of storage (i.e. Company/Institution Name, City, Country) and process for disposal, if applicable; |  |  |  |
| 37 |  | 12.2 |  |  | Any anticipated linkage of biological materials with information about the participant; and |  |  |  |
| 38 |  | 12.2 |  |  | The researchers’ plan for handling results and findings, including clinically relevant information and incidental findings. |  |  |  |
| 39 |  | X |  |  | Information on the participant’s right to request the withdrawal of biological materials, including any limitations on the feasibility of that withdrawal |  |  |  |
| 40 |  | 13.7 |  |  | Researchers who propose research involving the collection and banking of genetic material shall indicate how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups. |  |  |  |

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| **K/ WHAT ARE THE REPSONSIBILITIES OF STUDY PARTICIPANTS?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 41 |  | 3.2 b | 4.8.10 e |  | An explanation of the responsibilities of the participant. |  |  |  |

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| **L/ HOW LONG WILL PARTICIPANTS BE IN THE STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 42 |  | 3.2 b | 4.8.10 s |  | The expected duration of participation. |  |  |  |
| 43 | ✓ |  |  |  | The expected duration of the entire research. |  |  |  |
| 44 |  | 3.2 l | X | X | Information on stopping rules and when researchers may remove participants from the study without the participant’s consent. |  |  |  |
| 45 |  |  | 4.8.10 r |  | The foreseeable circumstances and/or reasons under which the subject’s participation in the research study may be terminated. |  |  |  |
| 46 |  | 3.2 d |  |  | An assurance that prospective participants are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements; and will be given information on the participant’s right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal. |  |  |  |
| 47 |  |  |  |  | A statement identifying those with the authority to modify the research subject’s participation (such as the Researcher or Sponsor) |  |  |  |

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| **M/ CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 48 |  |  |  | X | The process for participation withdrawal |  |  |  |
| 49 |  |  |  | X | The effects of a participant choosing to withdraw |  |  |  |
| 50 |  | X |  |  | Information on the participant’s right to request the withdrawal of data, including any limitations on the feasibility of that withdrawal |  |  |  |
| 51 |  |  | 4.8.10m |  | The subject may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |

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| **N/ WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 52 |  | 3.2 c | X | X | A plain language description of all reasonably foreseeable risks, both to the participant and in general, that may arise from research participation. |  |  |  |
| 53 |  |  |  | X | A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable |  |  |  |
| 54 |  |  | 4.8.10 q |  | The person to contact in the event of a study-related injury. |  |  |  |
| 55 | ✓ |  |  |  | Describe the risks as follows:   * Separate the risks by study drug, procedure or intervention as appropriate. * Address incidence/frequency, severity, and long term impact/reversibility. * List frequencies/percentages in order of importance (i.e. rare but serious, very likely, likely, less likely, rare). * Include percentage frequency with each side effect. * Any serious side effects or risks such as stroke, heart attack or death should be listed in a separate paragraph and not buried in the text, or listed first if using the table format. |  |  |  |
| 56 |  | 13.2 |  |  | Researchers conducting genetic research shall advise prospective participants of the plan for managing information revealed through the research. |  |  |  |

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| **O/ WHAT ARE THE REPRODUCTIVE RISKS?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 57 |  |  | 4.8.10 g |  | The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant. |  |  |  |
| 58 |  |  |  | X | A statement that the particular treatment or procedure may involve risks to an embryo or fetus (if the participant is or could become pregnant) that are currently unknown. |  |  |  |
| 59 | ✓ |  |  |  | Where there is a stated risk to an embryo, fetus or nursing infant, describe the need for birth control during and after the study as applicable. Provide details of what acceptable methods of birth control are. |  |  |  |

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| **P/ ARE THERE BENEFITS OF PARTICIPATING IN THIS STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 60 |  | 3.2 c | X | X | A plain language description of all reasonably foreseeable potential benefits, both to the participant and in general, that may arise from research participation. |  |  |  |
| 61 |  |  | 4.8.10 h |  | The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this. |  |  |  |

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| Q/ HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL? \*Provisions required by the Personal Health Information Protection Act (PHIPA) must also be considered and included when applicable | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 62 |  | 3.2 i |  |  | An indication of what information will be collected about participants and for what purposes; |  |  |  |
| 63 |  | X | X |  | An indication of who will have access to information collected on the identity of participants, including specification that the monitor(s), sponsor(s), monitor(s), auditor(s), regulatory authorities and TBRHSC REB will be granted direct access to the subject's original medical records for verification of clinical trial/research project procedures and/or data without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations. |  |  |  |
| 64 |  | X | X | X | A description of how confidentiality will be protected |  |  |  |
| 65 |  | X |  |  | A description of the anticipated uses of data (including secondary uses of data); |  |  |  |
| 66 |  | X |  |  | Information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made. |  |  |  |
| 67 |  |  |  | X | Any limits to the confidentiality of the research records |  |  |  |
| 68 |  |  | 4.8.10 o |  | That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. |  |  |  |
| 69 |  | 3.2 f |  |  | The measures to be undertaken for dissemination of research results, and whether participants will be identified directly or indirectly. |  |  |  |
| 70 |  | X | 4.8.10 o |  | If the results of the study are published, the subject’s identity will remain confidential. |  |  |  |

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| **R/ WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 71 |  |  |  | 21 CFR Part 50 | For clinical trials subject to FDA’s jurisdiction, include the following exact statement “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.” |  |  |  |

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| **S/ WHAT IS THE COST TO PARTICIPANTS?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 72 | ✓ |  | 4.8.10 l | X | The anticipated expenses, if any, associated with participation in the study. |  |  |  |

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| **T/ ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 73 | ✓ |  |  |  | Note: The TBRHSC REB recommends that all study participants receive reimbursement for parking for visits that are above standard of care. |  |  |  |
| 74 |  | 3.2 j |  |  | Information about any payments, including incentives for participants, reimbursement for participation-related expenses. |  |  |  |
| 75 |  |  | 4.8.10 k |  | The anticipated prorated payment, if any, to the subject for participating in the study. |  |  |  |

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| **U/ WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 76 |  | 3.2 j | 4.8.10 j | X | A description of the compensation, if any, that will be provided to the participant in the event that he or she is injured during the research |  |  |  |
| 77 |  | X | X | X | A description of the type of response that will be undertaken if injury occurs to a participant during the research (e.g. that treatment will be made available and covered by (x), or that no such response is planned |  |  |  |
| 78 |  | 3.2 k |  |  | A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm. |  |  |  |
| 79 |  |  | 4.8.4 |  | None of the oral and written information concerning the Research, including the written informed consent form, should contain any language that causes the subject or the subject’s 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 for negligence. |  |  |  |

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| **V/ WHAT ARE THE RIGHTS OF PARTICIPANTS IN THE RESEARCH STUDY?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 80 |  |  | 4.8.2  4.8.10 p |  | An assurance that new information will be provided to the subject or the subject’s legally acceptable representative in a timely manner whenever such information is relevant to a subject’s willingness to continue participation in a research study. |  |  |  |
| 81 |  | X | X | X | An assurance that participants will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation |  |  |  |
| 82 |  | 11.1 |  |  | For phase II clinical trials, provide details on the access to the new drug upon trial completion. |  |  |  |

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| **W/ WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 83 |  | 3.2 g | X | X | Person to contact for further information about the study (minimum Investigator).  The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants. |  |  |  |
| 84 |  | 3.2 h | X | X | The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research. |  |  |  |
| 85 |  |  | 4.8.10 q | X | The person(s) to contact for further information regarding the study and the rights of study subjects, and whom to contact in the event of study-related injury. Person to contact for further information regarding the rights of study subjects. |  |  |  |

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| **X/ SIGNATURES?** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 86 | ✓ | X | 4.8.8 | X | Signature, name and date of signature of the participant (or their substitute decision maker / legally authorized representative, if applicable) |  |  |  |
| 87 | ✓ |  |  |  | Participant/Substitute decision-maker  By signing this form, I confirm that:   * This research study has been fully explained to me and all of my questions answered to my satisfaction * I understand the requirements of participating in this research study (TCPS2 3.2) * I have been informed of the risks and benefits, if any, of participating in this research study * I have been informed of any alternatives to participating in this research study * I have been informed of the rights of research participants * I have read each page of this form * I authorize access to my personal << health >> information, << medical record >>, and research study data as explained in this form * I have agreed, or agree to allow the person I am responsible for, to participate in this research study (GCP 4.8.10 n) * I understand that my family doctor may be informed of my participation in this research study * This informed consent document may be placed in my medical records |  |  |  |
| 87 | ✓ |  |  |  | I **agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form.  I **do not agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form. |  |  |  |
| 88 | ✓ | 4.1 | 4.8.9 |  | Name, signature and date of person assisting with the consent process if applicable (only if translator/ for use if participant unable to read)\*\* |  |  |  |
| 89 | ✓ |  | 4.8.8 |  | Name, signature and date of person obtaining consent\* |  |  |  |
| 90 | ✓ |  |  |  | Person obtaining consent  By signing this form, I confirm that:   * This study and its purpose has been explained to the participant named above * All questions asked by the participant have been answered * I will give a copy of this signed and dated document to the participant |  |  |  |
| 91 | ✓ |  |  |  | [**Required for clinical trials**]  Name, signature and date of investigator |  |  |  |
| 92 | ✓ |  |  |  | [**Required for clinical trials**]  Statement of the Investigator  I acknowledge my responsibility for the care and well being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research. |  |  |  |
| 93 | ✓ |  |  |  | [**Required for clinical trials**]  Name, signature and date of investigator |  |  |  |
| 94 | ✓ |  |  |  | [**Required for clinical trials**]  Statement of the Investigator  I acknowledge my responsibility for the care and well being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research. |  |  |  |
| 95 |  | 3.5 |  |  | Research shall begin only after the participants, or their authorized third parties, have provided their consent. |  |  |  |
| 96 |  |  | 4.8.8 |  | Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion. |  |  |  |
| 97 |  |  | 4.8.11 |  | Prior to participation in the trial, the subject or the subject’s legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. |  |  |  |

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| **Y/ COMMUNICATION WITH YOUR FAMILY PHYSICIAN** | | | | | | | | |
| **#** | **REB** | **TCPS2** | **GCP** | **US-CFR** | **Element** | **Yes** | **No** | **N/A** |
| 98 |  |  | 4.3.3 |  | It is recommended that the investigator inform the subject’s primary physician about the subject’s participation in the study if the subject has a primary physician and if the subject agrees to the primary physician being informed. |  |  |  |

*\*The “person obtaining consent” serves as a witness that the consent process occurred.*

*\*\*An impartial witness need only be utilized if the participant or his/her legal representative is unable to read or if there is some concern about the participant’s level of understanding.*