Non-Interventional Study
Consent Form Template

STUDY TITLE:	The full study title should be placed here. An abbreviated study title that is more understandable to the subject may be used.
PRINCIPAL OR QUALIFIED INVESTIGATOR	The local principal or qualified investigator, their address, and contact telephone number needs to be provided.
ASSOCIATE INVESTIGATORS:	Please see the Research Team Contact Page for a full list of the investigators for this study. **[Please include only if applicable, following our Research Team Contact Page Template; do not include if there are no Associate Investigators for the study.]**
STUDY SPONSOR:	**[Where applicable; do not include if the study is unfunded]**

PART A.

Non-Interventional Studies – General Information

1. Introduction

This section is standard for all Non-Interventional Study consent forms, as per Tri-Council Policy Statement (TCPS) Article 2.4 a).

Required Wording

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you don't understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

We do not know if taking part in this study will help you. You may feel better. On the other hand it might not help you at all. It might even make you feel worse. We cannot always predict these things. We will always give you the best possible care no matter what happens.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

PART B.

EXPLAINING THE STUDY

2. Why Is This Study Being Done?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 b).

Required Elements: Provide background information (in lay terms) about the research and why it is being undertaken.

- What is the question(s) the study is designed to answer?
- Why can't the question(s) be answered without this research being conducted?

3. Why Am I Being Asked To Join This Study?

This section is standard for all Non-Interventional Study consent forms. In deference to potential research participants' right to autonomy, the CHREB requires that consent forms include this section to inform potential participants as to why they, specifically, have been approached regarding participation in research. The Board has added this requirement as per TCPS Article 1.2, and PRE Interpretation 002, Part A of Article 1.2 of the TCPS.

Required Elements: Include a statement indicating why any particular person was flagged as a possible candidate for inclusion in the study.

4. How Long Will I Be In The Study?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 b).

Required Elements: State how long the participant will be involved with the study (e.g. – the length of time over which the study visit[s] will occur) and the overall amount of time that the study activities will require of participants.

If your study involves one or more substudies, if at all possible please state the approximate amount of additional time this will require from participants, over and above the time required for participation in the main study.

5. How Many People Will Take Part In This Study?

This section is standard for all Non-Interventional Study consent forms. The Board has added this requirement as per TCPS Article 1.2, and PRE Interpretation 002, Part A of Article 1.2 of the TCPS.

Required Elements: Describe where the study is being done. If the study is being done only at Capital Health or only in Nova Scotia, please state "This study is taking place only in Nova Scotia." If the study is being done in multiple provinces but only in Canada, please state "This study is taking place throughout Canada." Finally, if the study is being done in countries other than Canada, please state "This study is taking place throughout Canada, as well as in **[list participating countries]**."

Please include the number of people expected to participate worldwide (globally) and the number of people planned to participate locally (at this study centre/site).

6. How Is The Study Being Done?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 b) and TCPS Article 2.4, Table 1, Item 8.

Required Elements: In this section, please provide an overview of the basic study design, in lay terms (e.g. – how is the study going to answer the research question(s) which it aims to answer?). Will participants be asked to complete questionnaires, or be expected to keep diaries? **[The specific study activities and/or procedures that participants will take part in or undergo will be covered in the next section. Please see our Consent Form Guidelines for requested language regarding randomization, blinding and the use of placebo.]**

Please also provide an estimate of the time commitment for participants for the various aspects or portions of the study. If blood will be drawn as part of the study, please provide an indication of the total amount of blood (in tablespoons/teaspoons and ml) to be drawn during the study.

If your study involves one or more substudies, please provide a brief overview in lay terms of how each of the substudies is being done.

7. What Will Happen If I Take Part In This Study?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 b) and TCPS Article 2.4, Table 1, Item 8.

Required Elements: Describe the research procedures or activities that participants will undergo or participate in as part of the screening process and study. Include information on randomization, blinding and the use of placebo (if applicable). **[Please see our Consent Form Guidelines for requested language regarding randomization, blinding and the use of placebo.]**

NOTE (if the study involves a particular patient population): In order to shorten the length of the consent form, please omit any procedures or activities that are considered standard of care. These procedures will be covered in the clinical consent for treatment.

Whenever possible, please use a table to describe the study procedures in regard to timelines. This is more efficient and is much easier for the participant to follow along with, and understand. This is especially true for studies that require a large number of study visits. This also provides participants with a schedule that they can refer to, by placing it on their fridge or wall (in the absence of a separate study schedule to be provided to participants). For this reason, please ensure that any study tables are contained on one page, instead of spread across several pages. **[If the study only involves one study visit and only a couple of procedures or activities take place at the study visit, a table is not required.]**

If your study involves one or more substudies, please describe what additional research activities this will entail for each of the substudies being done. In addition, this information should be added to the study table.

Describe any procedures the participant will be asked to follow if he/she withdraws from the research. Distinguish between those procedures that will be recommended for the participant's benefit as well as those requested for the benefit of the research.

IMPORTANT: Explicitly state that participants are free not to follow any or all of these procedures following withdrawal from the research.

Suggested Wording

SCREENING
If you want to be in this study and sign this consent form, you *will have to have some tests done* to see if you can take part. This is called screening. It is possible that the *tests* will show that you can't be in the study. *There may be other tests done as part of usual care. The research team will discuss these with you.* **[Please clarify what screening tests will be done in the first and third sentences. Please include the last two sentences only if the study involves a specific patient population and the study visits may coincide with visits related to their clinical care.]**

The research study screening tests that will be done are:

- **[List screening tests, either in a bulleted list or in paragraph form]**

[If no screening tests are required for participation, please omit the "SCREENING" subsection above.]

STUDY
We will do the following as part of the study:

- **[List study procedures, either in a bulleted list or in paragraph form]**

When the study is finished or if you decide to stop participating, you will have the following tests and procedures done: **[Include this paragraph and list follow-up procedures only if applicable to your study]**

Of course you may ask not to have further tests done, at any time. **[Please include a paragraph like this one which clearly states that the participant is free to choose not to participate in any further testing or study visits at any time. The wording will have to be adjusted to reflect your particular study. For studies that involve only the completion of a questionnaire, this paragraph is not required.]**

It is important that you tell the Principal Investigator about any drugs or medicines you are taking or wish to take. You must also tell the Principal Investigator about anything unusual that is happening with your health. This includes any medical problems that seem to be getting worse. If you have to see another doctor or have to go to a hospital, you must let the doctors know that you are in a research study. You should also tell your own doctor as quickly as possible, for your safety. **[Include this paragraph or parts thereof only if relevant to your study (e.g. – the drugs a participant is taking or changes in their health status could affect their study participation or the integrity of the study data).]**

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 c).

Required Elements: Provide information about the risks of the study, especially addressing the issues listed below.

- Possible adverse effects of any study procedures.
- Explain whether potential harms are reversible.
- Include a statement acknowledging the possibility of unforeseen harms.
- Risks of questionnaires/surveys and blood sampling need to be stated. **[If applicable]**
- **[Add additional sections as appropriate, to capture the risks of different parts or aspects of the study.]**

NOTE: Only list the harms of the research aspects of the study. Risks of standard care will be covered in the consent for treatment. **[If applicable]**

IMPORTANT: If your study involves genetic research, please provide all participants with a copy of our Supplemental Brochure for Population-Based Research Involving Genetics: "Informed Consent: Taking Part in Population-Based Genetic Research", which outlines additional, potential risks of the research. **Participants should be given an opportunity to review this information before they are asked to consent to participate in such a study.**

Suggested Wording

There are risks with this, or any study. To give you the most complete information available, we have listed some *possible* risks. We want to make sure that if you decide to try the study, you have had a chance to think about the risks carefully. Please be aware that there may be risks that we don't yet know about.

BLOOD SAMPLE
You may experience some temporary discomfort when the blood sample is taken. There is a small risk of bruising, infection or swelling at the site where the needle is inserted, and some people may feel faint and dizzy.

QUESTIONNAIRES
You may find the interviews and questionnaires you receive during the course of the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing.

If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research, please include the following, additional wording at the end of this section (**as per TCPS Article 10.2 c), e) and f)**). In addition, please provide all participants with a copy of our Supplemental Brochure for Research Involving Genetics: "Informed Consent: Taking Part in Genetic Research", which outlines additional, potential risks of the research. **Participants should be given an opportunity**

to review this information before they are asked to consent to participate in such a study.

For substudies requiring blood or tissue but not involving genetic research, please include only the last two paragraphs of the wording below, with the blanks filled in accordingly.

IMPORTANT: If your main study is a genetic research study (rather than involving genetic research as a substudy), please amend the wording below accordingly, to say "the study" instead of "the _____ substudy". Please do this with subsequent requested wording in this template that is specific to genetic research as well.

Please fill in the blanks in paragraphs 1 and 4 to reflect the name of the substudy in question (e.g. – "Biomarker Substudy"), and the blank in paragraphs 4 & 5 to reflect the type of sample involved in the study (e.g. – tissue sample, blood sample, etc.). Please include the italicized text in paragraph 3 only if your study deals with a particular patient population; otherwise please omit the text from the paragraph. If the text is included, please remove the italics.

Required Wording

The kind of information we will look for in the _____substudy is not likely to tell you anything specific about your personal health. If someone allowed your genetic facts to become public knowledge, it may affect your ability to get or keep a job and/or your ability to get or keep various types of insurance. We think the chance of this ever happening to you is very small.

To protect your information, we will not keep your name or other information that may identify you with the sample; only a code number. Files that link your name to the code number will be kept in a locked cabinet and only the study staff will be allowed to look at them. Although no one can absolutely guarantee confidentiality, using a code number makes the chance much smaller that someone other than the research staff or other authorized groups or persons (discussed later in the consent form) will ever be able to link your name to your sample or to any test results.

Although your name will not be kept with the sample, information provided with your sample may have other facts about you such as your race, ethnicity, and sex. These facts are important because they will help us learn whether or not the factors that cause _____ to occur or get worse are the same or different in men and women, and in people of different racial or ethnic backgrounds. Thus, it is possible that research findings could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with such a group. We do not know the effects that this knowledge could have on you or people like you.

Before you decide whether or not to participate in the _____substudy and give us a _____ sample, we want you to be aware that if the samples are ever sent to other countries, the same laws and regulations that we have here might not apply, and they may be used for purposes other than those that we outline in this consent form. They may even be used for things that are against your values and beliefs. Please consider this carefully before deciding whether or not to participate in the _____substudy.

Please be aware that after you provide us with a _____sample, you have released your permission over how it may be used.

9. What Happens at the End of the Study?

Briefly describe the participant's access to the study results when the study is completed. Will the participant be given a copy of the publication (if one is planned).

10. What Are My Responsibilities?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 b), and TCPS Article 2.4, Table 1, Item 5.

Required Elements: Provide statements concerning the following issues, if applicable:

- Needing to follow the directions of the Principal Investigator
- Needing to report all medications being taken or planned on taking
- Needing to report any changes in health status
- Needing to report any serious adverse events that have occurred as soon as possible

Suggested Wording

As a study participant you will be expected to:

- Follow the directions of the Principal Investigator
- **[List other participant responsibilities.]**

11. Can I Be Taken Out Of The Study Without My Consent?

This is standard wording for all Non-Interventional Study consent forms, as per TCPS Article 2.4, Table 1, Item 6.

Suggested Wording

Yes. You may be taken out of the study at any time, if:

- There is new information that shows that being in this study is not in your best interests.
- _____ *(the study sponsor)*, the Capital Health Research Ethics Board or the Principal Investigator decides to stop the study. **[Please include the study sponsor only if applicable.]**
- You do not follow the directions of the Principal Investigator. **[If applicable.]**
- You become pregnant. **[If applicable.]**

You will be told about the reasons why you might need to be taken out of the study.

12. What About New Information?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 d), and TCPS Article 2.4, Table 1, Item 1.

Required Wording

> It is possible (but unlikely) that new information may become available while you are in the study that might affect your health, welfare, or willingness to stay in the study. If this happens, you will be informed in a timely manner and will be asked whether you wish to continue taking part in the study or not.

13. Will It Cost Me Anything?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 e), and TCPS Article 2.4, Table 1, Item 7.

Points that need to be addressed are listed below:

- Are there any costs to participants?
- Will participants be paid? **[Payments should be prorated.]**
- State whether out-of-pocket expenses will be reimbursed with receipts provided.

NOTE: If your study involves genetic research, please consult our Consent Form Guidelines for additional information that should be included within the "Compensation" subsection.

THE RESEARCH RELATED INJURY SUBSECTION CANNOT CONTAIN ANY STATEMENTS THAT APPEAR TO LIMIT LIABILITY.

Required Wording

Compensation

You will not be paid to be in the study. *You will get a small amount of money to cover meals and parking on study visit days. Please bring your receipts with you.* **[Please adjust these two sentences to reflect the compensation policy for your study. The included sentences should not be italicized.]**

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the Principal Investigator, the research staff, the study sponsor or involved institutions from their legal and professional responsibilities.

If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research, (**as per TCPS Article 10.2 d)**) please add one of the following, additional paragraphs to the end of the **Compensation** subsection, as appropriate to your study. If the first option is used, please fill in the blank to reflect the type of sample involved in the substudy (e.g. – tissue sample, blood sample, etc.). Please fill in the blank with the name of the substudy irrespective of which option is used.

If you decide to participate in the _____ Substudy, please note: The aim of our research is to improve the public health. Your _____ sample will never be used to develop a process or invention that will be sold or patented.

OR

If you decide to participate in the _____ Substudy, please note: The aim of our research is to improve the public health. Sometimes, such research may result in findings or inventions that have value if they are made or sold. We may get a patent on these. We may also license these, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you would not receive any financial benefits.

14. What About My Right To Privacy?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4, Table 1, Items 4 and 10.

Required Wording

Protecting your privacy is an important part of this study. A copy of this consent will be put in your health record.

When you sign this consent form you give us permission to:

- Collect information from you
- Collect information from your health record
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The study doctor and members of the research team will see health and study records that identify you by name.

Other people may need to look at the health and study records that identify you by name. These might include:

- people working for the sponsor* - You may ask to see the list of persons working with the sponsor (if applicable)
- the CDHA Research Ethics Board and Research Quality Associate

Use of records.

The research team will collect and use only the information they need to complete the Study. This information will only be used for the purposes of this study.

This information will include your:

[The following is a sample list of what should be included here and must be modified to ensure it includes all of the information collected in the study]

- date of birth
- sex
- medical conditions
- medications
- the results of tests and procedures you had before and during the study
- information from study interviews and questionnaires

Your name and contact information will be kept secure by the research team in Newfoundland and Labrador [substitute the appropriate location]. It will not be shared with others without your permission. Your name will not appear in any

report or article published as a result of this study.
Information collected for this study will kept as long as required by law. This could be 7 years or more.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. It may not be removed.

After your part in this study ends, we may continue to review your health records. We may want to follow your progress and to check that the information we collected is correct.

Information collected and used by the research team will be stored by the Patient Research Centre, Eastern Health [substitute appropriate site, if applicable to this study]. The Manager of the Centre[substitute appropriate position] is the person responsible for keeping it secure.

You may also be contacted personally by Research Auditors for quality assurance purposes.

Your access to records

You may ask the study doctor to see the information that has been collected about you. If the study is 'blinded', you cannot see this information until the study ends. This is to prevent either you or your doctor from knowing which study arm you participated in.

If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research, (**as per TCPS Article 10.2 e), f) and g)**) please include the following, additional paragraph as the 2nd paragraph of this section. Please fill in the blanks to reflect the name of the substudy and the type of sample involved in the substudy (e.g. – tissue sample, blood sample, etc.).

If you decide to participate in the _____ Substudy, once we take your _____ sample, we will assign it a code number. We will separate your name and any other information that points to you from your sample. We will keep files that link your name to the code number in a locked file cabinet and office, away from your sample.

15. WHAT IF I WANT TO QUIT THE STUDY?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 d). Please ensure that this section includes all applicable information requested below:

- Disclose whether withdrawal of study participation cannot include withdrawal of personal data collected up until that point, or whether data collected up until that point will be included in the study analyses. **[If data may be withdrawn, please amend the third sentence of our requested wording to reflect this fact.]**
- **If and only if** your study is related to the participant's profession or education, please include one of the optional last sentences for this section. No italics should be included once the appropriate text is chosen.

Suggested Wording

If you chose to participate and later change your mind, you can say no and stop the research at any time. If you wish to withdraw your consent please inform the Principal Investigator. All data collected up to the date you withdraw your consent will remain in the study records, to be included in study related analyses. *A decision to stop being in the study will not affect any work performance evaluations you may have. // A decision to stop being in the study will not affect your grades.*

If your study includes a substudy for which blood or tissue samples will be required from participants for genetic research **and** the samples will be stored for future research, (**as per TCPS Article 10.2 c)**) please add the subsection heading below, and one of the following, additional paragraphs to the end of this subsection. If the samples will not remain linked to participants at the end of the study, please use the first option. If the samples *will* remain linked to participants at the end of the study, please use the second option.

Can I Withdraw My Sample?

If you agree to have your _____ sample stored for future research, you can change your mind up until the end of the study, when we store the remaining samples. At that time we will remove any information that may identify you. After we do so, we will not be able to withdraw your sample because we will not know which one is yours.

OR

If you agree to have your _____ sample stored, you may later decide that you want to withdraw it from storage. If you decide that you want to withdraw it from storage, you should call one of the research team contacts listed in this consent form, or on the research team contact page (that you will receive along with this consent form) and tell him or her to have your sample discarded. Your sample will be discarded, but any data collected from testing your sample up until that point will remain part of the research.

16. What Will Happen To My Sample After The Study Is Over?

[Please include this section (as per TCPS Article 2.4 b), TCPS Article 2.4, Table 1, Item 4, and TCPS Article 10.2 c), d), e) and f)) only if your study includes a substudy for which blood or tissue samples are required from participants for genetic research. Otherwise please omit this section from the consent form.]

IMPORTANT: If this section is omitted from the consent form, please renumber all subsequent sections appropriately.

If the samples will not be stored for future research, please use the 1st wording option (1 paragraph). If the samples may be used for future research, please use the 2nd wording option (4 paragraphs), and customize it as follows: Please select the appropriate option for the 2nd paragraph (**A.** or **B.**). Please remove the square brackets from the start and end of each of the above paragraphs, and the letter "**A.**" or "**B.**" from the start of either of the paragraphs after including the appropriate option.

After this study is over, we will dispose of all the samples we collected as part of the _____ Substudy by burning them.

OR

After our study is over, we would like to keep any unused _____ samples that are left over from the _____ Substudy and allow them to be used for future research related to _____. The samples will be stored for ____ years in total, during which time they will be made available for various types of research.

A. [If you agree to have your sample stored for future research, we will store the sample under a code number and we will keep the file that links the code number to your name private. We may share the samples with other researchers, but we will not give other researchers any information that would allow them to identify you. We will always know which sample belongs to you, but other researchers will not.]

OR

B. [If you agree to have your sample stored for future research, all information that might possibly identify you will be removed from your sample, and no one will ever be able to tell that it was yours. However, after this happens you will not be able to withdraw your sample, as we won't be able to tell which sample was yours; please keep this in mind when choosing whether or not to allow us to store your sample for future research.]

A Research Ethics Board, like the one that helps protect you during this research project, will review and approve all future projects before any other researchers gain access to your sample.

You can choose not to have your sample stored for future research and still be part of the _____ Substudy. You will have the chance to state whether or not you agree to have your sample stored for future research at the end of this consent form.

17. Declaration Of Financial Interest

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4 e).

IMPORTANT: If the Principal Investigator does have a vested financial interest in conducting the study, the last sentence of our requested wording should be amended to reflect this fact. If the study is unfunded and the Principal Investigator has no vested financial interest in conducting the study, please include only the last sentence of our requested wording.

Suggested Wording

The sponsor is paying the Principal Investigator and/or the Principal Investigator's institution to conduct this study. The amount of this payment is sufficient to cover the costs of conducting the study. The Principal Investigator has no financial interests in conducting this research study.

This section is standard for all Non-Interventional Study consent forms, as per

TCPS Article 2.4 b), and TCPS Article 2.4, Table 1, Item 2.

Suggested Wording

For further information about the study call **Dr./Mr./Ms. XXXXXX.** Dr./Mr./Ms. XXXXXX is in charge of this study at this institution (he/she is the "Principal Investigator"). Dr./Mr./Ms. XXXXXX's work telephone number is (902) XXX-XXXX. If you can't reach the Principal Investigator, please refer to the attached Research Team Contact Page for a full list of the people you can contact for further information about the study.

If you experience any symptoms or possible side effects or other medical problems, please let the Principal Investigator know immediately. **[Please include only if applicable to your study.]**

The Principal Investigator is **Dr./Mr./Ms. XXXXXX**.
Telephone: (902) XXX-XXXX

Your Research Coordinator is **Mr./Ms. XXXXXXX**.
Telephone: (902) XXX-XXXX

19. What Are My Rights?

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.4, Table 1, Item 3.

Required Wording

After you have signed this consent form you will be given a copy.

If you have any questions about your rights as a research participant, contact the **Chair of the Research Ethics Board at 863-2830 ext 4451.**

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", you will need to sign the form.

PART C.

20. Consent Form Signature Page

This section is standard for all Non-Interventional Study consent forms, as per TCPS Article 2.1 b). All appropriate elements must be included.

- Whenever possible, the witness to the participant's signature should be a person who is independent of the research team (e.g. – a relative or family member of the potential participant). When this is not possible, the witness to the participant's signature may be a member of the research team that is present when the participant's signature is obtained. The signature of this individual indicates only that they were present to witness the signature of the participant; not the entire consent process.
- Authorized Legal Representative field should be included **only** if required. This **must** be addressed within the answers to the relevant questions on the Ethics Approval Submission Form ("Informed Consent Process, Question #'s 5 & 6) included with your initial submission to the REB.
- If the consent discussion for all potential participants will be conducted in English, the subsection related to translation is not required. If some potential participants may have the consent discussion conducted in a language other than English, include the relevant subsection, and consult our Consent Form Guidelines for further guidance regarding the use of translation.
- All four signatures (Participant, Witness to Participant's Signature, Person Conducting Consent Discussion and Investigator) are required. The first three signatures should be obtained at the time the consent process takes place. The Investigator's signature should be obtained within 14 days of the other signatures. Participants must be provided with a copy of the signed consent form (which may be missing the Investigator's signature) prior to participation in the research. If they wish, participants may be given a copy of the Consent Form Signature Page that includes the Investigator's signature, when it becomes available.

Example of a properly formatted date:

2006 / Feb / 14
Year Month Day

IMPORTANT:

- **No new information regarding the study, or limitations on the rights of participants should appear on the consent form signature page.**

- **Please note that checkboxes for optional substudies should only be contained on the consent form signature page, and not anywhere else throughout the consent form document.**

- **The consent form signature page should be contained on a single, separate page. Consent forms with signature pages spanning more than one page will be <u>returned for revision</u>.**

<u>Required Wording</u>

Please see the attached signature page.

PART C.

21. Consent Form Signature Page

I have reviewed all of the information in this consent form related to the study called:

[Provide Full Study Title]

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

I agree to allow the people described in this consent form to have access to my health records. **[Only include this paragraph if health record access is required as part of the study]**

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

_____	_____	____ / _____ / ___
Signature of Participant	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Witness to Participant's Signature	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Investigator	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Participant's Authorized Legal Representative	Name (Printed)	Year Month Day*

If the consent discussion has been conducted in a language other than English, please indicate:

_____
Language

_____	_____	____ / _____ / ___
Signature of Translator	Name (Printed)	Year Month Day*

Note: Please fill in the dates personally

I Will Be Given A Signed Copy Of This Consent Form

Thank you for your time and patience!