*[Insert UBC & Institutional Letterhead*]

 **Please note: This is an example of a separate optional consent form for a DNA biobanking study. The same points may also apply when biobanking is a central part of the main study and therefore does not have a separate consent form. The purpose of this document is to demonstrate the level of detail and some of the specific points that the REB would like to see addressed in studies that plan to store tissue samples for future genetic research. Not all of the information in this example consent form will apply to all DNA biobanking studies and the consent form will need to be adapted accordingly. Exceptions to the practices described in this document will be necessary for many studies and such differences will be considered on a case-by-case basis by the REB. Please see the guidance notes on biobanking studies for further details. Required wording is highlighted in yellow.**

**Participant Information and Consent Form**

## Optional consent for DNA biobanking for future research studies

**Principal Investigator:** Name, degrees held

 UBC/PHC/CW/BCCA Department

 Institution/Center

 Contact Phone Number(s)

**Co-Investigator(s):** Name(s), degrees held

**(Optional)** UBC/PHC/CW/ Department

 Institution/Center

 Contact Phone Number(s)

**Sponsor:** *List names of all sponsors, granting agencies, and coordinating groups.*

**If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors, researchers and other staff.**

**INVITATION**

# In addition to the main study {e.g. Evaluation of the effectiveness of Drug X in treating childhood asthma}, you are being invited to have a small sample of your DNA from your blood stored for future use in other optional research studies. This process is referred to as biobanking. DNA is the genetic material unique to each individual that is found within that person’s cells, including some kinds of blood cells.

**YOUR PARTICIPATION IS VOLUNTARY**

Before you decide to consent to participate in this optional biobanking study and future studies, it is important for you to know why we wish to collect and bank your DNA and what will be done with it. This consent form will tell you about why the research is being done, how it is different from the main study, what will be collected and stored, where it will be stored, who will have access to it, how it may be used in the future, and the possible benefits, risks and discomforts associated with giving the sample and with the information obtained from it.

If you wish to participate in this study, you will be invited to sign this form. You have the right to refuse to have your DNA banked without affecting your participation in the main part of the study and without affecting your current medical care. If you decide to participate, you may still choose to withdraw your tissue at any time without giving any reason, and without any negative consequences to your medical care, education, or other services you are receiving now or in the future.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

# **WHO IS CONDUCTING THE STUDY?**

The main research study is sponsored by \_\_\_\_\_ through a grant to Dr. \_\_\_\_. The DNA banking process is also being sponsored by \_\_\_\_\_. Some of the genetic testing will be done by Dr. \_\_\_\_’s lab at the [*list name of institution, city, province, and country*]. Current funding levels are expected to maintain the DNA bank for at least 5 years, after which time the DNA bank will be maintained by Dr. \_\_\_\_’s operating fund from \_\_\_\_. Further research funding will be sought from Canadian granting agencies to fund any new research being done with the DNA samples in the future.

The researchers involved in this study are not receiving payment from \_\_\_\_\_ and do not expect to commercialize any of the research findings from these optional studies, and they do not have any conflicts of interest associated with this study

*[Note: if potential conflicts of interest exist, please insert the following wording:]*

The Principal Investigator [insert study personnel and/or institution] has received financial compensation from the sponsor [name the sponsor] for the work required in doing this clinical research and/or for providing advice on the design of the study/travel expenses/etc. Financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers and the sponsor. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.

# **BACKGROUND**

It is increasingly common for researchers to invite participants in different kinds of research studies to bank samples of their body tissues and/or DNA for use in future research studies. Often the exact nature of these studies is not entirely known because of new discoveries lead research in new and not always foreseen directions. However, samples collected for the purposes of one study may not get used completely and can sometimes be used to answer other research questions. For this reason, participants are asked to consider storing the remainder of the sample for future studies that are as yet undetermined.

# **PURPOSE OF THIS (OPTIONAL) STUDY**

The goal of the main study, [*insert study title*], is \_\_\_\_\_. One goal of the optional studies is to figure out why Drug X may work better in some people than others. This requires analysis of DNA. People often have different responses to the same drug because of genetic variation between individuals. For example, some genes can affect how much of the drug gets absorbed after it is swallowed, or how fast it is cleared from your body. Some of these genes are well-known and have been studied with other types of drugs. Knowing about genes that cause differences in drug response can help researchers develop drugs that behave more predictably in different people. We would like to take DNA from an extra blood sample taken at the same time as the blood sample in the main study to test for variation in some of these genes and to observe whether they seem to have any link with how people respond to Drug X. Since not all of the genes involved in different responses to drugs have been discovered yet, we would like to also bank your DNA sample to study in the future. This way, we can go back and test your DNA at a later date for other newly discovered gene variants (different versions of the same gene that can differ between individuals) that may be involved in your response to Drug X. We also have a research programme that studies genetic factors underlying asthma. There is an option at the end of this form that would allow us to use your DNA sample to search for genes associated with \_\_\_\_ in general. The exact plan for these future studies is not known at this time since it will depend on other discoveries being made in the area of \_\_\_\_\_ research. We will also ask for your consent to use your DNA for research on diseases other than \_\_\_\_\_ for which we may develop future research studies.

# **WHO CAN PARTICIPATE IN THIS STUDY?**

You may participate in this study if you are eligible to participate in the main study [*insert study title*].

# **WHAT DOES THE STUDY INVOLVE?**

As part of the main study, a small amount (about 10 mL or 2 teaspoons) of your blood will be drawn using a needle from a vein your arm. We are asking to take an additional 2 teaspoons of blood at the same time to test for genes that may affect how you respond to Drug X. This study is not designed to benefit you. No additional time, blood draws or hospital visits are required.

Once the blood is collected, your DNA will be extracted from the sample. The DNA will be labelled with a unique code so that no one will know who the sample came from. Dr. Y and those he or she designates (research coordinator or lab manager) will hold the key that links your identity to the individual code used to label the sample. Your DNA will be tested for genes known to be involved in different responses to other drugs. Some of this testing will be done by researchers that Dr. Y’s lab works with who are located in the US, which requires us to send some of your DNA sample outside of Canada. No personal information that directly identifies you will be sent to the US, only the coded DNA sample. Any remaining DNA not used for testing by the US researchers will be destroyed or returned to Dr. Y. We will compare your response to Drug X in the main study with your profile of genes to see if there is any relationship between how well you respond to the drug and particular genes.

Similar to the main study, we are asking your permission to access your medical records and to obtain a family medical history, but in this case to link the data with the DNA sample. All of this information will remain in Canada. Answering questions about your race or ethnic background is voluntary. We also invite you to allow us to store the rest of the DNA for future testing of genes involved in drug responses that have not yet been discovered and for studies of genes that may be involved in asthma. If you consent to these studies, your DNA will be stored in a freezer to preserve it for future testing for an indefinite period of time at Dr. Y’s lab at Hospital M. Every measure will be taken to ensure your privacy. The DNA will only be used for research described in this consent form and will not be sold. You will not receive the results of this or any future tests and your participation in this part of the study will not become part of your medical record. It is very unlikely that the research testing on your DNA will uncover findings that may affect your current or future health. *(Note: some studies will be more likely to uncover findings, either incidental or not, that will affect the future health of participants. In these cases a more lengthy discussion of how these situations will be handled will be required by the REB).*

# **WHAT ARE MY RESPONSIBILITIES?**

After your blood sample has been taken you do not need to do anything else in the short term for these optional studies.

#

# **WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS OF PARTICIPATING?**

The possible harms and discomforts of the study mostly involve the collection of the blood sample, as described in the main study consent form. There may be some slight pain and discomfort when the needle is inserted into the vein and some minor bleeding, bruising, swelling or feeling faint or dizzy after it is removed. There is a very small chance that an infection could occur but all appropriate measures will be taken to prevent this and trained staff (a study nurse) will take the blood sample.

There are also possible non-physical risks associated with taking part in this study. There is a small chance that some genetic information could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released to these outside parties is estimated to be small as the results of this research will not be added to your medical records. Because every person’s genes (DNA) are unique, even when we have removed all information from your sample that could identify you, it might be possible to identify you or your family members by comparing the de-identified DNA sample to an identified sample from you or your family members. The chances of this occurring are small.

# **WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?**

The research that may be done with your DNA sample is not expected to benefit you or your family members directly.

We hope that the information learned from this study can be used in the future to benefit \_\_\_\_\_.

You will receive no payment for taking part in this study, nor will you receive payment or money if this research ultimately leads to new knowledge or technology with commercial potential.

**WHAT ARE THE ALTERNATIVES TO BIOBANKING?**

You can participate in the optional study looking at genes involved in responses to Drug X but may choose not to bank your DNA for future use. In this case your DNA will be destroyed after testing by autoclaving (heating to a high temperature with steam) or by mixing with bleach, instead of being frozen for future use.

**WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**

You have the right to know about new information that may affect your health, welfare, or your willingness to participate in the main study and optional studies. You will be provided with this information as soon as it becomes available.

**WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?**

If you wish for your stored DNA samples to be removed once you leave the study, you may call Dr. Y at [*insert phone number*] and she/he will ensure that your sample is located, removed from the freezer and destroyed. If you prefer, you can also send Dr. Y a letter (at the address listed at the top of this form) or email, asking to be removed from the study, but this is not required. If you do choose to send a letter or email, Dr. Y will destroy it to protect your privacy after it has been read. Any other information collected about you will also be destroyed. However, if your sample has already been tested at the time you withdraw, it may be impossible to withdraw the results once they have been compiled with the results of others participating in the study or if they have been published. Furthermore, if some of your sample has been shared with other researchers, it may not be possible to remove this part of the sample. In these cases of total withdrawal being impossible, your identity will still be protected and the chance of anyone knowing that you were ever involved in the study is small.

# **CAN I BE ASKED TO LEAVE THE STUDY?**

The investigator may decide to discontinue the study at any time. He or she may also decide not to use your sample or withdraw you from the study at any time.

# **WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?**

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of [*insert here, if relevant, the name of the sponsoring company or cooperative group conducting the study*,] [*insert here, if relevant, Health Canada*], [*insert here, if relevant, the U.S. Food and Drug Administration*,] and [*insert name of your REB, i.e. UBC Clinical Research Ethics Board*] for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

**US FDA Regulated Study**

***For US FDA****-regulated studies only, include the following wording in separate paragraphs. The first paragraph is mandatory US FDA wording and cannot be amended.*

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.

**If data is being transferred out of Canada**

***Include*** *the following information if data is being transferred out of Canada.*

1. *The participant information that will be sent outside of Canada.*
2. *A description of the coding of the data, if different from the coding described elsewhere in the consent form.*
3. *To whom the information will be sent (e.g. individuals, organizations, regulatory agencies).*
4. *Where the information will be sent (e.g. USA, UK, Australia).*

***Clarify*** *whether data and/or samples will be sent outside of Canada, and include the following wording:*

Any study related data [and/or samples], sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, [insert (for e.g.) the Patriot Act in the United States] dealing with protection of information may not be as strict as in Canada. However, all study related data [and/or samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information [and/or samples], to organizations located outside of Canada.

* [Insert organization/s]

*Other sample wording can include any of the following statements incorporated into the required wording listed above:*

Protecting your privacy is very important to us. Although there are no specific genetic protection laws in Canada, your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy and personal data is respected. These laws also give you the right of access to the information about you that has been provided to the researchers and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to Dr. Y. In most cases, your personal information or information that could identify you will not be revealed to any third party, including other family members and your family physician, without your express consent. However, if as a result of your participation in this study, facts become known to the researchers which must be reported by law to public health authorities or legal authorities (e.g. reportable diseases, evidence of neglect or abuse), then your personal information will be provided to the appropriate agency or authority.

Several things will be done to ensure that your participation in this study is kept confidential. After your blood is collected for the main study, the DNA from it that will be used in the optional studies will be labelled with a unique code of numbers and letters that has no link to information that could identify you. No names, initials, birthdays, personal health numbers or any other information about you will be used in the code to label the DNA sample. Access to your DNA sample will be recorded on a separate computer file every time a sample of your DNA is used for testing and the type of testing will also be noted. *[Note: not all researchers will have the capability to track each use: this is a suggestion but not a requirement.]* We will also look in your medical record for information about your disease [*if applicable*] and response to Drug X. This information and any other research-related material will also be labelled with the same code used to label the DNA sample and will be encrypted as soon as it is collected to further protect your identity. The code linking information that could identify you with your sample and medical data will be stored on a secure computer that is located in Dr. Y’s office/lab within the \_\_\_\_\_ Institute. A back-up copy will be kept on the secure internal server of the \_\_\_\_ Institute. Both the computer and server are firewall and password-protected and are located in the \_\_\_\_ building, which can only be accessed with a photo ID keycard. The original paper records used to collect your medical information will be kept in a locked filing cabinet in Dr. Y’s office/lab and only Dr. Y or his designated representative will be able to access these files. Dr. Y will hold the linker key that matches your identity to the code used to label your DNA sample and data for the foreseeable future. The study’s project manager, Mr. So&So, will also have access to the linker key and has signed a confidentiality agreement.

Since your sample and information will be kept for many years or until it is used entirely or withdrawn, we will update our security measures for protecting your data and for preserving your sample as they become available.

If in the future, other researchers not involved in this study request your DNA sample and information, they may be given access only to the coded samples and data but they will not know your identity. Furthermore, Dr. Y will look at what they want to study and make sure it is in keeping with the types of research that you wish your sample to be used for, as indicated at the bottom of this form. The outside researcher will also need to get proper research ethics approval to be allowed access to the information and samples. Your sample will not be sold. It is possible that some of these researchers might be located outside of Canada.

As part of this study we will be sending your coded DNA sample for genetic testing of some of the genes that may be involved in your response to Drug X. This testing will be done by members of the lab of Dr. USA at the University of America located in Town, State USA. Any samples sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countriesdealing with protection of genetic or other information may not be as strict as in Canada.  However, all study related samples transferred outside of Canada will be re-coded before leaving the study site to further protect your identity, and the samples held in Dr. USA’s lab will be destroyed after testing or returned to Dr. Y. By signing this consent form, you are consenting to the transfer of your information and samples to researchers and organizations located outside of Canada now and potentially in the future*. [Note: If the transfer of the sample and/or data outside of Canada can be optional according to the study design, the investigator may wish to put a checkbox option at the end of this form for participants who do not wish to have their sample and/or information sent outside of Canada.]*

**WHAT WILL THE STUDY COST ME?**

You will not have to pay anything to be part of this study, nor will you be paid for participating in it.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and/or by the study sponsor [insert name of sponsor].

# **WHO DO I CONTACT** **IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?**

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Y at [*insert contact number*].

**WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?**

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

**AFTER THE STUDY IS FINISHED**

Listed below are some different options of types of studies that might be conducted with your DNA sample in the future. We are also asking your permission to re-contact you to see if you might be interested in participating in future studies not listed here (for example, future studies related to \_\_\_\_ that involve studying something other than your DNA). Please read the different options and think carefully about what you are comfortable with. Tick the boxes next to the types of studies that you agree for your sample to be used in. Your wishes will be respected and you will not be contacted again regarding using your DNA sample for these purposes. You may choose not to participate in some or all of the options – just leave the box blank if you do not consent to the use described. If you do not want your DNA sample to be collected or used in any of the optional research then leave the form blank and do not sign it.

If you are consenting for your child who is under 19 years of age, a member of the research team will attempt to contact your child when he or she reaches approximately 19 years of age. The purpose for contacting your child in the future is to obtain his or her consent for continuing to bank his/her tissue. To maintain your child’s privacy, a letter will be mailed to the address we have for your child on file. You can also choose to have this letter sent to your family doctor rather than your child’s home. If your child’s contact information changes without updating us, please have your child re-contact the researcher when he or she reaches 19 years of age. We will provide your adult child with their own consent form. *(Note to researchers: If samples are taken from children under the age of approximately 7, then their assent should be sought when they reach ~ 7 years and their consent sought when they reach ~19. It is also possible that some adolescents may be mature enough to consent to the research before the age of 19 if the study poses minimal risk. If they are scheduled for a follow-up visit related to the study and the investigators judges them to be competent, their consent can be sought before the age of 19 to avoid re-contacting the participant at a later time when a visit is not scheduled, for example. Please see the UBC REB guidance notes for further information on assent and consent in children.)*

***The following are examples of checkboxes that could be included in the consent form if relevant for your particular study.***

If my child is currently under the age of 19, I prefer that when my child reaches the age of 19 years old and can make his or her own decision about consenting to the use of his or her DNA sample for research purposes that a letter explaining this process to be mailed to:

□ my child’s home address Please inform Dr. Y at [*insert contact number here*]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ if your child’s contact information

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or family physician changes.

□ my child’s family physician

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If I check the boxes below, I agree to have my DNA sample and associated information described in this form stored (banked) for use in the following types of future studies without requiring further consent or contact from Dr. Y:

□ future studies to learn about genes involved in responses to Drug X

□ future studies to learn about, prevent or treat \_\_\_\_

□ future studies to learn about, prevent or treat other health problems

 (for example, diabetes or heart disease)

□ I agree that a member of Dr. Y’s research team may contact me in the future for follow-up or further research related to this study.

□ I agree that a member of Dr. Y’s research team may contact me in the future to ask if I am interested in participating in other research studies not described in this form.**CONSENT TO PARTICIPATE**

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have had enough time to think about the information provided.
* I have been able to ask for advice if needed.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I authorize access to my health records [*insert “and samples” if applicable*] as described in this consent form.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.
* I understand that there is no guarantee that this study will provide any benefits to me.
* [*Insert any other research specific clauses that may be important to reiterate*.]

***Required wording*** *where participants who lack capacity are capable of assent:*

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

*“Participant’s Signature” should be replaced with “Participant’s or Substitute Decision-maker’s Signature” if third party consent may be obtained from a legally authorized representative.*

Participant’s Signature Printed name Date

 Signature of Person Printed name Study Role Date

 Obtaining Consent

***Where******applicable*** *include the following elements:*

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the participant assisted during the consent process in one of ways listed below?

□ Yes □ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check “no”.]

If yes, please check the relevant box and complete the signature space below:

□ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read ).

□ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

 Signature of Person Assisting Printed Name Date

 in the Consent Discussion

**Witness Signature**

***Optional, except*** *where an oral consent is necessary such as when the participant is illiterate or blind, or disabled, or for cultural reasons so that they either cannot or will not sign the consent form. In such circumstances, the witness must be independent of the Principal Investigator or designate. For blind or illiterate participants, an REB approved summary of what is to be said to the participant or his or her authorized representative must be signed by both the person providing the consent and the witness. In such circumstances, the signature of the witness is intended to attest to the fact, and to state, that what is included in the summary was actually said to the participant or legally authorized representative.*

**Investigator Signature**

***Some REBs*** *may require an investigator signature for all consent forms. Check local REB requirements. As well, a signatory line for “investigator signature” (example below) must be added if required by the sponsor, but this may not replace the line for the “person obtaining consent” if this is a different person:*

Investigator Signature Printed name Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.