**Additional Informed Consent Template Language**

This document contains template language that is specific to certain situations. Include the required language in the applicable sections of the informed consent document.

**A. Does the study involve genetic testing?** *[Include only if genetic analysis will occur as part of this research or if biospecimens will be stored for possible genetic analysis in the future.]*

The cells of your body contain deoxyribonucleic acid or DNA for short. DNA is passed down from your parents. It carries the genes that determine physical features such as the color of your hair and eyes. Differences in our genes help explain why we all look different. They may also determine how different people get certain diseases and respond to drug treatments. The use of genetic material in research to study the causes of disease and to help understand how individuals respond to drug treatments is called genetic research.

*Genomic* information relates to the structure and function of all of the genetic material in your body.

We will submit your genomic information to a repository to be used for scientific purposes. A repository contains information from many people. Some repositories are maintained by the University of Illinois at Chicago (UIC), some are maintained by the federal government, and some are maintained by private companies or other academic institutions. Other researchers can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different.

* *Describe the genetic testing to be performed (i.e., genome wide association studies or directed analysis of candidate genes, diseases or conditions to be studied, what will occur with samples and genetic data after study is completed, how will confidentiality be protected).*
* *Will the results of the genetic analysis be shared with others? If so, indicate with whom and the conditions for sharing. Will samples and data contain direct or indirect identifiers or be de-identified before sharing?*
* *If the genetic testing is optional and not required to participate in the main study, clearly indicate that the individual is not required to consent to the genetic analysis to take part in the main study, and retain the applicable checkbox options at the end of this section.*
* *State whether or not the results (individual or group) will be provided to the subjects and, if so, under what circumstances and disclosure procedures.*
* *State whether genetic samples or data will be stored for future use. If so, the following information should be provided, as applicable:*
	+ *Types of subsequent research;*
	+ *Where samples or data will be stored (e.g., researcher’s lab, pharmaceutical company repository, NIH GWAS database);*
	+ *Who will have access;*
	+ *Whether samples or data will contain direct or indirect identifiers;*
	+ *Describe other data about the subject (e.g., phenotype information) which will be provided to the databank, the repository or other researchers;*
	+ *Types of medical conditions or diseases to be studied;*
	+ *Duration of storage and how samples/data will be disposed of; if there is a plan to store indefinitely, state this.*
* *Describe procedures for withdrawing consent and having sample or data removed from the bank or database. Include as applicable: Data and/or samples that have been de-identified can no longer be linked back to the subject and therefore cannot be withdrawn from further use.*

*[The instructions that follow are divided to reflect two different scenarios: non-NIH-funded research and NIH-funded research. Select the instructions applicable to your genomic study, based on whether your research is NIH-funded and therefore subject to the* [NIH Genomic Data Sharing Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)*.]*

***Scenario 1: Genomic research not receiving NIH funding***

*For non-NIH-funded research, insert the following language:*

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally.

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

***Scenario 2: Genomic research receiving NIH funding and subject to the GDS Policy***

*As of January 25, 2015, NIH‐funded research that generates large‐scale human or non‐human genomic data is subject to NIH’s policy on broad sharing of genomic and phenotypic data.* [Click here](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) *to review the NIH policy.*

*For research that is subject to the NIH policy, insert the following language. Be certain to specify at paragraph 3 whether researchers will have controlled* ***or*** *unrestricted access to repository data.*

Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

Researchers will have *controlled access* to your specific genomic information. Controlled access means that researchers will need approval from NIH in order to obtain genomic information from the repository.

***or***

Researchers will have *unrestricted access* to your specific genomic information. Unrestricted access means that researchers may obtain genomic information from the repository without special approval from NIH.

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

*[The following check boxes should be used when applicable to document the subject’s consent to current or future use of samples or data for genetic analysis. If the testing and/or storage is required for the study, do NOT include the checkboxes below.]*

Select and initial one option for each of the following:

1. Genetic testing will be performed on my [Specify: blood or tissue] sample for the current present research study.

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

2. My [Specify: blood or tissue samples, genetic data] will be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future genetic research to learn more about how to prevent, detect, or treat [Specify diseases or conditions].

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

3. My [Specify: blood or tissue samples, genetic data] will be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future genetic research to learn more about how to prevent, detect, or treat other health problems.

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

4. Researchers can contact me about future genetic research.

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

**B. Does the study involve data and/or tissue banking?**  *[Include only if banking of data and/or tissue specimens will occur as part of this research. Use the appropriate term(s) as applicable. If the information is included in the genetic testing section above, do not include the information here.]*

* *Explain purpose of the data and/or tissue banking and the types of research to be conducted with data and/or samples.*
* *Where will the data and/or samples be stored (e.g., encrypted database, researcher’s lab, pharmaceutical company repository, NIH GWAS database)?*
* *Who will have access to the data and/or samples?*
* *Will the data and/or samples contain direct or indirect identifiers and how will they be provided to other researchers (i.e., de-identified or coded)?*
* *Describe whether data about the subject (e.g., demographics, clinical information, outcomes,) will be provided to the databank, repository or other researchers.*
* *Describe the types of medical conditions or diseases to be studied.*
* *Describe the duration that the data and/or samples will be stored, and how the data and/or samples will be destroyed. If the data and/or samples will be stored indefinitely, state this.*
* *Describe procedures for withdrawing consent and having the data and/or samples removed from bank or database. Include as applicable: Data and/or samples that have been de-identified can no longer be linked back to the subject and therefore cannot be withdrawn from further use.*

*[The following check boxes should be used when applicable to document the subject’s consent to data and/or tissue banking. If the banking is required for the study, do NOT include the checkboxes below.]*

Select and initial one option for each of the following:

1. My [Insert applicable type: data, specific tissue, blood, other body fluid, DNA] will be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future research to learn more about how to prevent, detect, or treat [Specify diseases or conditions].

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

2. My [Insert applicable type: data, specific tissue, blood, other body fluid, DNA] will be kept by [Specify name and location of bank, repository and databank] for use by other researchers for future research to learn more about how to prevent, detect, or treat other health problems.

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

3. Researchers can contact me about future research.

[ ]  I agree - Initials \_\_\_\_\_\_\_\_\_.

[ ]  I DO NOT agree - Initials \_\_\_\_\_\_\_\_\_.

**C. What will happen with my information and/or biospecimens used in this study?**  *[Required if identifiable private information and/or identifiable biospecimens will be collected]*

Biospecimens are samples of material, such as urine, blood, tissue, cells, etc. Biospecimens are stored in a repository or bank and are used for laboratory research. We may use biospecimens collected as a part of this study for whole genome sequencing, which describes the positions of genes (the basic unit of heredity).

*[Delete the paragraphs that do not apply]*

Your identifiable private information and/or identifiable biospecimens collected for this research study will not be used for future research studies or shared with other researchers for future research.

***OR***

Your identifiable private information and/or identifiable biospecimens collected for this research study may be used for future research studies and/or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information and/or biospecimens are shared. Once the identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked for additional consent.

***OR***

*If re-identification for future research is possible (i.e., more than a theoretical risk), insert a statement to that effect and describe any risks.*

*[Delete if not applicable]* We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA.

* *Describe what information will be gained, how the information will be used and stored, any risks of whole genome sequencing, and whether the information will be provided back to the subject, and, if so, whether it may be clinically relevant.*

**D. Will I receive my results from the study?** *[Required if clinical results may be provided back to the subject]*

*[Iinsert one of the following:]* We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. [Describe the types of research results that may be returned (including incidental findings, if applicable), under what circumstances subjects will be provided research results, and how subjects will be notified.] You may need to meet with experts to help you learn more about your study results. The study will not cover the costs of any follow-up actions.

***OR***

 *[If clinically relevant results will not be returned, insert the following:]* We will not share results of the study with you.

**E. What are the potential risks and discomforts of the study?** *– Include additional language as required*

**Risks of Genetic Information**

*[The following two paragraphs are only required for research involving genetic testing.]*

While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research studies. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. In addition, there may be undue stress, anxiety, or embarrassment resulting from inadvertent disclosure of information on family relationships, ethnic heritage, or potentially stigmatizing conditions.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. For example, life insurance companies may charge a higher rate based on this information. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease that is being tested in this research study.

**Reproductive Risks** *[Delete paragraphs/sentences that do not apply]*

**If you are a woman:** Participating in this research study may involve risks to pregnant women and/ or an unborn baby which are currently unforeseeable. To protect against possible side effects of the study drug, if you are pregnant or nursing a child you may not take part in this study. If you are a woman of childbearing ability, you and the researcher must either agree on a method of birth control to use or you must agree to be abstinent (i.e., not have sex) throughout the study.

* *If applicable, specify the time period after stopping study treatment or completing study that contraceptive control should continue.*
* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, abstinence, etc., if applicable).*

If you think that you have become pregnant during the study, you must tell the researcher immediately. *[Add the following when true:]* If you become pregnant, your participation will be stopped.

**If you are a man:**  To protect against possible side effects of the study drug to an unborn baby, you must not get a partner pregnant while taking the study drug and for [Insert the number of days/weeks/months] after the last dose.

You and the researcher must agree on a method of birth control to use throughout the study or you must agree to remain abstinent, as applicable.

* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, etc., if applicable).*

**F. What about privacy and confidentiality?** *– Include additional language as required*

**Focus Groups or Group Discussions:**

Although we ask everyone in the group to respect everyone’s privacy and confidentiality, and not to identify anyone in the group or repeat what is said during the group discussion, please remember that other members of the group may accidentally disclose what was said.

**Online Survey Research**: *[Include if the research uses online survey tools]*

Online privacy can never be fully guaranteed and that privacy and confidentiality will be protected to the extent that it is technologically possible.

Please remember that while [Insert name of survey provider, (e.g., Survey Monkey, Zoomerang, SurveyGizmo, etc.)] may not share the specific data collected during this research, it does collect information regarding your online activities, as per the usage agreement you accepted to use [Insert name of survey provider, (e.g., Survey Monkey, Zoomerang, SurveyGizmo, etc.)], and will share this information with others, including advertisers.

**Abuse/Neglect of Child, Disabled or Elderly Adult:** *[Delete if included in the CoC section]*

Please remember that there is an exception to protecting subject privacy and confidentiality if child, elder, and/or disabled adult abuse or neglect of an identifiable individual, or the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities.

**For studies involving HIV/STI, TB** *(tuberculosis)***, or HCV (hepatitis) testing, include the following language:** *[Delete if included in the CoC or NIJ/DOJ section]*

If you test positive for a reportable infectious disease during the research study (for example, HIV/STI, TB (tuberculosis), or HCV (hepatitis), we will be required by law to report this positive test to the Illinois Department of Public Health. This means that your test result and personal identification (name, birth date, phone number, and address) will be released to this public health authority. The researchers will refer you to a doctor or clinic for counseling and treatment *[state whether the researcher and/or UIC will cover this cost, or whether the subject/subject’s insurance will be expected to cover this cost].*

**Chicago Public Schools (CPS) language required in Parental Permission Forms:**

Parents/Guardians please be aware that under the Protection of Pupil Rights Act, 20 USC Section 1232(c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your child.  If you would like to do so, you should contact [Insert Investigator's Name and Contact Information] to obtain a copy of the questions or materials

**Certificate of Confidentiality (CoC):**  *[If this study is funded by NIH or the study has obtained or intends to obtain a CoC, delete any template language referring to releasing data or subject information “required by law” and include the following three paragraphs:]*

To help us protect you and the information, documents, [and biospecimens *(delete if not applicable)*] we will be collecting from you, this research has been given a Certificate of Confidentiality by the National Institutes of Health (NIH). This Certificate means that researchers cannot be forced, even by courts or the police, to disclose information, documents, [and biospecimens *(delete if not applicable)*] that may identify you. However, your information [and biospecimens *(delete if not applicable)*] may be given to personnel of the United States Government to audit or evaluate projects that are federally funded or to meet the requirements of the Food and Drug Administration (FDA).

The Certificate does not stop you or a family member from disclosing, or agreeing in writing to allow researchers to disclose, information, documents, [and biospecimens *(delete if not applicable)*] about you, including your participation in this research. For example, if you would like an employer or insurer to know something about you that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

Even if the research has a Certificate, the research or any member of the study staff must report (even if it is without your consent) evidence of harm to self or others, including actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult. In addition, if the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.

**National Institute of Justice (NIJ)/Department of Justice (DOJ):** *[If this research is funded by the NIJ/DOJ and the NIJ privacy certificate has been submitted and approved, include the following four paragraphs:]*

To help us protect you and the information we will be collecting from you, the researcher submitted a privacy certificate that was approved by the National Institute of Justice and, therefore, is covered by the Department of Justice statute. This privacy certificate makes the identifiable data collected for this study immune from any legal action. The researchers will use the Certificate to resist any demands of information that would identify you, except as explained below.

Your private, identifiable information will be kept confidential and will only be used for research and statistical purposes. Only de-identified data will be submitted to the National Archive of Criminal Justice Data.

If the researchers become aware that you may cause serious harm to yourself or others, the researchers may report this to the appropriate authorities without your consent.

If the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to state and/or federal public health authorities without your consent.

*[Under the National Institute of Justice privacy certificate, current or past domestic, child or elder abuse is not reportable, unless a separate consent to allow this reporting is obtained from the subject. A template for the separate consent is available at:* <http://www.nij.gov/funding/humansubjects/Pages/faqs.aspx>*. Contact OPRS with any questions: 312-996-1711.]*

**G. What if I am injured as a result of my participation?** *[This section is required for research involving more than minimal risk.]*

* *There are three options for this section:* ***1)*** *Full payment from Sponsor;* ***2)*** *Partial payment from Sponsor; or* ***3)*** *No payment for injuries.*
* *Delete the options that do not apply from the template.*
* *Based on negotiations between OVCR ORS and the Sponsor, University Counsel may recommend changes to the template language.*
* *Do not delete any component of the Option chosen.*

*[Option 1 – Use for Industry Sponsored studies where the Sponsor has agreed to pay for injuries regardless of insurance and in non-Industry Sponsored cases where the Sponsor has agreed to pay for research-related injuries.]*

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact [Insert names and titles] at [Insert phone number(s)]. *[For research involving greater than minimal risk, emergency contact information should be included here.]*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you get ill or injured as the direct result of being in this study, the [Insert sponsor name] will pay the costs for your medical treatment of the illness or injury if it:

1. Is not a medical condition that you had before you started the study;
2. Is not the result of the natural progression of your disease or condition;
3. Is not caused by your failure to follow the study plan; and
4. Is not proved to be directly caused by the negligence of an employee or designee of UIC. “Negligence” is the failure to follow a standard duty of care.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

*[Option 2 – Use if the Sponsor will pay injury costs for uninsured subjects or subjects with Medicare/Medicaid and part of injury costs for privately insured subjects that are not covered and/or paid by their private insurance]*

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact [Insert names and titles] at [Insert phone number(s)]. *[For research involving greater than minimal risk, emergency contact information should be included here.]*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you have a private health insurance plan, your plan will be billed for the costs of treatment. If there are any costs that are not paid by your plan, the [Insert sponsor name] will pay these costs. You will still be responsible for any co-payments or deductibles required by your health insurance plan.

If you are covered by Medicare, Medicaid HMO plans or any other governmental healthcare insurance or if you are not covered by a health insurance plan, the [Insert sponsor name] will pay these costs. If you have Medicare or another governmental insurance plan, the Sponsor may request your Social Security number, as the Sponsor may have mandatory reporting requirements under the Medicare Mandatory Reporting provisions.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

*[Options 3 – There is no plan to pay the costs for injuries.]*

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact [Insert names and titles] at [Insert phone number(s)]. *[For research involving greater than minimal risk, emergency contact information should be included here.]*

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. [*Include if applicable –* The study staff will assist you in obtaining pre-authorization from your insurance company.] Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

**H. What are the costs for participating in this research study?** *[Include the appropriate language if there are costs associated with the research]*

* *If the sponsor will not cover all costs related to the research, use the language in the following four paragraphs:*

If you take part in this study, you may have to pay extra costs. The following items and services will be provided to you free of charge by the [Insert study sponsor or others as relevant]. [List any items/ services, if any, that the Sponsor is paying for in full.]

* *Ensure that the cost terms of the clinical trial agreement, informed consent, and protocol all match*

You or your insurer will be responsible for paying for the cost of the following: [Itemize and estimate the charges that subjects participating in the research will be expected to pay if the charges are not paid by their insurance or other third payer].

* *List the items/services and estimate the charges that subjects participating in the research will be expected to pay*

If you have health insurance the insurance may or may not pay for your participation in the research. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires.

* *Indicate who will contact the insurance provider to verify coverage.*
* *Ensure that the cost terms of the informed consent matches the protocol.*

If you do not have insurance, you will be billed for the amount you have to pay.

**I. Will I be reimbursed for any of my expenses or paid for my participation in this research study?** *– Include the following language if specimens are involved*

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to compensate you for any of these developments.

*[Include all or part of the following, as applicable]*

If a commercial product is developed from the tissue or blood samples collected as part of this research project, the commercial product will be owned by [Insert appropriate entity]. You will not profit financially from such a product.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one which will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

* *If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, the subject must be informed of the fact in the consent form.*

**J. What other things should I know?** *[Include the following language in the consent document if there is a COI issue]*

Dr. [Insert PI name] has an external relationship with [Insert name of company/entity] for which he/she was paid. *[Provide a brief description of the nature of the relationship.]* This is information we think you should know when you are making a decision whether or not to participate in this study. You should ask your doctor about this if you have any questions.

* *If the researcher is recruiting potential subjects from their own patients and/or from patients in a clinical program under their direction, it is recommended that the researcher disclose this dual-role in the informed consent.* **\**Suggested Text\**** Your health care provider may be a researcher on this study, and as a researcher, is interested in both your clinical welfare and in the conduct of this study. Before entering this research study or at any time during the research study, you may ask for a second opinion about your care from a health care provider who is not associated with this research study. You are not obligated to participate in any research study offered by your health care provider. Your participation in this research study is voluntary and you do not have to participate. The decision to not participate will not affect your clinical care now or in the future.
* *If the UIC Conflict of Interest Office (COI Office) recommends that you disclose a conflict of interest to subjects, please include the language recommended by the COI Office here so the IRB can review and make a final determination. Examples of COI disclosure language may be found at:* [http://research.uic.edu/sites/default/files/form/files/Model Language.doc](http://research.uic.edu/sites/default/files/form/files/Model%20Language.doc)

**K. Will I be told about new information that may affect my decision to participate?** *[Include the following language in the consent document if there are multiple study visits]*

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

**L. What if I am a UIC student?** *[This section is required if UIC students are being recruited]*

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

**M. What if I am a UIC *OR* UI Health employee?** *[This section is required if UIC or UI Health employees are being recruited]*

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC ***OR*** UI Health. You will not be offered or receive any special consideration if you participate in this research.

**N. Vulnerable Populations**

**Bureau of Prisons:**

*[Include the following language in the text box* ***“Are there any benefits to taking part in the stduy?”****]*

Please note that your participation will have no effect on your release date or parole eligibility.

 *[Include the following language in the section* ***“What about privacy and confidentiality?”****]*

Confidentiality cannot be guaranteed if you indicate that you intend to commit future criminal conduct, you intend to harm yourself or someone else, or, if you are an inmate and you indicate that you intend to leave the facility without authorization.

 *[Include the following language in the section* ***“Can I withdraw or be removed from the study?”****]*

Participation is completely voluntary and you may withdraw your consent and end your participation at any time without penalty or prejudice. If you are an inmate, you will be returned to your regular assignment or activity by staff as soon as practicable.

**If research involves Prisoners:**

*[Include the following language to the* ***“Are there any benefits to taking part in the study?”*** *box:*] Please note that your participation in this research will have no impact on your release date, parole eligibility, and/or eligibility for special programs.

*[Include the following language to the* ***“What about privacy and confidentiality?”*** *section*] Confidentiality cannot be guaranteed if you indicate that you intend to commit future criminal conduct, you intend to harm yourself or someone else, or if you are an inmate and intend to leave the facility without authorization.

*[Include the following language to the* ***“Can I withdraw or be removed from the study?”*** *section]* If you are an inmate, and your participation in the research involves assignment to a special project or activity, you may be returned to your regular assignment and activities by facility staff as soon as staff consider it reasonable and manageable.

*[Include the following to the “Signature” section]*

I understand that my participation (or refusal to participate) in this research project will have no effect whatsoever on any criminal charges pending against me or any sentence, including imprisonment, parole, probation, or placement in any other correction or treatment program, and will have no effect on my release from custody or the likelihood of future incarceration.