COOK COUNTY HEALTH

Office of Research & Regulatory Affairs

**Informed Consent for Adult Research Subjects Document Template – Instructions**

***Please remove instructions pages prior to submitting your informed consent document for IRB review and approval.***

This informed consent document template is designed to help you draft and finalize an informed consent document which is compliant with federal regulations and institutional expectations. Informed consent documents provide information to research subjects to ensure they can understand the research and make an informed, voluntary decision whether to participate. Office of Research & Regulatory Affairs (ORRA) staff and IRB members will carefully review the informed consent document you submit to ensure that all required elements and language are included.

**Important notes**

* The templates and the suggested language within are suggestions only (in most cases), meant to provide a guideline for language which might be acceptable.
* Templates and language should be customized carefully for each individual study to facilitate subjects’ clear understanding of the research. This template has been customized for use with research subjects who are adults (over the age of eighteen (18) years old).
* The following sections must include the mandatory language provided in the informed consent statement template, unless otherwise approved by the IRB and ORRA. Please see the Informed Consent Document Checklist for details.
	+ Important Information
	+ How will my information be protected?
	+ Will my information be used for research in the future?
	+ What will you do with my genetic information? *first paragraph only; the second paragraph should be customized for your study*
	+ Who will pay for my treatment if I am injured?
	+ Who should I call with questions or problems?
	+ What financial interest does the researcher have?
* Studies which already have a template consent form provided by a sponsor or funding agency are welcome and encouraged to utilize those templates. In those situations, investigators should utilize the Informed Consent Document Checklist to ensure all requirements have been included in the informed consent document. ORRA staff will compare the submitted consent form to the checklist during the pre-review process to ensure compliance with all requirements.
* This informed consent also includes a HIPAA authorization. Unless your study has received approval from the CCH IRB to alter or waive the HIPAA authorization requirements or your study will not be collecting protected health information (PHI), the HIPAA authorization section is required and should not be deleted.
* **Under no circumstances should the informed consent include any exculpatory language through which the subject or the legally authorized representative is required to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents for liability for negligence.**

**Using the template**

* Instructions to you are in brackets and are highlighted in gray. Be sure to address each highlighted item and to remove all bracketed/highlighted template instructions before submission.
* Be sure that formatting and grammar are consistent throughout the document. **Font size should be at least 12 pt**., please be sure font and size are consistent throughout. Be careful not to use font in specific sections to over or underemphasize the information provided. For example, don’t use bold or larger font in the payment section, or smaller font in the risks section.
* Leave a **1.5” x 2” space on each page** of your informed consent form for the approval stamp.
* The informed consent must be on **CCH letterhead**.
* Per federal regulations, your consent form should begin with a concise presentation of information, referred to as Important Information. If your consent is very short, there is no need to begin with the concise presentation. For example, if your consent is only two pages long, a concise presentation will only serve to lengthen the document.
* If a section does not apply to your study, please remove it.
* Where the suggested language does not adequately address your study or uses more complex words than is appropriate for your subject population, please customize the language carefully.
* Make use of images, lists, and tables where appropriate to clarify procedures.
* Review your final version carefully for consistency with other study documents.

**Comprehensibility**

* Use simple language, aim for a **7th grade level**, or language that is appropriate to the specific subject population. You can edit the suggested language to improve readability.
* Consider the environment and context in which the consent is presented to a potential research subject.
* As much as possible, avoid the use of or replace complicated or medical/technical language with lay language to ease subject comprehension.
* Write in second person so as to not be interpreted as suggestive or coercive.
* Define any abbreviations and acronyms.
* Use short, simple and direct sentences.

The following resources are publicly available for suggested lay terms and testing the readability of consent forms:

1. CDC Plain language Thesaurus <http://www.plainlanguage.gov/populartopics/health_literacy/thesaurus_v-10.doc>
2. CDC Everyday Words for Public Health Communication <https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf>
3. Glossary of Clinical Trials Terms - <https://clinicaltrials.gov/ct2/info/glossary>
4. Federal Plain Language Guidance <http://www.plainlanguage.gov/howto/quickreference/quicktips.cfm>
5. Document Checklist for Plain Language - <http://www.plainlanguage.gov/howto/quickreference/checklist.cfm>
6. Readability calculator - <https://www.online-utility.org/english/readability_test_and_improve.jsp>

**Language for Special Situations/Populations**

* **Detainees**: “I understand that choosing to participate in this study will not help my status in judicial system in any way and refusing to participate will not be held against me. This study will not affect my sentence, parole or prison conditions.”
* **Pregnancy**: “As described above, you should not become pregnant during this study. If you do become pregnant during this study, you will no longer be given the study drug. Your pregnancy will be cared for through another department, however with your permission, your pregnancy and baby will be followed by the research study”
* **Questionnaires**: “Completing the survey questionnaire will take about n minutes. The survey will not contain your name but the code number will be linked to you. (if true). The questions are about xyz. Answering them may make you feel (sad, uncomfortable –if true). You may skip any question you do not want to answer.”
* **Focus Group**: “Confidentiality in focus groups depends on the participants. You will not use your name in the group. Participants will be reminded not to repeat anything in the group but there is no way to be sure that they will follow this direction or that you may not know someone in the group.”
* **Decisionally Impaired**: A legally authorized representative may consent for persons who may not be able to consent due to developmental delay, extreme pain or anesthesia, or mental illness (mental illness does not automatically preclude the ability to consent). If a legal representative is used, language should be revised in order to reflect the appropriate relationship (“Your family member”).

**Informed Consent Document Checklist**

* **Concise & focused presentation of key study information (45 CFR 46.116(a)(5)(i))**

*The informed consent statement must begin with a summary of the following key information about the study. Please use the language and format provided in the informed consent statement template, customizing the language carefully for your study and ensure that it is easy to read and understand. This information should help the subject understand the reasons why they may and/or may not want to participate in the research study.*

* Statement that the project is research and that participation is voluntary
* Purpose, duration, procedures
* Risks, discomforts
* Benefits
* Appropriate alternative procedures or courses of treatment
* Costs
* Payment
* **Required elements (45 CFR 46.116(b))**

*The following elements must be included in the informed consent statement. The informed consent statement template provides a guideline for language which might be acceptable; however, language should be customized carefully for your study. Sections which are starred (\*) require use of the mandatory language provided in the informed consent statement template, unless otherwise approved by the IRB and ORRA.*

* Statement that the study involves research, explanation of the purposes of the research and the expected duration of participation, description of the procedures, and identification of any procedures which are experimental
* Description of reasonably foreseeable risks or discomforts
* Description of any benefits that may be reasonably expected
* Disclosure of appropriate alternative procedures or courses of treatment, if any
* Statement describing the extent to which confidentiality of records identifying the subject will be maintained\*
* For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs\*
* Explanation of whom to contact for questions about the research and research subjects’ rights, and in the event of a research-related injury\*
* Statement that participation is voluntary, refusal to participate will not result in penalty or loss of benefits, and subjects may withdraw without penalty
* Statement that identifiers might be removed and de-identified information/biospecimens used for future research studies or distributed to another investigator for future research studies without additional consent OR statement that subject’s information/biospecimens will not be used or distributed for future research\*
* **Additional elements, if applicable (45 CFR 46.116(c))**

*The following elements should be included when applicable. The informed consent statement template provides a guideline for language which might be acceptable; however, language should be customized carefully for your study.*

* Statement that treatment may involve risks to the subject or fetus that are currently unforeseeable
* Anticipated circumstances in which subjects’ participation may be terminated
* Any additional costs to the subjects
* Consequences of the subject’s decision to withdraw
* Statement that significant new findings that may relate to the subject’s willingness to participate will be provided
* Approximate number of subjects
* Statement that the subject’s biospecimens may be used for commercial profit and whether the subject will/will not share in those profits
* Statement regarding whether clinically relevant research results will be disclosed to subjects and, if so, under what conditions
* For research involving biospecimens, whether the research will involve whole genome sequencing
* **Additional requirements, if applicable**

*The following elements should be included when applicable. You must use the mandatory language provided in the informed consent statement template for these sections, unless otherwise approved by the IRB and Human Subjects Office.*

* ClinicalTrials.gov (21 CFR 50.25(c))
* Certificate of Confidentiality, if NIH-funded or a Certificate has been granted (NIH Certificate of Confidentiality policy and FAQs)
* Genetic Information Nondiscrimination Act (GINA) notification (OHRP Guidance on Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards)
* Financial interest disclosure, if an investigator on the protocol has a related financial interest (OHRP Guidance on Financial Conflict of Interest, FDA Guidance: Informed Consent Information Sheet)
* Radiation risk language, if radiation/radioactive materials are used for research purposes.

*Questions or suggestions regarding this template should be sent to the ORRA at* *CCHHSIRB@cookcountyhhs.org*

***PARTICIPANTS MUST RECEIVE A COPY OF THIS DOCUMENT!!!***

***Please remove instructions pages prior to submitting your informed consent document for IRB review and approval.***

 **INFORMED CONSENT STATEMENT FOR RESEARCH**

***Consent forms MUST use the most current version of CCH letterhead***

**[Insert Protocol Title]**

**[Insert Sponsor Name and Sponsor Protocol Number]**

**[Insert Name of Principal Investigator]**

**Key Information:**

**The first few pages of this document include summary information about this study that
will help you decide whether or not to participate. More detailed information is provided after
this summary section.**

**About this research**

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. This consent form explains the research study and your part in the study. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand. You may take this description home and discuss it with your family or friends to help you decide.

**Taking part in this research study is voluntary**

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Cook County Health.

1. **Why is this research being done?**

[Insert a short, 1-2 sentence summary of the purpose of the research]. For more information, please see the *Why is this Study being Done* section below.

1. **What will happen to me during the study?**

[Insert a short, high-level summary of the procedures]. For more information, please see the *What Will Happen during the Study* section below.

1. **How long will I participate?**

[Insert a description of the length or duration of subject participation]

1. **Will I benefit from the study?**

[Insert one of the following:]

We don’t expect you to receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future. **Or** It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you. For more information, please *see What are the Potential Benefits of Taking Part in the Study* section below.

1. **Will taking part expose me to risks?** [Insert one of the following:]

[For greater than minimal risk research] Taking part in this research may expose you to significant risks. We may not know or understand all the risks at this time. Some people may experience side effects or discomfort, some of which may be serious. It is very important that you understand the risks in this research study before you decide whether to participate. For details and a list of risks you should know about, please see the *What Are the Risks of Taking Part in the Study* section below. **Or** [For minimal risk research] This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. For details and a list of risks you should know about, please see the *What Are the Risks of Taking Part in the Study* section below.

1. **Do I have other options besides taking part in this study?** [If research involves treatment, insert the following:]There may be other options for treatment of your [Insert applicable condition], including creating a treatment plan with your doctor. **[\*\*If this is not a treatment study, this section is not applicable to the research. Please remove this section from the document\*\*]**
2. **Will I be paid to participate?** [Insert one of the following:]

You will not receive any payment for taking part in this study. **Or** Payment for your time or travel is available if you decide to take part in this study. For more information, please see the *Will I be Paid to Participate* section below.

1. **Will it cost me anything to participate?** [Insert one of the following:]

There is no cost to you for taking part in this study. **Or** You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care. **Or** Taking part in this study may lead to additional costs to you or your insurance company. For more information, please see the *Will it Cost me Anything to Participate* section below.

**Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.**

**Detailed Information:**

**The rest of this document includes detailed information about the study. This is additional information that was not already discussed in the previous pages.**

**WHY IS THIS RESEARCH BEING DONE?**

The purpose of this study is to [Insert explanation for why the research is being completed using language understandable to the subject (i.e., seventh grade level). Explain if the study involves the use of an investigational drug or device, including that “investigational” means it is not approved by the Food and Drug Administration (FDA).].

The study is being conducted by [Insert investigator(s) name(s) and CCH/Departmental affiliation]. It is funded by [Insert Sponsor name, if any, and include if the Sponsor is also the manufacturer of the drug/device being studied, if applicable. Where possible, include all parties who are providing monetary and non-monetary support for the research].

**WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?**

You were selected as a possible participant because [Insert explanation regarding how the subject was identified]*.*

**HOW MANY PEOPLE WILL TAKE PART?**

If you agree to participate, you will be one of [Insert local number of subjects if the study involves only one site or insert local and national/international number of subjects if the study involves multiple sites. It may also be appropriate to include the number of subjects in different cohorts or groups, if applicable.] participants who will be taking part in this research.

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

[Insert explanation of all procedures/tests that are included in the study (e.g., randomization, assignment to study groups, study visits, administration of study medications, X-rays or imaging, blood draws, surveys and questionnaires, focus groups, audio or video recordings, etc.) using language understandable to the subject (i.e., seventh grade level). Be careful to distinguish what is part of usual care and what is part of the research study. Include the following:

* Where the procedures are performed and how frequently they are performed
* The expected amount of time each procedure and/or visit will last
* Indicate the length or duration of subject participation
* Identify which procedures are experimental and which are standard
* If blood is to be drawn, explain how and from where the blood will be drawn (e.g., from a vein in your arm) and indicate the total number of times blood will be drawn, the amount of blood to be drawn, and the total amount of blood to be drawn over the course of the study. Translate the amount of blood to be drawn to common measurement terms (e.g., teaspoons, cups)]

[For research involving deception or incomplete disclosure, insert the following (or similar), as appropriate:]We are not able to provide you with the full purpose of the study at this time, but willprovide additional information at the conclusion of the study.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

[Insert explanation of the risks, side effects, and/or discomforts of each of the procedures completed in the study (e.g., physical, psychological, social, legal) using language understandable to the subject (i.e., eighth grade level). Include risks and side effects of all medications given to subjects for the purpose of the study, as well as the likelihood of the risks and/or side effects (e.g., rare, common, percentage).

Examples of risk/side effect statements include:

* A risk of completing the survey is being uncomfortable answering the questions.
* There is a risk of possible loss of confidentiality.
* The risks of drawing blood include pain, bruising, and, rarely, infection.
* The side effects associated with taking [Insert study medication] are mild diarrhea, confusion, sleepiness, depression, anxiety, and headaches. In rare instances, side effects may include hair loss, rash, and a decrease in the number of red and white blood cells and blood platelets, which could cause fatigue and an increase in infection and/or bleeding.]

[Insert an explanation of measures that will be employed to minimize the risks and side effects listed above. If applicable, include an explanation of any psychological, social, or medical services that may be required because of participation in the research (e.g., counseling, social support services, or medical services). If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study.

Examples include:

* While completing the survey, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question.
* Blood will be drawn by experienced technicians and, whenever possible, it will be obtained at a time when blood is being drawn for other tests your doctor has ordered.
* While you are receiving [Insert study medication], you will be questioned weekly about possible side effects, and you will be monitored by the blood tests we are obtaining.]

[If appropriate, insert the following:]There also may be other side effects that we cannot predict.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

The benefits to participation in the study that are reasonable to expect are [Insert a description of any direct benefit to the subject or if no direct benefit that benefit to others that may reasonably be expected from the research in the future.] NOTE: Payment to subjects is not considered a benefit of participating in the study and should not be listed in this section. If applicable, list it under the *Will I be Paid to Participate* section.

**WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?**

If you take part in this research, you will be responsible to: [list out the responsibilities that the individual will be responsible for][\*\***If this is not applicable to the research (for example, it is not a clinical trial), remove this section from the document\*\*]**

**WILL I BE PAID TO PARTICIPATE?**

[Insert a description of the details and any conditions of payment, including if partial payment is applicable. If there is no payment, state this.]

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: [Insert a list of the procedures, tests, office visits, medications, etc. for which the subject or the subject’s insurance is responsible. If appropriate, state that all standard of care procedures, drugs, tests, etc., will be the responsibility of the subject or his/her insurance. Also, include what is considered standard of care procedures.]. You will not be responsible for these study-specific costs: [Insert a list of the procedures, tests, visits, medications, etc. for which the study will pay. If appropriate, include the following: “If during the study, [Insert name of study drug] becomes commercially available, you may have to pay for the amount of drug needed to complete the study.”]

[\*\***If there are no added costs to subjects per page 1 (#8), remove this section from the document\*\*]**

**WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?**

[If a source of funds for payment of treatment costs is NOT available, insert the following:] You will get medical treatment if you are injured as a result of taking part in this study.  However, your medical care will be covered in the same way you usually get medical care at Cook County Health.  No funds are set aside to pay for medical treatment or any other research participant expense.  You are not asked to give up any of your legal rights.

[If applicable, insert the following:] If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

[If a source of funds for payment of treatment costs IS available, insert a description of the source and conditions for payment of those costs.]

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**WILL I RECEIVE MY RESULTS?**

[If clinically relevant results will be returned, insert one of the following:] We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.] You may need to meet with professionals with expertise to help you learn more about your research results. [Insert if study team/study will help arrange follow-up for these conditions.] The study team/study will not cover the costs of any follow-up consultations or actions.

**or**

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]  If you decide that you want this information, you may need to meet with professionals with expertise to help you learn more about your research results. [Insert if study team/study will help arrange follow-up for these conditions.] The study team/study will not cover the costs of any follow-up consultations or actions. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I want to be provided with this information.

\_\_\_\_\_\_ I do NOT want to be provided with this information.

**or**

[If clinically relevant results will not be returned, insert the following:] We may learn things about you from the study activities which could be important to your health or to your treatment; however, we will not share this information with you.

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. [Include the following, if applicable, “and databases in which results may be stored.” Also, if audio or video recordings will be made, insert an explanation regarding who will have access to the recordings, if the recordings will be used for educational purposes, and when the recordings will be destroyed.]

Please see the “How will I be identified in this research?” and “How will information about me be kept PRIVATE?” sections below for the ways in which your information will be protected. Please see the “WHO will be able to use my information?” section below for the list oforganizations that may inspect and/or copy your research records for quality assurance and data analysis.

[If the study is an FDA-regulated or NIH-funded clinical trial, insert the following:] A description of this clinical trial will be available on [**ClinicalTrials.gov**](http://clinicaltrials.gov/), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

[If the study is NIH funded, you automatically receive a Certificate of Confidentiality, and must include this section. If the study is not NIH funded but the study has obtained or intends to obtain one, insert the following as appropriate:] For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects
4. for the purpose of auditing or program evaluation by the government or funding agency
5. [If FDA-regulated] if required by the federal Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

**Begin HIPAA Authorization Language**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**WHO WILL HAVE ACCESS TO MY HEALTH INFORMATION AND HOW WILL IT BE USED AND SHARED?**

Cook County Health (CCH) is required to get your written permission to use or disclose (share) your health information in order for you to take part in this research study. Researchers would like to use your health information to perform a study. This information may include data that identifies you. Please carefully review the information below and if you agree that the researchers and others identified below may use your health information in the ways indicated on this form, please sign and date this form.

**How will I be identified in this research?**

[Be specific – check one of the boxes below or write text describing the method]

☐A code will be made up combining elements of my name and date of birth

☐My medical record number will be used

☐A random number will be assigned to me and the only person with access to the list that links me to that number is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐Other, be specific \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**What INFORMATION do the researchers want to use?** The following information will be used for this research study:

[List data – as specific as possible]

[After listing the data, FOR THE BELOW – limit the check boxes to the Specific Information needed for this research.]

**SPECIFIC CONSENT**

**The researcher has indicated the information that is needed by placing a check mark in the box next to the type of information. Your provider has discussed this information with you.**

**Instructions. By initialing any of the boxes next to a kind of confidential information, I specifically authorize the use and disclosure of the related confidential information indicated next to the box in the manner described in this Authorization.**

|  |  |  |
| --- | --- | --- |
| Information Requiring Specific Consent | ***Researcher*** ***Check indicates “Required for this Study”*** | ***Research Subject*** ***Initials indicate Consent*** |
| Information about a Mental Illness or Developmental Disability |  |  |
| Psychotherapy Notes (which are not part of the official medical record) |  |  |
| Information about HIV/AIDS Testing or Treatment (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of these tests were positive or negative) |  |  |
| Information about Communicable Diseases |  |  |
| Information about Sexually Transmitted Infections |  |  |
| Information about Substance (i.e. alcohol or drug) Use Disorder or Abuse |  |  |
| Information about Abuse of an Adult with a Disability |  |  |
| Information about Sexual Assault |  |  |
| Information about Child Abuse and Neglect |  |  |
| Information about Genetic Testing |  |  |
| Information about Artificial Insemination |  |  |

**WHO will be able to use my information?**

[List – as specific as possible]:

**Why do researchers want my information?**

[Answer – as specific as possible]:

**How will information about me be kept PRIVATE?**

* 1. The information you permit us to use and share will be transmitted in a secure way. It will be password protected and encrypted. Encryption is a process that converts the information on a computer into a format that cannot be easily understood by unauthorized people.
	2. The information you permit us to use and share as well as the research information for this study will be stored in a secure manner. Paper information is stored in a locked cabinet in a locked office with limited access. Information stored on a computer will be encrypted and accessed only by the persons listed above.
	3. The researchers will keep your information private to the extent possible. Only those listed above will have access to your information. Your information will not be released to others unless required by law.

**What if I DO NOT SIGN this form?** If you do not sign this Authorization, you will not be able to take part in the research study for which you are being considered, however, Cook County Health will still take care of you.

**May I REVIEW my medical information or the information used or disclosed (shared) as part of this Authorization?** You may review your medical record. You will be told if viewing the record will make the research design invalid. In that case, if you choose to review your record before the study ends, you will be withdrawn from the study.

**What if I want to WITHDRAW my permission?** You can change your mind at any time and withdraw your permission (called, “revoke” or “revocation”) to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new health information will be used for research. This will not affect any actions taken by CCH before receiving your revocation. Your withdrawal will be acknowledged by mail unless you request otherwise.

To withdraw your permission, please contact the person below. S/He will make sure your written request to withdraw your permission is processed promptly.

 [PI Name]:

 [PI Address]:

 [PI Phone]:

 [PI Fax]:

**How LONG will my permission last?** Your participation and the length of participation are described in the Consent Form. This Authorization will remain in effect until the research project is over or you withdraw your permission. Data will not be taken from your medical record once your participation, as defined in the Consent Form, is complete.

**End HIPAA Authorization Language**

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

[If the research involves the collection or use of identifiable private information or biospecimens, insert one of the following:]

Information or specimens [collected from you] for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we cannot ask for your additional consent. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

**or**

Information or specimens collected from you will not be used for future research studies or shared with other researchers for future research.

[If the research involves the storage and maintenance of identifiable private information or biospecimens for future use, please ensure the following are addressed: proposed use, collection and storage procedures, procedures for oversight of security and maintenance, who will have access, procedures to protect confidentiality, procedures for withdrawal, etc. For more information what should be included, please see HSO [Guidance on Biospecimens](http://researchcompliance.iu.edu/hso/hs_biospecimens.html).]

[If specimens may be used for commercial profit, insert the following:] Specimens collected from you for this research may be used to develop products which could be sold in the future. The investigator does not plan to share any profits or losses from the sale of those products with you.

**WHAT WILL YOU DO WITH MY GENETIC INFORMATION?**

[If the study involves genetic testing or the tracking of a particular disease or disorder in an individual’s family, insert the following:] This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

[For research involving biospecimens, insert the following, as appropriate:] We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. [Insert a description including 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.]

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?**

[If an investigator has a financial interest in this research, insert the following:] One or more individuals involved in this research may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, contact the researcher, [Insert name of investigator], at [Insert telephone number]. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 4 p.m.), please contact the CCH Office of Research & Regulatory Affairs at 312-864-4821 or at CCHHSIRB@cookcountyhhs.org. After business hours, please call [Insert alternate number and person/title the subject should request (e.g., on-call physician)].

In the event of an emergency, you may contact [Insert name of investigator] at [Insert 24-hour emergency number].

[If this is an investigational drug study using IDS, insert the following:]If you are unable to reach the investigator at the above number(s) in an emergency, you may contact the pharmacy at [insert phone number].

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the CCH Office of Research & Regulatory Affairs at 312-864-4821 or at CCHHSIRB@cookcountyhhs.org

**WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?**

[If subjects may be recontacted in the future:] If you agree, we may contact you after your participation is over to request additional information or biospecimens. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

\_\_\_\_\_\_ I do NOT agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

**WITHDRAWING FROM THE STUDY**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future by following the steps in the “What if I want to WITHDRAW my permission?” section above. [If withdrawal from the study prior to completion could pose risk to the subject, insert a description of what those risks might be and how orderly termination will occur.]

[If appropriate, insert the following:] Your participation may be terminated by the investigator without regard to your consent in the following circumstances: [Insert a description of when and why study participation may be terminated and how orderly termination will occur]. This study may be terminated by [Insert Sponsor/investigator, as appropriate] if [Insert a reason for possible premature termination].

[If appropriate, insert the following:] You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

**WHAT DOES YOUR SIGNATURE ON THIS CONSENT FORM MEAN?**

Your signature on this form means that:

• You understand the information given to you in this form

• You accept the provisions in the form

• You agree to join the study

* You are permitting researchers to use and disclose personal health information collected about you (include if using HIPAA authorization section).

You will not give up any legal rights by signing this consent form.

**PARTICIPANT’S CONSENT**

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this document to keep for my records. I agree to take part in this study.

**Participant’s Printed Name:**

**Participant’s Signature**: **Date**:

**Printed Name of Person Obtaining Consent:**

**Signature of Person Obtaining Consent**: **Date**:

 [If the study involves individuals who cannot consent for themselves, include the following:]

**Participant’s Printed Name:**

**Printed Name of Legally Authorized Representative (LAR)**:

**Signature of LAR**: **Date:**