**Drexel University**

**Consent to Take Part**

**In a Research Study**

## 1. Title of research study: ***[insert title of research study here with protocol number, if applicable]***

## 2. Researcher: ***[insert name of Principal Investigator]***

## 3. Why you are being invited to take part in a research study

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects them eligible for the research.]

## 4. What you should know about a research study

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part now and change your mind later.
5. If you decide to not be a part of this research no one will hold it against you.
6. Feel free to ask all the questions you want before you decide.

## 5. Who can you talk to about this research study?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (IRB). An IRB reviews research projects so that steps are taken to protect the rights and welfare of human subjects taking part in research. You may talk to them at (215) 762-3944 or email HRPP@drexel.edu for any of the following:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research subject.
5. You want to get information or provide input about this research.

## 6. Why are we doing this research?

[Tell the subject the purpose of the research. Explain the background of the research problem.]

## 7. How long will the research last?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

## 8. How many people will be studied?

We expect about \_\_\_\_\_ people here will be in this research study out of \_\_\_\_\_ people in the entire study nationally [or internationally].

## 9. What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The drugs or biologics that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient visits and telephone or written follow-up
* The length and duration of visits and procedures
* If blood will be drawn, indicate the amount [in English units] and frequency
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care
* What procedures are part of regular medical care that will be done even if the subject does not take part in the research
* When applicable indicate that the subject will be contacted for future research.

[Include for a clinical trial. Otherwise delete.]

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment. [For double-blinded research add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded research add] You will not be told which treatment you are getting, however your study doctor will know.

## 10. What are my responsibilities if I take part in this research?

If you take part in this research, it is very important that you: [Describe any responsibilities of the subject.]

* Follow your physician’s or researcher’s instructions.
* Tell your study physician or researcher right away if you have a complication or injury.
* ***[Add additional responsibilities as applicable.]***

## 11. What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

[Include if there are no alternatives other than not participating. Otherwise delete.]

Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

[Include for a clinical trial. Otherwise delete.]

The important risks and possible benefits of these alternatives are listed below: [Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]

## 12. What happens if I say yes, but I change my mind later?

You agree to take part in the research now and stop at any time it will not be held against you.

[Include if there are no adverse consequences to withdrawing from the research. Otherwise delete]

If you decide to leave the research, [Describe the adverse consequences.] If you decide to leave the research, contact the researcher so that the researcher can [Describe the procedures for orderly termination by the subject, if any.]

[Include for a clinical trial. Otherwise delete.]

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the researcher can collect data from your routine medical care. ***[Note: The consent document cannot give the subject the option of having data removed.]*** If you agree, this data will be handled the same as research data. ***[Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an researcher may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]***

## 13. Is there any way being in this study could be bad for me?

[Delete this section if there are no risks or discomforts.]

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. When known describe the probability and magnitude of the risk.]

* Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks

[Include for research that involves risks to an embryo or fetus. Otherwise delete.]

The procedures involved in this research may harm a pregnancy or unborn child in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You should not become pregnant or father a baby while on this research study.

[Include for research that involves an investigational product or procedures whose risk profile is not well known. Otherwise delete.]

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of child-bearing potential and procedures whose risk profile in pregnancy is not well known. Otherwise delete.]

If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for a clinical trial. Otherwise delete.]

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## 14. Do I have to pay for anything while I am on this study?

***[If the study is social or behavioral, explain who will bear the responsibility for cost. If there is no cost, use the following sentence:]***

There is no cost to you for participating in this study.

***[If this study is clinical/medical and only involves reviewing subjects’ medical records (e.g. observational study), use the following:]***

This study will only involve reviewing your medical records. No additional procedures or medicine will be given to you. [Delete if N/A]

***[If this study is clinical/medical and additional procedures and/or medication will be administered, use the following:]***

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered “standard of care” and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these “standard of care” charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

You will not be charged for study drug or device (pick which one if either is involved).

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

## 15. Will being in this study help me any way?

 [Include the section below if there are benefits to participation. Otherwise delete.]

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include this section for a clinical trial with no benefits to participation. Otherwise delete.]

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit and should be described in a later section.]

[Include for research involving prisoners]

Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## 16. What happens to the information we collect?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

***[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained. Institutional policy requires research related data to be retained a minimum of 3 years.]***

[Include for a clinical trial. Otherwise delete.]

The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

[Include for a clinical trial. Otherwise delete.]

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for FDA-regulated pediatric post-market surveillance trials of devices, and FDA-regulated controlled drug and device trials (except Phase I drug trials). Otherwise delete.]

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.

[Include for research involving prisoners. Otherwise delete.]

If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

[Include for research granted a Certificate of Confidentiality. Otherwise delete.]

[*Name of research site and investigator*] have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, the subject may choose to voluntarily disclose the protected information and this certificate do not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality/Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

## 17. Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.]

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.]

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## 18. What else do I need to know?

[Include for industry sponsored research. Otherwise delete.]

The sponsor [Insert name of sponsor] is paying “place in here whom” to conduct the study.

***[If you are faculty or a student of Drexel University, include:]***

This research study is being done by Drexel University.

[Include for all research involving more than minimal risk. Otherwise delete.]

If you become ill during this study, please contact Dr. [name] at telephone no. (XXX) XXX-XXXX. If you require immediate medical attention, you should go to the nearest emergency room or call 9-1-1. It is important that you inform all emergency medical staff that you are participating in this study.

[Use this language for internal/government funded research involving more than minimal risk. Otherwise delete.]

If a “research related injury” results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.

OR

[Use this language for industry sponsored research involving more than minimal risk. Otherwise delete.] If a “research related- injury” results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

Include the following two statements.

It is important for you to follow your physician’s instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this research study.

[Include if subjects will be paid. Otherwise delete.]

If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

If payments to subjects are $600 or more in a calendar year the following language is required.

Research Payments greater than $600.00 per year (or cash equivalent) are reported by the Institution providing payment, to the Internal Revenue Service for federal tax purposes. The level of reimbursement for this study is such that the IRS must be informed of the payments received.

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.]

Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners. Otherwise delete.]

If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

***[When applicable indicate that the researcher believes that the biologic specimens obtained could be part of or lead to the development of a commercial product.]***

***[When applicable indicate when and how the subject will be informed of the results of the research.]***

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent.]

[If you are using any medical information that pertains to a research subject, you need to obtain authorization from the subject to access their Protected Health Information (PHI) using the pages in this document with the header “Authorization to Use and Disclose Protected Health Information.” Otherwise delete these pages with this header.]

[If you do not require any information that would identify a research subject (e.g. identifiers) and you only want to access the PHI, you can obtain Waiver of Authorization. With a Waiver of Authorization you can delete the pages with the header “Authorization to Use and Disclose Protected Health Information.”]

Federal law provides additional protections of your personal information that are described here.

## Individually Identifiable Health Information That Will Be Collected

The following personal health information about you will be collected and used during the research study and may be given out to others: [Modify the following list as needed]

1. Your name, address, telephone number, date of birth;
2. Personal and family medical history;
3. Information from laboratory tests, blood and urine tests, x-rays, physical exams and other tests or procedures described in this consent form.
4. Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
5. Information in medical records located in your doctor’s office or at other medical facilities you may have received treatment.
6. List any additional information that may be obtained from participants that is not covered by the activities and procedures listed in the Consent Form. Examples might include information about financial and social circumstances, or educational level.

## Who Will See and Use Your Health Information within Drexel University

The researcher and other authorized individuals involved in the research study at Drexel University will see your health information during and may give out your health information during the research study. These include the researcher and the research staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly. Your health information may be disclosed or transmitted electronically.

## Who Else May See and Use your Health Information

Other persons and organizations outside of Drexel University may see and use your health information during this research study. These include: [List the following as applicable]

1. Governmental entities that have the right to see or review your health information, such as The Office for Human Research Protections, and the Food and Drug Administration
2. Doctors and staff at the hospital where this research study will take place.
3. Doctors and staff at other places that are participating in the research study.
4. The sponsor of this research study and persons that the sponsor may hire to work on the research study. The name of the sponsor is [Insert name of sponsor].
5. A data safety monitoring board.
6. The contract research organization that is helping the sponsor manage this research study. The name of the organization is [Insert name of contract research organization].
7. The research data management organization that is analyzing data collected during this research study. The name of the organization is [Insert name of data management research organization].
8. [Add other outside entities with whom health information will be shared]

If your health information is given to someone not required by law to keep it confidential, then that information may no longer be protected, and may be used or given out without your permission.

## Why your health information will be used and given out

[If this is an FDA study, add one or both of the above statements, if applicable]

Your health information will be used and given out to carry out the research study and to evaluate the results of the study. Your health information will also be used so the sponsor may receive FDA approval for a new product or drug resulting from this research study.

[AND/OR]

Your information may also be used to meet the reporting requirements of governmental agencies.

## If you do not want to give authorization to use your health information

You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

## How to cancel your authorization

At any time you may cancel your authorization to allow your health information to be used or given out by sending a written notice to Human Research Protection at 1505 Race Street, 7th floor, Bellet Building, Mail Stop 444, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be gathered after you leave. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

## ***When your authorization ends***

[Include one of the two following statements as applicable.]

Your authorization to use and give out health information will continue until you withdraw or cancel your authorization.

[OR]

Your authorization to use and give out your health information will end when the research study is finished.

[Insert this paragraph if research database will be maintained after the study is completed]

After the research study is finished, your health information will be maintained in a research database. Drexel University shall not re-use or re-disclose the health information in this database for other purposes unless you give written authorization to do so. However, the Drexel University Institutional Review Board may permit other researchers to see and use your health information under adequate privacy safeguards.

## Your right to inspect your medical and research records

[Include one of the two following statements as applicable.]

You have the right to look at your medical records at any time during this research study. However, the researcher does not have to release research information to you if it is not part of your medical record.

[OR]

You will not be able to look at your research records while you are taking part in this research study. Your personal information will be made available in an emergency if doctors need this information to treat you.

Use this paragraph for blinded or other studies where access will be denied.

You can have access to your medical record and any research study information when the study is over. However, the researcher does not have to release research information to you if it is not part of your medical record.

##  Information about Genetic Information Nondiscrimination Act (GINA)

The Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.  This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research study.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

However, GINA will not protect you if you already have a genetic disease or disorder and does not prohibit discrimination on the basis of an existing genetic disease or disorder.  In addition, this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Please Note: The GINA language section above MUST be included in your consent form if the research proposal involves ANY genetic evaluation of human tissue samples. If the proposal does not involve genetic analysis, this section may be omitted from the consent form.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent.]

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. |
| **DO NOT SIGN THIS FORM AFTER THIS DATE** | 🡪 |  |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | Form Date |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

|  |  |  |
| --- | --- | --- |
| **DO NOT SIGN THIS FORM AFTER THIS DATE** | 🡪 |  |
|  |  |  |
| Printed name of subject |  |  |
| I am willing to serve as a legally authorized representative for the above named subject. The investigators have explained to me the role and responsibilities of a legally authorized representative. My signature documents my permission for the above named subject to take part in this research. |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |
| Address |
|  |
| City, State, ZIP |
|  |  |  |
| Phone |  | Email |
| Highest | The following individuals in descending order of priority are capable of serving as a legally authorized representative (LAR). Check the category that best describes the LAR’s relationship to the subject. |
| [ ]  | Health care agent appointed by the subject in a Power of Attorney; |
| [ ]  | Court-appointed guardian authorized to consent to the subject’s participation in the protocol in a current court order issued within the subject’s jurisdiction; |
| [ ]  | Spouse or domestic partner (unless an action for divorce is pending) and adult children of the subject who are not the children of the spouse or domestic partner; |
| [ ]  | Adult child; |
| [ ]  | Natural or adoptive parent; |
| [ ]  | Adult brother or sister. |
| [ ]  | Adult grandchild |
| [ ] Lowest | Adult who has knowledge of the subject’s preferences and values, including, but not limited to, religious and moral beliefs, to assess how the principal would make health care decisions. Unless related by blood, marriage, or adoption, the adult may not be the principal’s attending physician or other health care provider nor an owner, operator or employee of a health care provider in which the principal receives care. |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | Form Date |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

**Signature Block for Children**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
| **DO NOT SIGN THIS FORM AFTER THIS DATE** | 🡪 |  |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | Form Date |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |