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| The purpose of this worksheet is to provide guidance to researcher coordinators drafting consent forms when Drexel IRB has agreed to rely on external IRB review. Drexel’s Human Research Protection Program requires specific language to be included in sections of the consent form. |

When engaging in a sponsored or multi-site study, the research team will likely be provided a template consent form. Fill in the Drexel-specific information at the indicated fields. In order to comply with Drexel’s Human Research Protections Program, the RESPONSIBILITY FOR COSTS, COMPENSATION FOR RESEARCH-RELATED INJURY, and CONFIDENTIALITY AND PRIVACY sections should not be modified. However, sometimes the negotiated Clinical Trial Agreement does not reflect our language. In those cases, The IRB will review that language to compare it with the executed Clinical Trial Agreement. Revisions to the consent form may be required if there are discrepancies between the coverage described in Clinical Trial Agreement and the coverage described in the consent form. Additional guidance is provided in the specified sections below.

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| **PAYMENT FOR PARTICIPATION** |

If using ClinCard, the language below must be included in the consent.

You will be paid $$ for each study visit completed. You will be paid a total of $$ if you complete all the scheduled study visits. If you do not complete the study you will be paid only for the study visit you completed. You will be paid using a Drexel University Clincard debit card and the funds will be loaded on the card within \_\_\_ working days of each visit. It is important that you do not lose the Drexel University debit card. If you lose the payment debit card the amount of $5.00 will be subtracted from your next study payment amount.

You will be paid $[enter amount] if you complete all scheduled study visits. If you do not complete the study, you will be paid $[enter amount] for each completed study visit.

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. Additionally, a completed 1099 form will be collected.

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| **RESPONSIBILITY FOR COSTS** |

This language is required for clinical studies that involve medical/behavioral intervention.

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.

Select the most appropriate language if either is involved:

You [will or will not] be charged for the study [drug or device].

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.

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| **COMPENSATION FOR RESEARCH-RELATED INJURY** |

If the study sponsor will provide coverage for research related injury, please include the language below. Revisions to the consent form may be required if there are discrepancies between the coverage described in Clinical Trial Agreement and the coverage described in the consent form.

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.

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.

The university and hospital make no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

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.

If you are injured or have an adverse reaction, you should also contact Human Research Protection at 215-762-3944.

If the study is part of the Columbia Perinatal Consortium, insert this language below.

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.

This medical institution and the NICHD have not made any provision for monetary compensation in the event of injury resulting from the research. In the event of such injury, treatment will be provided, but it is not provided free of charge. Since this is a research study, payment for any injury resulting from your participation in this research study may not be covered by some health insurance plans.

The university and hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

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.

If you are injured or have an adverse reaction, you should also contact Human Research Protection at 215-762-3944.

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| **CONFIDENTIALITY AND PRIVACY** |

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.

For studies involved in the Columbia Perinatal Consortium, use the language that is provided in the consent form.

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:

* Your name, address, telephone number, date of birth;
* Personal and family medical history;
* Information from laboratory tests, blood and urine tests, x-rays, physical exams and other tests or procedures described in this consent form;
* Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
* Information in medical records located in your doctor’s office or at other medical facilities you may have received treatment;

**Who will see and use your health information within Drexel University.**

The research study investigator and other authorized individuals involved in the research study at Drexel University will see your health information and may give out your health information during the research study. These include the research investigator 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:

* Governmental entities that have the right to see or review your health information, such as the U.S. Office of Human Research Protections and the Food and Drug Administration
* Doctors and staff at the hospital where this research study will take place;
* Doctors and staff at other places that are participating in the research study;
* The sponsor of this research study and persons that the sponsor may hire to work on the research study.
* The contract research organization that is helping the sponsor manage this research study. The name of the organization is [*insert CRO name*];
* Remove this statement if not using a commercial IRB. The [*insert IRB name, e.g., Western Institutional Review Board® (WIRB®) WIRB*] is a group of people who perform independent review of research as required by regulations.

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.

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 if the sponsor may receive marketing approval for a new product or drug resulting from this research study.

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

If you do not want to give authorization (permission) 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, Bellet Bldg. 7th Floor, 1505 Race Street, 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.

Select the most appropriate statement;

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.

After the research study is finished, your health information will be maintained in a research database. Drexel University will 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.

You have the right to look at your medical records at any time during this research study. However, the investigator does not have to release this 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.

Please provide notice if these are relevant to protocol:

1. You [will/will not] receive a share of financial gain resulting from commercial biospecimens profits.
2. Your clinically relevant research results [will/will not] be given to you by the research team (include conditions, eg. telephone, letter or in person).
3. This trial [will/will not] include whole genome sequencing.

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| **CERTIFICATE OF CONFIDENTIALITY** |

Include the information below if you have received a Certificate of Confidentiality.

Information about a Certificate of Confidentiality for this research.

[*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.

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| **GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)** |

The GINA language section below 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.

**Information about Genetic Information Nondiscrimination Act (GINA)**

A 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.

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| **CLINICAL TRIALS** |

FDA regulations require that the consent form include disclosure that clinical trial information collected as part of the study will be entered into the clinicaltrials.gov databank. Therefore, any study that needs to be registered in clinicaltrials.gov must include the above statement on the consent form. If you are not sure whether your consent form requires this disclosure, please contact Human Research Protection at 215-762-3944.

A description of this clinical trial will be available on http://[www.Clinical](http://www.Clinical)[Trials.gov](http://Trials.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.