**Emory University IRB**

**MODULAR LANGUAGE FOR INFORMED CONSENT FORMS**

Note: The font used in the “Sample Language” and “Required Language” sections of this document matches the one used in the Emory IRB consent templates.

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# Genetic Information, Risks and Protections

*If genetic information will be produced by the study or future research, please reference the NIH guidance on informed consent for genomics research at* [*http://www.genome.gov/27559024*](http://www.genome.gov/27559024) *as well as the section below on Sharing data with NIH Repositories.*

**Required language:**

 **How is my Genetic Information Protected? What are the Risks?**

The Genetic Information Nondiscrimination Act (GINA) is a federal law that 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.
* 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 when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers’ compensation equivalent coverage, or other similar limited accident and sickness policies.

**Privilege**

In the State of Georgia, in some circumstances your genetic information may have special legal protections called “privilege.” This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

# Data/Specimen Sharing via Repository (including language for compliance with NIH Genomic Data Sharing Policy of 2015)

**Remove references to genetic information if not applicable…**

*It is important to note that for NIH-funded genomic studies initiated after January 25, 2015 (the effective date of the NIH Genomic Data Sharing Policy), NIH expects investigators to obtain consent for participants' genomic and phenotypic data (which may include some clinical information) to be used for future research purposes and to be shared broadly through databases. These expectations for informed consent also include studies using genomic data from de-identified cell lines or clinical specimens that were created or collected after the effective date of the policy. See*[*http://gds.nih.gov/*](http://gds.nih.gov/)*for more information.*

*For information specific to consent in pediatric biobanking, see*[*Studies involving children*](http://www.genome.gov/27559024#_Studies_involving_children)*.*

All language taken from www.genome.gov

**Information to be shared with participants (sample language follows later)**

***What samples and/or data will be shared:****The informed consent process should specify what samples and/or data will be shared (e.g., deposited in a repository) and available for use by investigators outside of the study team. Expectations about control over future use of data and confidentiality of identifiable information can affect participants' willingness to participate in research, so explaining the extent to which identifiable information will be shared is critical. Implications for the protection of participants' privacy and confidentiality also should be addressed in the consent process (see*[*Confidentiality*](http://www.genome.gov/27559024#_Privacy,_confidentiality,_and)*).*

***How the samples and/or data will be shared****:  Biobanks and databases may be generally accessible to the public (unrestricted access) or accessible only with the permission of governance committees or other processes (controlled access) depending on the nature of the data, local policies, qualifications of the user, and other factors.*

***How the samples and/or data might be used:****Participants may provide broad consent for unrestricted future research uses of their samples and/or data or they may provide specific consent that limits future research uses of their samples and/or data (see*[*Broad versus specific consent*](http://www.genome.gov/27559024#_Broad_vs._specific)*). If the study involves depositing samples into a biobank, it is important to consider the derivatives (such as cell lines or other products that could be propagated and used for many years) and data (including genomic data, epigenetic data, and other unanticipated types of data) that may be generated from those samples, and to include this information in the informed consent process. Some of these derivatives and data types may raise unique ethics concerns, for example, creating induced pluripotent stem cells (iPSCs) from donated samples for regenerative medicine. Because some participants will be uncomfortable with some potential uses, the consent process should explain for what purposes cell lines might be used, including those uses related to genomic information. Research participants should also be informed about whether there may be any future commercial use of their data (or samples), and whether or not there is any potential that they will receive financial benefit from these activities.*

***If participants may be contacted in the future:****The informed consent process should include discussion of any potential re-contact of the participant for additional information collection or requests to participate in other studies. In particular, an explanation of any planned genotype-based recruitment to subsequent studies should be included. Asymptomatic biobank participants may be surprised to learn that their genotype may link them to a disease or disorder, so this should be considered within the informed consent process for the primary and the secondary studies. Similarly, plans or any potential for returning results from future research using stored samples and data should be discussed (see*[*Return of results to participants*](http://www.genome.gov/27559024#_Return_of_results)*).*

***What will happen to a participant's samples and/or data following a change in participation status:****The informed consent process should include discussion about what will happen to stored samples and/or data if the participant withdraws from the study, (if relevant) reaches the age of majority, has some other change in status that might affect his or her willingness to participate, or dies. This discussion should include whether the investigators and/or secondary investigators might continue to use the participants' stored samples or genomic data after participants have withdrawn from the study (see* [*Withdrawal from research*](http://www.genome.gov/27559024#_Withdrawal_from_research)*for more information);*

***What will happen to samples and/or data if the repository closes:****Participants should understand whether samples and/or genomic data will be destroyed or transferred if the repository closes.*

##### Sample Language

*Remember to remove references to genomic data if not applicable. You can make the following optional – use the Optional Substudies area of the HIPAA authorization section and please initial lines in the Signature area of the consent form, unless you choose to submit a separate addendum consent/HIPAA form for the options (more likely if optional substudy information is very lengthy*

**Storage and release of samples, genomic data, and health information**De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared.

While the databases will not have information such as your name, address, telephone number, or social security number, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low. Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them. If your genomic information is linked back to you, someone might use this information to learn something about your health.

The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

[If appropriate add cell line creation language from next section of this document]

**Unrestricted access databases**The information from this study will be freely available in a public, unrestricted database that anyone can use. [For example] The public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

**Controlled access databases**Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.

# Cell Line Creation

Please modify the sample language according to your research protocol and plans (or possible options) for sharing the cell lines in the future. Any language that you use in the consent form will dictate what can be done with the cell lines over the long term, so please consider carefully. For cell lines especially, it may be impossible to predict how they will be used in the future; please consider being as expansive as possible.

(Language taken from www.genome.gov)

**Sample language – use what is applicable**

Your tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

We may use the cells taken from your (specify source of cells, e.g. skin) to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including (specify type of cells, e.g. cardiac, muscle, etc.) cells. Your cells might be used in research involving genetic alteration of the cells.

Your cells [will/may] be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

We will store the cell lines and other samples and data in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. The cell bank will only release cell lines to researchers and others under certain conditions. [Specify the terms of release established by the repositories, such as IRB approval or approval by a governance committee.]

What you should know about the cell lines that will be derived in the course of this study:

* The cell lines created will be similar or identical to you genetically.
* The cell lines may be kept indefinitely.
* There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in the animal models.
* The cell lines may be shared with researchers both inside and outside of Emory University, including commercial partners.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

# Return of Research Test Results (Including Genetic Tests) to Participants

***The plan for offering research results to participants should be carefully articulated at the outset of any study and made clear to potential research participants.***

***Some types of results to consider when developing any plans for return include:***

* *Medically treatable/preventable conditions*
* *Medically relevant results with unclear treatment implications*
* *Results without personal health implications, but which may be useful for reproductive planning*
* *Results of uncertain significance*

***Genetic research with children: see separate section in this document***

*For men and women of reproductive age and for women known to be pregnant at the time of enrollment, the informed consent process should include information about the relevance to reproductive planning of any results that are returned. Considerations of reproductive planning may also be relevant to parents of children involved in research.*

*Any plan to offer research results must be IRB approved, and a* ***CLIA-certified*** *lab must normally confirm all individual results that will be returned to participants.*

*Be sure to mention whether any expert consultation or confirmatory testing prior to sharing results will incur* ***costs to subjects****, and whether they will be reminded before those charges are incurred.*

*For more information on return of genetic results and incidental findings, see* [*www.genome.gov/issues/*](http://www.genome.gov/issues/)*.*

##### Sample Language

##### Remember to remove references to “genetic” if not applicable

**[No results returned to participants]**

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**[Participants will receive aggregate results]**

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

**[Participants have option to receive individual results]**

As they become available, do you want us to contact you and ask whether you want to receive your genetic results?

What types of results would you like to receive?

* Results about my genetic risks that I can do something about, like start a new medication or have preventive screening.
* Results about my genetic risks that I cannot do anything about but that might affect my future health.
* Results that might be important for my family members or for my plans to have future children (if relevant).

Do you want to be contacted by other researchers with results from studies using your samples, genomic data, and health information?

Some things you should know about results:

* Any results we return to you will first be verified in a clinical lab.
* The results will be explained to you by a genetic counselor, a health professional who has training in genetics and counseling [if applicable]
* Sometimes the meaning of the results will be uncertain. It is important to know that our understanding of genetics is changing quickly, and in many cases, we will not know for sure what the results mean for your future health.
* Sometimes, even if you learn of a clear diagnosis, there will be no clear treatment.
* For many participants, only certain genes will be analyzed, so we will not find all gene variants that cause disease. You should not assume that if you are not contacted, that you do not have any gene variants that might be related to a disease.

**[Incidental findings]**

It is possible that we will discover that you have a gene variant/medical issue that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you. You should not assume that if you are not contacted, that you do not have any gene variants that might be related to a disease.

# Genetic Research with Children

All language taken from www.genome.gov

*Genomics research that involves children can reveal information that might raise concerns for children and their families. Specifically, genomic analyses could reveal the presence of particular conditions, disease susceptibilities, or carrier statuses that are relevant for the enrolled children or their family members, including adult onset conditions. Some questions that may arise include whether it is appropriate to disclose the risk of adult-onset conditions to children; whether to honor future autonomy (and the right to an open future) when the child has a condition where he is unlikely to gain capacity; and whether researchers must honor a parental decision not to learn about a piece of information that has clinical significance for their child. Researchers should anticipate how such issues will be managed, including informing parents about the circumstances under which results will be disclosed to the parents and/or the child*

*Researchers should also consider whether minors enrolled in their studies will reach the legal age of consent during the study period and what, if any, re-contact should take place at that time. In many pediatric studies, samples, genomic data, and health information analyses continue after the direct involvement of the child in the research has ended. This is an important consideration for genomics research in which samples, genomic data, and health information are stored for future use. The initial informed consent process should communicate any plans for obtaining legal consent for research participants who reach the age of majority during the conduct of research with their samples, genomic data, and/or health information, including what will be done if research participants cannot be reached at the age of majority and the possibility of a waiver of consent being issued to continue research use of study data. When surveyed about a hypothetical situation, respondents in one study felt that researchers should attempt to obtain consent from children who reach the age of majority, but that it is acceptable to continue research when it is impossible to locate individuals. An NHGRI-funded consortia has begun to distill some of the known challenges of consent in pediatric biobanking into concrete practical recommendations on topics including tailored educational materials, developmental level and assent, what will be done at the age of majority, and return of results.*

**Sample Language**

As a part of the study, your child's samples, genomic data, and health information will be stored and used for future research. When your child reaches age 18, we will try to contact him or her to ask whether he or she wants to continue to participate in research. If we cannot find your child, we will remove identifying information, and continue to include his or her samples, genomic data and health information in research.

We may learn information relevant to your child's or your family's health. [Tailor based on the plans for returning results, for example:] If this happens, we will tell you only information directly related to diseases and disorders that affect children. Your child can request additional information when he or she is 18.

# Incidental Findings from Imaging Tests and Scans (e.g. fMRI)

*There is an excellent resource for more considerations about incidental findings, tailored toward researchers: [The National Bioethics Commission’s Researcher Primer: Incidental and Secondary](http://www.bioethics.gov/sites/default/files/Researcher%20Primer%20-%20FINAL.pdf)*

*[Findings](http://www.bioethics.gov/sites/default/files/Researcher%20Primer%20-%20FINAL.pdf)*

**Required Language for fMRI/other imaging modalities**

*For any studies without a certified radiologist on the study team, and that involve scans that could detect anomalies beyond what is specifically being looked at for the research study, the following language is required (per consultation with the Office of the General Counsel):*

You will be getting a scan for research purposes only. The research does not require health professionals to read the scan. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

*If the study team does include a certified radiologist or other member who is qualified to interpret the test being done, please modify the language to reflect your plan for discussing incidental findings with the participants. Suggestion:*

You will be getting a scan for research purposes only. The research does not require the scan to be read for healthcare purposes. However, if the researchers are concerned about something they see on the scan they will tell you, and ask you if you want the scan to be reviewed for healthcare purposes (possibly by other clinicians), and you may then be referred for medical treatment. You or your insurance company may have to pay for the review for healthcare purposes, and for any such treatment.

# Studies under Risk Evaluation and Mitigation Strategies (REMS ):

A Risk Evaluation and Mitigation Strategy ([REMS](file:///C%3A%5CUsers%5Cswilli7%5CDownloads%5CA%20Risk%20Evaluation%20and%20Mitigation%20Strategy%20%28REMS%29%20is%20a%20safety%20strategy%20to%20manage%20a%20known%20or%20potential%20serious%20risk%20associated%20with%20a%20drug%20or%20biological%20product)) is a safety strategy to manage a known or potential serious risk associated with a drug or biological product.

A REMS will be required if the Food and Drug Administration (FDA) determines that a REMS is necessary to ensure the benefits of the drug or biological product outweigh its risks. A REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use, and an implementation system. Click here for more information on REMS.

Things to consider for the informed consent:

* Does the consent document describe REMS requirements for subjects?
* Does the subject have to register with a REMS program?
* Does the REMS apply to all subjects?
* Does REMS require subject counseling?
* Does REMS address reproductive risks?
* Does the consent cover approved methods of contraception?
* Does the consent cover details regarding pregnancy testing?

# Greenphire

We are planning to provide compensation to you by a personal payment card. We issue this to you free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. You will be paid following each time your child completes a visit. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.