

**Informed Consent Template: Biospecimens/Genetics/Genomics**

Informed consent is required to provide potential participants or their legally authorized representatives with the information necessary for a “reasonable person” to make a decision about participating in research.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level or lower. The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age of the child.

Because your study involves the collection of biospecimens and/or genetic or genomic analysis, we strongly recommend the use of this template to create the informed consent document(s) for your study, particularly for federally sponsored clinical trials that will be required to post a consent document on a public website. Please note:

1. Federal regulations require that the informed consent contain a concise and focused presentation of the key information that is most likely to help potential participants understand why they might or might not want to participate in the study. The key information must be presented first and should include the following:
	1. Identification of the project as a research study
	2. Purpose of the research, duration of participation, and a description of research procedures
	3. Foreseeable risks or discomforts, if any
	4. Expected benefits to participants or others, if any

**e.** Statement that participation is voluntary

Most federally sponsored projects involving collection of biospecimens, particularly those involving genetic/genomic analyses, will require this new concise “Key Information” as the first section of the informed consent. The IRB many require this summary for complex non-federally sponsored projects.

1. Text that is not highlighted is required information; text in [brackets] represents information about your study that you must add.
2. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not” or “I/we”).
3. Additional instructions are highlighted in light grey.
4. Before you upload your consent document to the eResearch application, delete this cover page, backslashes, brackets, and highlighted text. The finished document should reflect what you will give to the participant.
5. Use a file name for each consent document that clearly identifies the type of consent and for which participants it is intended (e.g. child assent, parental permission, adult consent, etc.).

For questions about informed consent, please contact the IRB-HSBS at 734-936-0933 or irbhsbs@umich.edu.

For more information on plain language go to <http://www.plainlanguage.gov/>.

**University of Michigan**

**Consent To Be Part Of A Research Study**

**1. Key Information About the RESEARCHERS and This Study**

**Study title:**

**Principal Investigator:** [Name, credentials, institutional affiliation]

**Co-Investigator(s):** [Name, credentials, institutional affiliation] Delete if this does not apply.

**Faculty Advisor:** [Name, credentials, institutional affiliation] Required for projects with a student PI; Delete if this does not apply.

**Study Sponsor:** [Name] Delete if this does not apply.

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study. If this document will be used to obtain parental permission for their child to participate in research, replace “you” with “your child” throughout.

The revised Common Rule requires a concise and focused description of the research project to be included at the beginning of the consent document. This section is required for complex research projects such as those involving multiple study procedures, those posing more than minimal risk to participants, and for all projects involving the collection of biospecimens for genetic/genomic analysis. If this does not apply to your project, delete Section 1.1 below.

* 1. **Key Information**

Things you should know:

* The purpose of the study is to [briefly describe the study purpose, including a simple, non-technical description of any planned genetic/genomic analyses including whole genome analysis].
* If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
* Risks or discomforts from this research include [briefly describe].
* The direct benefits of your participation are [description of potential direct benefits to participants – or state that there are no direct benefits].

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

**2. PURPOSE OF THis STUDY**

Briefly, in one paragraph, explain in simple, non-technical language, the scientific reason for doing this study. Do not describe the details of the protocol here – protocol details should be described in Section 4 “Information about Study Participation.”If your project, will include whole genome analysis, include the following: We may use the [type of biospecimen] collected for this study for whole genome sequencing which involves mapping all of your DNA for [what purpose].

**3. Who can Participate in the study**

**3.1 Who can take part in this study?** List important eligibility criteria (e.g., age, gender, language, health condition, etc.) in simple, non-technical language. Also, include a discussion of any important exclusion criteria, if applicable.

**3.2 How many people are expected to take part in this study?** This question is optional. Some participants may wish to know how many others will be taking part. Delete this section if you will not provide this information.

**4. information about study participation**

**4.1 What will happen to me in this study?**

Explain in lay terms, typically in chronological order, what will happen to participants during the study. List all research/experimental procedures in this section. The following should always be included, if applicable:

* The location where research activities/procedures will take place
* Description of all research interactions/experimental activities or interventions
* Data collection procedures (surveys, interviews, audio-visual recording, collection of biospecimens)
* Identification of which procedures are standard and which are experimental
* Randomization procedures
* Use of medical records
* Linking of data collected or created as part of the research to other information, such as protected health information, administrative data such as from the U.S. Census or state agencies, or publicly available information
* For projects involving the collection of sensitive information or questions that might be upsetting, include examples of the types of questions asked or describe the sensitive topics involved.

**4.2 How much of my time will be needed to take part in this study?** Explain as needed, describing time in hours, number of interactions or study visits, and duration of the research. For example, “Participants will be asked to take one survey each month for a period of six months. Each survey is expected to take about one hour.” Be liberal in the estimation of how much time is required and ensure that it is consistent with what you have described in the eResearch application. If this is a longitudinal project, tell participants that you may contact them again the future and provide the interval if known.

**4.2.1 When will my participation in the study be over?** Necessary only if not addressed in 4.2 above, otherwise delete this section.

**4.3 If I decide not to take part in this study, what other options do I have?**

For projects that involve an intervention that might improve a condition or disease, describe alternatives to participating in the research. These could include an intervention or treatment available outside the research context. Required only for studies that treat a condition or disease. Delete this section if not applicable.

There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options.

**5. information about Study RISKS and benefits**

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

Describe the known or expected risks of the study. These may be physical, psychological, legal or informational. Breach of confidentiality (i.e., informational risks) is a potential risk in all research that collects or maintains personally identifiable information and may be the only risk in some studies. Include information about any specific risks associated with genetic or genomic information. See National Human Genome Research Institute guidance on informed consent <https://www.genome.gov/27565451/informed-consent-required-elements-of-the-consent-form/#4> for information that may be helpful in identifying the risks of your project.

The researchers will try to minimize these risks by [describe what you will do to protect participants against risks.] For example, psychological risks could be mitigated by providing participants with counseling resources.

For projects that involve surveys/interviews/focus groups, include the statement: You do not have to answer any questions you do not want to answer.

For informational risks state: Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

For genomic data, state: Because everyone’s DNA is unique, it is possible that in the future someone could find out who you are just from your DNA sequence although that is not possible now.

**5.1.1 What happens if I get hurt, become sick, or have other problems because of this research?** For **more than minimal risk** projects only - delete section 5.1.1 for minimal risk projects (most projects reviewed by IRB-HSBS do not require this section).

The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. For health-related research involving treatment, include: You should also tell your regular doctors. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

**5.2 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. **or** You might benefit from being in the study [describe direct benefits]. Note: Compensation for research participation is not considered a benefit of the research. Information about compensation should be described in Section 7.

**5.2.1 Will the researchers provide information to me about what they learn from analyzing my [type of biospecimen]?** If clinically relevant results will or will not be returned, insert one the following options. Delete this section if not relevant to the research.

If clinically relevant results will be returned, insert the following: We may learn things about your health as part of the research. If this happens, this information will be provided to you. [Insert a description of the types of research results that may be returned, under what circumstances participants will be provided research results, and how participants will be notified.] You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

-or-

If clinically relevant results will not be returned, insert the following: We may learn things about your health as part of the research, however we will not share this information with you because [describe rationale].

**5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?** Include this section for health-related research involving an intervention, otherwise delete. Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

**6. ENDING THE STUDY**

**6.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9 “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information [and type of biospecimen] collected about you for the research unless you ask us to remove the information from our records and destroy the [type of biospecimen]. If the researchers have already used your information in a research analysis, it will not be possible to remove your information.

**7. Financial Information**

**7.1 Will I be paid or given anything for taking part in this study?** You will receive [type and total amount of compensation] for your participation in the study. Describe how compensation will be distributed if the participant withdraws from the research before the end of the study.

[Include the following paragraph if participants will receive incentive payments]

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes.  If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

**7.1.1 Will I need to pay anything to be part of the study?** To be part of the study, you will need to pay for [indicate what costs, if any, participants will have to pay (such as parking)].Delete this section if there are no costs to participants.

**7.2 Who could profit or financially benefit from the study results?**

The sub-headings under this question related to potential conflict of interest scenarios. Delete this section 7.2 if none of this scenarios apply to this study. If a person or organization involved in the conduct of this study has or may have a conflict of interest, address any of the following issues that may apply:

How is the research supported or financed?

Where and by whom was the study designed (i.e., industry-sponsored versus investigator-initiated)?

Do individuals or the institution receive any compensation that is affected by the study outcome?

Do individuals or the institution

have any proprietary interests in the product (including patents and licensing agreements);

have an equity interest in the sponsor;

receive significant payments of other sorts (e.g., grants or consultant retainers); and/or

receive payment per participant or incentive payments?

The company whose product is being studied:

Disclose under this sub-heading if a company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study, particularly if the company/organization is also the sponsor of the study or has a financial relationship with the investigators (as described under the next sub-heading). Delete this sub-heading if it does not apply.

The researchers conducting the study:

**Information regarding suggested language for this section:**

If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here in accordance with the management plan approved by the [OVPR](https://research-compliance.umich.edu/conflict-interest-coi) or [Medical School’s Conflict of Interest Committee](https://research-compliance.umich.edu/conflict-interest-coi). If your plan is reviewed and approved by the Institutional Conflict of Interest Committee (ICOC), your plan may include suggested/required language. Please review your plan accordingly. Delete this sub-heading if it does not apply.

**Suggested Language if there is a Tech Transfer/Financial Interest:**

The University of Michigan is an owner and [CONFLICTED INDIVIDUAL’S NAME HERE] is a named inventor on patents or patent applications or is a creator of copyrighted material that is licensed or optioned to [STATE COMPANY NAME]. This means, the University of Michigan and [CONFLICTED INDIVIDUAL’S NAME HERE] could gain financially from this study. Delete this sub-heading if it does not apply.

**Suggested Language if there is Stock Ownership:**

[STATE CONFLICTED INDIVIDUAL’S NAME HERE] owns stock or stock options in [COMPANY NAME] who is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there are Other Financial Interests (Paid):**

[STATE CONFLICTED INDIVIDUAL’S NAME] serves as a paid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there is Other Non-financial Interests (Unpaid):**

[STATE CONFLICTED INDIVIDUAL’S NAME] serves as an unpaid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there is a Relative/Family-Related Conflict of Interest:**

[STATE CONFLICTED INDIVIDUAL’S NAME, STATE RELATIONSHIP TO YOU.] Delete this sub-heading if it does not apply.

**Suggested Language if the University of Michigan has a financial interest in the future**:

If the UM intends to be paid licensing fees for the investigational technology, **or could in the future**, so disclose under this sub-heading (e.g., when there is a tech transfer agreement in place or anticipated, or if there are tissues collected or cell lines developed for which the University and/or creators could be paid licensing fees). Contact the [*Innovation*](https://innovationpartnerships.umich.edu/) *Partnerships* if you are uncertain. Delete this sub-heading if you are certain it does not apply.

Although rare for research reviewed by IRB-HSBS, if the biospecimens that are collected as part of this project could be used or shared with other entities for commercial profit, include the following required text:

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

**8. Protecting and sharing Research information [and biospecimens]**

**8.1 How will the researchers protect my information?** Describe procedures that will be followed to keep participant information and biospecimens secure and confidential. Note: any research data that will be linked to individual identifiers is considered identifiable.

If the research will use cloud storage for data, include the following language (modify, as needed):

Your research information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

**8.1.1 Special Protections (Delete this section if not applicable)**

If your project is **NIH-funded and collects identifiable, sensitive information,** it will be covered by an NIH Certificate of Confidentiality, or if **you will apply for a CoC** for non-NIH sponsored research collecting health-related, identifiable, sensitive information, use the following required language:

This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes [Briefly summarize. For example, “This includes placement of your research information into your medical record, and sharing your de-identified data with other researchers.”] [If you are not required by law to report to authorities in specific cases but plan to do so, include a statement here. For example, “We may also disclose your information to the appropriate authorities if we suspect or learn about cases of child or elder abuse or neglect, or that you may harm yourself or others, or if we learn that you have [condition/disease].” [***NOTE:*** where reporting **is** required by law, do not discuss here. Discuss in the next paragraph.]

**[*Use this paragraph only as applicable]***We will disclose your information if the [enter name of federal or state sponsor], the agency funding this research, requests information to audit or evaluate our procedures.

Please note that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates may be found at the NIH CoC webpage**:** https://humansubjects.nih.gov/coc/index

**Adult Abuse -** Michigan law requires the reporting by certain persons of actual or suspected adult abuse, neglect, or exploitation. Required reporters include physicians, nurses, therapists, and other persons employed by healthcare institutions. More information about required reporting is available [here](http://www.legislature.mi.gov/%28S%2805je2555daxqvkmg2xxdpsfh%29%29/mileg.aspx?page=GetObject&objectname=mcl-400-11a). A study team may consist entirely of required reporters, a combination of required and non-required reporters, or entirely of non-required reporters. The following language should be inserted if actual or suspected adult abuse, neglect, or exploitation may be revealed during this study:

If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

**Child Abuse –** The University of Michigan Minors in Research (MiR) policy requires all study team members (including university employees, students, and volunteers) who interact with minors participating as subjects in university-sponsored research to adhere to the policy, including reporting actual or suspected child abuse or neglect of any adult responsible for the child’s health and welfare. Additional information may be found [here](https://childrenoncampus.umich.edu/researchers/).

In addition, Michigan law requires the reporting of actual or suspected child abuse or neglect by certain persons (called mandated reporters). Mandated reporters include physicians, nurses, therapists, and other medical professionals. A complete list may be found [here](http://michigan.gov/dhs/0%2C4562%2C7-124-7119_50648_44443-157836--%2C00.html). A study team may consist entirely of mandated reporters, a combination of mandated and non-mandated reporters, or entirely of non-mandated reporters. The following language should be inserted if actual or suspected child abuse may be revealed during this study:

If you tell us or we learn something that makes us believe that your child or others have been or may be abused or neglected, we may, and in some cases must, report that information to the appropriate agencies.

**Or**, use the following if this form will be used to obtain assent from minor participants (e.g., 15-17 year old participants):

If you tell us or we learn something that makes us believe that you or others have been or may be abused or neglected, we may, and in some cases must, report that information to appropriate agencies.

[Genetic Information Nondiscrimination Act (GINA)](http://www.ginahelp.org/GINA_you.pdf) -- If the research involves analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes, insert the following two paragraphs:

The federal 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 does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

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

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

* Members of the US Military receiving care through Tricare
* Veterans receiving care through the Veteran’s Administration (VA)
* The Indian Health Service
* Federal employees receiving care through the Federal Employees Health Benefits Plans

**8.2 Who will have access to my research records?**

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
* If applicable, state: Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

**8.3 What will happen to the information [and/or biospecimens] collected in this study?**

We will keep the information [and/or biospecimens] we collect about you during the research, [including information we learn from analyzing your [type of biospecimen]], [for future research projects/for study recordkeeping or other purposes (describe)]. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. Note:any research data that will be linked to individual identifiers is considered identifiable.Linking of data to individual identifiers, length of time data will be linked to identifiers, and whether destruction of identifiers will occur should be described here.

**Or:** We will not keep your name or other information that can identify you directly.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

If the investigator wishes to identify a participant in a presentation or article, state: The results of this study could be published in an article or presentation, but would not include any information that would let others know who you are without your permission.

**8.4 Will my information [and/or type of biospecimens] be used for future research or shared with others?**

**[If the study is not NIH-funded, use the following instructions to complete section 8.4:]**

The Common Rule requires that investigators tell participants whether their data will be stored and shared for future research, even if de-identified.

We may use or share your research information [and/or type of biospecimen] for future research studies. If we share your information [and/or type of biospecimen] with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

If you plan to retain and share identifiable information or biospecimens for unspecified future research, state: We would like to share your identifiable information or [type of biospecimen] with other researchers for future research. We will ask for your consent to do so at the end of this consent document. You can be a part of this current research project without agreeing to this future use of your identifiable information [or type of biospecimen].

**or**  We will not store or share your research information or biospecimens with other researchers. The IRB does not recommend the use of this statement, as it will preclude the secondary use of these data/biospecimens in the future.

**[If the study is NIH-funded, use the following instructions to complete section 8.4:]**

The National Institutes of Health (NIH)’s Data Management and Sharing (DMS) policy, which took effect in January 2023, requires researchers receiving NIH funding to develop plans for making research data available to other researchers, in accordance with criteria and definitions outlined in the policy, which can be viewed here.

NIH’s policy does not forbid what it refers to as the “open sharing” of data, meaning utilization of sharing mechanisms that are publicly available without securing special authorization from the data’s holders. Open sharing is permitted provided that it occur “in ways that are consistent with consent practices [this includes compliance with all federal and institutional consent requirements], established norms, and applicable law” and “as long as participants are appropriately informed and prospectively agree to them.”

Select where indicated the statement that reflects whether you plan to make data available through open access or plan to use sharing mechanisms that require special authorization before data are shared. Likewise, select the appropriate statement, where indicated, that reflects whether data sharing is a necessary condition of study participation or an optional component that subjects may choose not to allow.

If your research receives NIH funding and the accepted funding proposal includes a DMS plan, insert the following:

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it’s possible that unauthorized people might gain access to your information.

Select the statement that reflects the identifiability of data according to your NIH sharing plan:

[IF DATA WILL BE CODED] We will assign your information a random code, rather than your name or any other details that others could use to identify you, before sharing it with other researchers. [PARTY IN POSSESSION OF CODE KEY] will securely store the code key that links your coded information to you.

[IF DATA WILL BE DEIDENTIFIED] We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

[IF DATA WILL BE FULLY IDENTIFIABLE, THE STUDY TEAM SHOULD CONTACT THE IRB-HSBS OFFICE FOR GUIDANCE AS TO CONTENT.]

Select the statement that reflects your NIH data sharing plan:

[Controlled access plan] Researchers who wish to access your information must obtain permission to access your information.

[Open access plan] Your information will be openly available to the general public. Researchers who wish to access and use your information in their studies will not be required to obtain permission.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

Select the paragraph that reflects your NIH data sharing plan:

[Optional data sharing plan] You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information near the end of this document.

[Nonoptional data sharing plan] Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your information with other researchers, you should not take part in this study.

**8.4.1 Special Requirements (Delete this section if not applicable).**

**If your project is NIH-funded and meets the definition of an NIH clinical trial, include the following required language:** A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by the National Institutes of Health (NIH). 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 you will register your project on ClinicalTrials.gov voluntarily or in order to meet journal or other requirements, include the following:** This trial will be registered and may report results on [www.clinicaltrials.gov](file:///%5C%5Cisss-users.m.storage.umich.edu%5Cisss-users%5Chomefolders%5Ccshindle%5Cdocuments%5CInformed%20Consent%5Cwww.clinicaltrials.gov). This site 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.

**For NIH-funded research covered under the NIH Genomic Data Sharing Policy, include the following language:**

As part of this study, we will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

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

We will submit your genomic information to a repository [managed by the University of Michigan/federal government/external sponsor] to be used for scientific purposes. A repository contains information from many people.

[OPTIONAL, IF APPLICABLE:] Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different (NIH, GWAS, etc.).

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

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

[Select one of the following:]

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

[UNRESTRICTED access to individual-level data] Researchers will have *unrestricted access* to your specific genomic information. Unrestricted access means that researchers may obtain genomic information from the repository without special approval from NIH.

[Include the following statement if genomic summary (e.g., aggregate) results will have unrestricted access:]

Summarized information about you and others may be shared in scientific literature or made publicly available. This summarized information does not contain individual-level information about specific people, but summarizes information about a group of people.]

**For non-NIH funded projects that will contribute genomic data to a repository, use the following language:**

We will submit your genomic information to a repository. The repository contains information about many people. We will label your information with a code, instead of your name or other information that could be used to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic or racial group or people having a particular disease), or less likely, you personally. [Add additional information regarding data protections provided by the repository.]

If we put your genomic information into the repository, you can change your mind later and ask us to remove it. We will not be able to take back information that researchers have already obtained from the repository.

**For projects that will contribute research data (other than genomic data) to a repository, use the following language:**

We will put the information we collect from you into a repository. The repository contains information about many people. Your information will be [de-identified –or- labeled with a code, instead of your name or other information that could be used to directly identify you.] Add additional information regarding data protections provided by the repository.

**9. Contact Information**

**Who can I contact about this study?**

Please contact the researchers listed below to:

* Obtain more information about the study
* Ask a question about the study procedures
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Leave the study before it is finished
* Express a concern about the study

**Principal Investigator:**

**Email:**

**Phone:**

**Faculty Advisor (for student projects; delete if does not apply):**

**Email:**

**Phone:**

**Study Coordinator (if applicable; delete if does not apply):**

**Email:**

**Phone**:

**For international studies,** include the US Country Code for the phone numbers above. Include the name, email, and phone number for the local collaborator, if any.

**If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:**

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144

Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933 For International Studies, include the appropriate [calling codes](http://www.countrycodes.com/international-dialing-codes.php).
Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

**For international studies,** include the US Country Code for the IRB-HSBS phone number. For projects reviewed by an in-country IRB or ethics committee, include contact information for that organization and place it before the IRB-HSBS contact information.

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

**10. Your Consent**

**Consent/Assent to Participate in the Research Study**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For projects obtaining written consent, investigators are reminded that they should give a copy to the participant and retain a full copy of the consent including a copy of the signature page as part of your research records. Participants must complete all of the required information (printed name, signature and date).

**Parent or Legally Authorized Representative Permission (delete this section if it does not apply)**

By signing this document, you are agreeing to [your child’s] **or** [the person’s named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child]* ***or*** *[the person named below] to take part in this study.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Participant Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Parent/Legally Authorized Representative Name

Relationship to participant: Parent Spouse Child Sibling Legal guardian Other

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Parent/Legally Authorized Representative Name (when two parent signatures are required) Two signatures are required for more than minimal risk research with no direct benefit to the child.

Relationship to participant: Parent Sibling Legal guardian Other

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

*Reason second parent permission was not collected:*

 Parent is unknown

 Parent is deceased

 Parent is incompetent

 Only one parent has legal responsibility for care and custody

 Parent is not reasonably available\*; explain:

*\* Note: “Not reasonably available” means the other parent cannot to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

**11. Optional Consent**

Separate signatures should be obtained for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent document. Some common optional research activities are included below. Delete this section or any of the following consent statements that do not apply to your research. Participants must complete all of the required information (printed name, signature and date) if an optional consent section is offered.

**Consent to use video recordings/audio recordings/photography for purposes of this research. (Use this ONLY if recording is not required to participate in the research.)**

This study involves [video recordings/audio recordings/photography]. If you do not agree to be [video recorded/audio recorded/ photographed], you can still take part in the study.

\_\_\_\_\_ Yes, I agree to be [video recorded/audio recorded/photographed].

\_\_\_\_\_ No, I do not agree to be [video recorded/audio recorded/photographed].

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent to use of [video recordings/audio recordings/photographs] for publications, presentations or for educational purposes.**

I give permission for [audio recordings/video recordings/photographs] made of me as part the research to be used in publications, presentations or for educational purposes.

\_\_\_\_\_ Yes,

\_\_\_\_\_ No

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent to use and/or share your identifiable information and [type of biospecimen] for future research**

The researcher(s) would like to use or share your identifiable biospecimens [and information, including genomic information] for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research. We may also share your [type of biospecimen and/or] information with other researchers. You can contact us at any time to ask us to remove your information [and/or type of biospecimen]. However, once we have shared this information [and/or type of biospecimen] with other researchers, we will not be able to get it back.

If biospecimens could be used for commercial profit, include: The [type of biospecimen] collected from you and used by U-M or shared with other researchers may be used to develop products, such as tests, drugs or medical devices that could be sold in the future by researchers, their organizations or by companies. You will not have any rights to these products or financial benefits from them.

Note: This separate consent is not necessary if you will only store and share de-identified data or biospecimens.

\_\_\_\_\_ Yes, I agree to let the researcher(s) keep and share my personally identifiable information [and type of biospecimen] for future research.

\_\_\_\_\_ No, I do not agree to let the researcher(s) keep and share my personally identifiable information [and type of biospecimen] for future research.

Print Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent to be Contacted for Participation in Future Research**

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

\_\_\_\_\_ Yes, I agree for the researchers to contact me for future research projects.

\_\_\_\_\_ No, I do not agree for the researchers to contact me for future research projects.

**Include this HIPAA Authorization form if your research project requires access to or disclosure of identifiable Protected Health Information from a HIPAA covered entity as part of the research**

**HIPAA Authorization**

**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for this research study.

The health information to be used for this research includes: [Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

The health information listed above may be used by and/or disclosed (released) to: [Name or class of persons involved in the research; i.e., researchers and their staff].

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity(ies)] has/have already acted based on this Authorization. To revoke this Authorization, you must write to: [name of the covered entity(ies) and contact information].

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of participant orparticipant's personal representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Printed name of participant or participant's personal representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ If applicable, a description of the personal representative's authority to sign for the participant  |