*[This template is designed to help you create a consent document in accordance with current NIH Certificate of Confidentiality policy to facilitate obtaining fully informed consent from human research participants.*

**Key Information for {Project Title}:**

 *[Before the subject reads the rest of the consent form, they should be given the opportunity to read the study’s key information section. This section should include a brief but concise description of study elements crucial to the subject’s decision to be in the study. There are five key elements that need to be considered: 1. Consent is being sought for research purposes and that participation is voluntary; 2. the purpose of the research, the expected duration of the subject’s participation, and the research procedures; 3. a list of reasonably foreseeable risks and/or discomforts to the prospective subject; 4. Listing direct benefits to the subject (if any) and the scientific/social benefits of the study; and 5. Alternative procedures or courses of treatment, if any, that may be advantageous to the prospective subject.]*

**What Am I Being Asked To Do?**

[*This section is required.* *Briefly state that subjects are being asked to be in a research study and that their participation is voluntary.]*

* [Example Language:] “You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation of voluntary. As you read, please feel free to ask any questions you may have about the research.”

**What Is This Study About and What Procedures Will You be Asked to Follow?**

*[This section is required. Briefly describe the purpose and procedures of the study in lay terms.]*

* [Example language:] “The purpose of this study is to see if white blood cell counts change after a dose of Aspirin is given. First, we will intravenously draw 10 ml of blood from your arm. Then we will administer to you one 25 mg dose of aspirin via mouth. 30 minutes afterward, we will draw another 10 ml of blood from your other arm. Your participation in this study is expected to last no more than 1 hour.”

**Are There Any Risks or Discomforts you Might Experience by Being in this Study?**

*[This section is required. Briefly describe any risks or discomforts that subjects may experience, as well as the probability of said risks and/or discomforts, as a result of this study.]*

* [Example language:] “Common risks of drawing blood from your arm include discomfort at the site of puncture, possible bruising, redness, swelling, or feeling light-headed. There is also a chance you might get an infection at the site of puncture, however, this is rare. Aspirin is generally well tolerate, however, in very rare cases in can cause stroke or Gastrointestinal bleeding. If you have an allergy to Aspirin or have a history of adverse effects while taking aspirin, you should not be in this study.”

**What Are the Reasons You Might Want to Volunteer For This Study?**

*[This section is required. Briefly describe any direct personal benefits there may be to the subject, and also how this study might benefit the scientific field/society.]*

* [Example language:] “You are not likely to benefit in any way from joining this study. However, your participation in this study may assist researchers in understanding how over-the-counter pain-relievers, like Aspirin, affect the immune system.

As compensation for your time, we are offering a $5 Amazon gift card. You will be given the gist card even if you decide to leave the study early.”

**Do You Have to Take Part in the This Study?**

*[This section is required. Briefly state that the subject is not required to participate in the study and any alternative procedures or courses of treatment, if applicable.]*

[Example Language:] “It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.”

 *[This template is designed to help you create a consent document to facilitate obtaining fully informed consent from human research participants for studies at the GSU/GT Joint Center for Advanced Brain Imaging. Federal regulations specify the several required elements of consent; those required items, indicated throughout this template, must be included in the consent document before the IRB can issue approval. Regardless, you should edit the template language so that it fits your research needs.*

*Note that the average person reads at the 8th grade level, so prepare this document accordingly. Investigators are encouraged to use computer software applications or other techniques to assess reading level of the finished document; use a large font (at least 12 point); use short, simple sentences and avoid technical language; define all abbreviations and acronyms when they first appear in text; write the document in second person as though you are verbally giving instruction; and follow the format, including headings, given below.*

*Instructions are included in brackets, and examples are bulleted in some sections. Please remove all bracketed instructions and quote examples before submitting the consent form for IRB review].*

**Consent Document for Enrolling**

**Adult Participants in a Research Study**

**at the**

**Georgia State University / Georgia Institute of Technology**

**Joint Center for Advanced Brain Imaging**

**831 Marietta Street**

**Atlanta, GA 30318**

*[In the state of Georgia, persons 18 years and older are considered adults].*

Project Title:

Investigators: *[List the Principal Investigator (John Doe, Ph.D.)]*

Address: *[PI’s University and Department Name]*

Telephone: *[contact telephone]*

**Introduction:**

You are being asked to be a volunteer in a research study.

*[The word* RESEARCH *is required. Protocols proposing experimental medical treatments or that pose greater than minimal risk to participants must include the following two sentences*: “You are encouraged to take your time in making your decision. Discuss this study with your friends and family.” *Do not include these two sentences in minimal risk studies.]*

**Purpose:**

*[This section is required. Give a brief description of the background and purpose of the study. Include an estimate of the number of subjects expected to participate.]*

*[An example of a Purpose Statement follows:]* “The purpose of this study is to identify which regions of the brain are involved in memory and thought, and to compare how those regions of the brain interact when tasked. We expect to enroll 24 people in this study.”

**Exclusion/Inclusion Criteria:**

*[This section is required.* *It must also address any scientifically justified exclusion/inclusion criteria that limit participation to certain categories of subjects. NOTE that the Center for Advanced Brain Imaging requires that researchers also utilize the CABI screening forms].*

Subjects may experience nausea if they have certain conditions such as migraines, vertigo, anxiety or stress, fatigue, pregnancy, food poisoning or digestive disorders, fibromyalgia, concussion or brain injury, appendicitis, kidney or liver disorders, central nervous system disorders, brain tumors, some forms of cancer, or other illnesses.  If you are currently experiencing nausea for any reason, you should not have an fMRI scan until your nausea has subsided.

It may not be safe for people with certain metals in their bodies or with certain medical conditions to undergo MRI, which uses a very strong magnet. The researchers will ask you to review a list of conditions and tell them if any apply to you. If you have any of the following, you will be excluded from this study for your own safety: Cardiac pacemaker; hearing aid; any other implant metal in your body or eyes, including pins, screws, shrapnel, plates, braces on your teeth, or dentures; Parkinson’s; Alzheimer’s or other dementia; sickle cell anemia; epilepsy; bipolar disorder; multiple sclerosis; or brain surgery.

If you have tattoos, you could experience some irritation and redness at those sites.  Tattoos on the head, such as eye liner or other permanent makeup, may make it impossible to get clear and usable images.  If you have tattoos or permanent makeup of any type, you should inform the researchers.

*[Be sure to mention any other exclusionary and inclusion criteria in this section.]*

**Procedures:**

*[This section is required and must include a description of all research procedures; the frequency, scheduling and time commitment of each procedure and visit; and the total time commitment. It should be written like a set of instructions for human subjects to comprehend what they are being asked to do. Audio- and video-taping should be briefly addressed in this section; see MODEL RELEASE guidance later in this template.]*

*[If participants are being randomly assigned to different groups, this should be disclosed with a statement such as* "You will be randomly (by chance, like flipping a coin) assigned to one of…."]

*[An example of a procedures statement follows:]* “If you decide to be in this study, your part will involve one visit which will take about three hours. You will review the screening questionnaire and complete the health screening form. We will discuss the study, and you may ask all the questions you have. After giving your consent, you will be asked to lie down on a platform that can be slid into the center of the magnet.  An MRI imaging coil made of plastic will be placed around your head.  The coil will not touch your head, and foam pads will be placed around your head to limit movement during the scan.  You will then be slid into the magnet. You will be asked to lie still. You will be asked to listen to music through headphones we will provide. We will ask whether the music provokes happy memories or other types of memories. You will give verbal responses or pressing a button you will hold with your hand. The scan will take about 60-90 minutes. You will be given specific instructions at the start of each new task.  Tell the researcher if you want to quit the study or just need a few minutes break.”

**Risks or Discomforts:**

*[This section is required and must disclose any reasonably foreseeable risks and discomforts that a participant may experience. Risks and discomforts should be grouped according to probability of occurrence, whether rare or common. If there are special risks to pregnant or nursing women, women of childbearing potential, or to fetuses, these should be disclosed in* ***bold print****, with special instructions regarding need for acceptable birth control. Similar disclosure should be made for studies in which effects on sperm are possible.]*

[*If women of childbearing potential will be enrolled, and if there are no other known risks to them or their possible fetuses, the following statement is required:*] “For women of childbearing potential, there are no known cases of a fetus being harmed by MRI procedures.”

*[The following five paragraphs are required language for MRI scans done at CABI****.]***

* “This MRI is done for research purposes only. The MRI scan being done is designed to answer research questions, not to medically examine your brain. The MRI scan is not a substitute for one a physician would order. It may not show problems that would be picked up by a medical MRI scan. None of the researchers are medically qualified radiologists. However, if we see something unusual in your scan, your scan may be referred to a radiologist and you may be informed by the research group if follow up with your physician is suggested. Any follow-up evaluation or treatment that you seek will be at your own expense. Even if your physician rules out any problems, you may be unnecessarily worried if a problem is suspected.
* The following risks or discomforts may occur as a result of your participation in this study. The energy levels used to make MRI measurements are far less than those used in a single X-ray. While MRI is painless and there are no significant risks from MRI as it is to be performed, participation may mean some added discomfort for you. In particular, you may be bothered by the beeping and hammering sounds made by the scanner as it collects measurements. Disposable earplugs will be provided to diminish the noise. The magnet is a small enclosure. Despite the use of an “open” head-coil, some people become claustrophobic inside it. You may also experience mild numbness or tingling in your fingers and toes. This feeling is similar to the feeling you get when your arm has fallen asleep – not the painful needling feeling, but the numb tingling you feel afterward. Again, you are free to quit the experiment at any time you choose.
* The room may be cold. You may ask for a blanket. You may become tired or bored from lying in the scanner. Some people feel nervous or claustrophobic while lying in the scanner. You may ask to leave the scanner at any time.
* Because the MRI scanner attracts certain metals, it could move metallic objects within the MRI room during your examination, which could possibly harm you. Precautions have been made to prevent such an event from happening.
* Further, because of the high magnetic field, people with pacemakers, heart rhythm disturbances, or certain metallic implants in their body cannot participate in this study. You will be screened for these conditions.”

**Benefits:**

*[This section is required and must include a description of any benefits expected for the participants or for society. It is okay NOT to expect the participant to benefit; in such a case, you should describe possible eventual benefits of this research to society. Note that compensation is not a benefit of being in the study.]*

*[An example of a Benefits Statement follows:]* “You are not likely to benefit in any way from joining this study. We hope that what we learn will help us to improve treatment for people with X.”

**Compensation to You:**

*[This section is required even if there is no compensation. If there is no compensation at all, this fact should simply be disclosed. This section should specify participant compensation and reimbursement, whether monetary, gift card, or class credit.* ***Be sure to review the tax language at the end of this section.*** *Compensation should**be prorated in cases where participants may make several trips or go through a number of sessions. It is generally inappropriate to pay bonuses for completion or to withhold payment until the study is completed. You should disclose that full compensation will not be given to those who withdraw early or do not complete the study, if that is the case. In studies such as this example, the IRB recommends that full compensation be given when participants must stop due to a physical inability to complete the study. For example, if the test boot causes irritation, the participant should be compensated for his/her time and effort anyway.]*

*[Protocols for Class Credit: Class credit may be offered for participation in some studies which enroll Georgia Tech students. In these cases, students should be given other options for fulfilling the research component that are comparable in terms of time, effort, and educational benefit. To fulfill the research component, students could participate in another research study, write a brief research paper, or attend faculty research colloquia. The paper should not be graded, and students who attend the colloquia should only have to attend. If students do elect to participate in research studies, they should be given several studies from which to choose.]*

* *[An example of a Compensation to You Statement follows:]* “You will be compensated $20 per hour for your time and effort. You will make two visits to the laboratory, for one hour each time, so your total compensation is $40. If you do not come for the second visit, you will be compensated a prorated amount. For example, if you complete the first visit, you will receive $20. If you do not come for the second session, you will receive no additional compensation.”
* *[An example of a Compensation to You Statement when class credit is being offered follows:]* “Instead of monetary compensation, Georgia Tech students will receive 1.0 Sona credits for each hour of participation.”
* *[An example of a Compensation to You Statement when there will be no compensation follows:]* “There is no compensation for participation.”
* *[The statement in quotes below is required when monetary compensation will be provided. Note that if U.S. tax residents receive $600 or more per calendar year, a 1099-misc will be issued. At that point, researchers need to collect tax reporting information from those human subjects. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required.]*

“U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.”

**Storing and Sharing and Future Use of Your Information:**

*[This section is required if researchers wish to retain images/data for future research use. During the consent process, researchers are**encouraged to consider whether**they should also obtain consent at this time to utilize subjects’ data/images/recordings in future, unspecified research. (If you intend to build a repository, please see the separate guidance in the IRB Policies and Procedures Manual). Several suggested statements are provided below; you should include and edit as needed to fit your purposes.*

* *An example of a consent statement for future, unspecified research use of subjects’ data follows: “Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.”*

*[Protocols Using, Analyzing, and/or Storing Human Genetic Information: NIH-funded genomic studies are required 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 (January 25, 2015). See http://gds.nih.gov/ for more information].*

* *[An example of a Human Genetic Storing and Sharing Statement follows:]* “Your samples, genomic data and health information will be stored and shared with other researchers. 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.”

*[Protocols Storing and Sharing Human Biological Samples and/or Data: This section is required for studies that plan on storing and sharing samples and/or data for future research use See also the IRB Policies & Procedures Manual for additional guidance on storing biological specimens and on establishing a repository). The following section should describe what samples/data are being stored, who will have access to it, how long it will be stored, how it might be used in future research (keep broad if unclear), if subjects will be contacted in the future, what will happen if participation status changes, if subjects will be contacted in the future, what will happen if participation status changes, and what will happen if the storage protocol closes].*

*[An example of a Human Biological Storing and Sharing Statement follows:*  “Your blood samples will be stored and shared with other researchers. Your blood will be stored in a controlled access biobank. 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. (If using a public database: Your blood will be stored in an unrestricted access biobank. This means that the information from this study will be freely available in a public, unrestricted database that anyone can use.) As such, the use of your samples in future research (even of identifier are removed) may be used for commercial profit. However, you will not receive any future profits if the research results in products that are eventually developed and sold for commercial purposes. Your blood will only be used to further research specifics in HIV/AIDS. We may contact you with any new information regarding the sample and its relation to any abnormalities. If you withdraw from this study, we will destroy your sample. Furthermore, if this study closes, your sample will be destroyed.

* *[This section is required for protocols where biospecimens will be collected and will (or might) include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen. The following section should include a clear statement as to whether the subject’s collected biological samples will undergo genome sequencing. If so, clearly and briefly describe what genome is, and what it will be used for (if known) (e.g. establishing cell lines):*
	+ *[Example language:]* The tissue we collect from you can provide us with a lot of information. One of the ways we may use your tissue is by using your samples for Whole Genome Sequencing. Whole Genomic Sequencing is a process in which researchers can look at, or “read”, each part of your DNA all at one time. By doing this, researchers may use this information 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. Your cells [will/may] be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.
* These the cell lines and other samples may be stored 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.]”

**Use of Photographs, Audio, or Video Recordings:**

*[This section is required if you are collecting photographs, audio, or video recordings. Specifically address who has access to these, how they are stored, for what purposes they will be used, and what happens to them once the study ends. Disclose whether recordings are erased after all the necessary information is collected from them and whether they are kept for archival purposes.*

* *[An example of using photographs, audio, or video recordings in public presentations statement follows:]* “We may want to use some of the photographs, audio, or video recordings of you in public presentations related to the research. We will not use any videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.”

**Confidentiality:**

*[****This section is required*** *and should describe the extent, if any, to which confidentiality of records identifying the participant will be maintained.]*

* *[This example of a confidentiality statement is offered for your consideration. However, researchers should use language that accurately reflects the extent to which confidentiality can be assured. The IRB also recommends that researchers consider asking human subjects to allow their de-identified images/data to be stored and shared for future unspecified research purposes.]*

“The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. We will take measures to protect your privacy and the security of all your personal information. Your name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team for the duration of the study. All of the information we collect about you will be coded with a unique research subject identifier (URSI) and will be kept on password protected computers and stored securely in restricted and protected databases according to CABI information security policies. At the end of the study, the record linking your name and other identifying information to your URSI (which the study data is labeled with) will be made unavailable to the research team; however, it will be kept indefinitely (forever) at CABI in a confidential manner so that you may continue to have access to your MRI information. Data from this study that does not contain any identifiers may be presented at meetings, published in journals/books, used in classrooms for training/teaching purposes, and may be used and shared with other researchers for future research purposes, which includes scientists at other universities and institutions. However, your name and other identifying information will not be used in any published reports about this study. **(If you do not want to store and share data and/or bio-specimens for future research:)** Even if all identifiers have been removed from your data and/or bio-specimens, your data will not be used or distributed for the purposes of future research. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records. The Office of Human Research Protections may also look over study records during required reviews. **(If your study is regulated by the FDA, then use in place of the previous sentence)** The Office of Human Research Protection and/or the Food and Drug Administration may also look over study records during required reviews. The sponsor of this study, National Institutes of Health *[sponsor]*, has the right to review study records as well.

*[When confidentiality of participant identity is not proposed, such as when participants will be quoted by name, this section should be very clear regarding where and how the quotes will be used. Participants should also have the opportunity to review the text in which their quotes or identities appear to ensure proper attribution.]*

**Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant’s identifiable or sensitive information (data and/or biospecimens):**

*[Information in italics for Investigator information only. Please delete italicized information when producing consent document.*

*This section is required of protocols funded by NIH in whole or in part of. Effective 10/1/17: This NIH Policy applies to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information. The term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research.*

*The Investigator shall not:*

*Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or*

*Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.*

*Disclosure is permitted only when:*

*Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;*

*Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;*

*Made with the consent of the individual to whom the information, document, or biospecimen pertains; or*

*Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.*

*Recipients conducting NIH supported research applicable to this NIH Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.*

*Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by this Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act.  Recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by this Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.*

*When a Certificate of Confidentiality is issued for a study or will be obtained for a study, the enrolling human subjects must be informed during the consent process about the protections afforded by the certificate and any exceptions to that protection.*

*Information should be included in the informed consent form, such as provided in these examples:*

“We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality 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 the researchers may not use the Certificate to withhold that information.”

*The following language should be included in the consent form if researchers intend to make voluntary disclosures about child abuse, intent to hurt self or others, or other disclosures:*

“The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances.”

**Costs to You:**

*[This section is mandatory and must disclose the cost, if any, that participants will bear as a result of being in this study. If there are no costs, this information should be specified.]*

* *[An example of a Costs to You Statement, when there is no cost to the participant, follows:]* “There are no costs to you, other than your time, for being in this study.”
* *[An example of a Costs to You Statement, when there IS cost to the participant, follows:]* “If you participate in this study, you will be responsible for the cost of the doctor’s visit.”

**Alternative Treatments:**

*[This section is only used when the study involves clinical or medical treatment, and is not needed for social and behavioral studies. If applicable, describe other medical treatments or procedures available if the person chooses not to participate or later withdraws from the study.]*

1. *[An example of an Alternative Treatments Statement follows*:] “If you do not participate in this study, the only alternative is to continue with your current program of medical treatment. If you withdraw from the study, you must consult your personal physician regarding ….”

**If this is a Clinical Trial, this section is required:**

*[Per 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:*

*“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”*

*Additional guidance, including the definition of applicable clinical trials, may be found at* [*https://researchintegrity.gatech.edu/clinical-trials*](https://researchintegrity.gatech.edu/clinical-trials)*..]*

**Clinically Relevant Information:**

[*This section is required if the study team is conducting clinical research and is collecting information, biospecimens, genetic data, etc. that could result in findings that may be clinically relevant to the subjects. In this section, please include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*

* (Example language for not disclosing clinically relevant information:] “As a part of this study, we will be collecting blood samples from you and running genetic tests. However, it is important for you to know that these result will not be disclosed to you under any circumstances, even if the results prove to be clinically relevant. If you are concerned about your health, we recommend you contact your personal healthcare giver.

(Example language for disclosing clinically relevant information:] “As a part of this study, we will be collecting blood samples from you and running genetic tests. It is important for you to know that results may uncover something of clinical importance. If we discover something that could be of clinical importance to you, we will invite you in for a meeting and debrief you of what we found. However, after this, the responsibility will be yours to follow-up with your healthcare giver and pursue future medical care.

**Conflict of Interest:**

*[This section is required if the Principal Investigator or anyone else on the research team has a conflict of interest in this study.  Such conflicts must be disclosed to the faculty member’s department, and an approved management plan must be on file with the Office of Conflict of Interest.  When COI disclosure is required for consent documents, the Office of Conflict of Interest Management will provide such language].*

**Questions about the Study:**

*[This section is required.]*

*[An example of a Questions about the Study Statement follows:]* “If you have any questions about the study, you may contact Dr. P. Investigator at telephone (XXX) XXX-XXXX) or Principal.Investigator@dept.gatech.edu.”

**In Case of Injury/Harm:**

*[This section is required for studies posing greater than minimal risk. The Principal Investigator, not a student researcher, must be named as the point of contact. If the study is taking place in another country, include the PI’s email address and telephone number, including international dialing information.]*

*[An example of an In Case of Injury/Harm Statement follows:]* “If you are injured as a result of being in this study, please contact Principal Investigator, Ph.D., at telephone (XXX) XXX-XXXX. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.”

**Questions about Your Rights as a Research Participant:**

*[This section is required]*

If you have any questions about your rights as a research participant, you may contact the Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

**Participant Rights:**

*[This section is required and must include the following language:]*

* Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
* You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
* Any new information that may make you change your mind about being in this study will be given to you.
* You will be given a copy of this consent form to keep.
* You do not waive any of your legal rights by signing this consent form.

*[Finally, include the following signature language. If this study is clinical, participants must write in the date AND TIME of their signature. If you are using electronic signatures, verbal consent, or electronic consent, please see the instructions at the end of the document.]*

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

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

Participant Name (printed)

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

Participant Signature or Date / Time

Legally Authorized Representative

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

Person Obtaining Consent (printed)

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Signature of Person Obtaining Consent Date

**Consent to Store and Share your Information:**

*[Insert signature line with clear options for subjects to agree or decline.]*

*“I agree that my de-identified information/data/scans may be stored and shared for future, unspecified research.*

*SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*I do not allow my de-identified information/data/scans to be stored and shared for future, unspecified research. These may only be used for this specific study.*

*SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”*

*[ELECTRONIC SIGNATURES: If the consent process will take place online and you intend to obtain electronic signatures, then a Waiver of Documentation is not needed. You will need to keep the signature section in this document and state in your IRB Wise submission what software will be used to obtain the electronic signature. Currently, only DocuSign is approved by OIT to obtain electronic signatures. Additionally, please state in the IRB Wise submission which survey software will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

*[CONSENT WITHOUT SIGNATURES: If the consent process will take place online or verbally and the study qualifies for a Waiver of Documentation of Consent; you may simply remove the signature section and replace that language with either “Agree” and “Disagree” buttons or the following statement listed below. Additionally, please state in the IRB Wise submission which survey software or teleconference tool will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

* “By completing the online survey, you indicate your consent to be in the study.”

*[Before uploading the consent document, be sure to delete all of the bracketed instruction language from the document. Consent documents will be returned without review if instruction language is not removed.]*