# Informed Consent to Participate in Research Involving Minimal Risk

# *[If applicable:]* and Authorization to Collect, Use and Share Your Health Information

Information to Consider Before Taking Part in this Research Study

**Title:** ***[Title of study, as it appears on the IRB application, grant/contract, or sponsored protocol. Best to bold title so it is more visible.]***

*[****Red*** *or italicized text is considered help text or identifies areas that require study specific information. Optional language that can be removed if not applicable to your study are noted in* ***other colors****. Remove all instructions in italics and color all text black so that they are not contained in the final version of your consent.]*

**Study # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***[For minimal risk research, the key information (the “Overview” herein) may comprise the majority of the consent document. Information in the Overview does not have to be reiterated in the sections below the Overview.]***

**Overview:** You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by *[insert name of PI]* who is a *[list PI’s role]* at/in *[list name of PI’s employer].* This person is called the Principal Investigator. *[The following sentence should be included if there is a faculty advisor involved] [He/She]* is being guided in this research by *[insert name of faculty advisor]*. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at *[insert location at which research will be conducted]* and is supported/sponsored by *[insert name of sponsor].* The purpose of the study is to *[insert brief summary of purpose]. Briefly explain in a few sentences, in lay language (understandable at a 7th grade reading level), the purpose of the study and the expected duration of the prospective subject’s participation. Example: The purpose of this study is to find out.... Tell the person, in lay terms, how the research will be carried out and whether the research includes a one-hour interview, a two-hour focus group, a 20-minute questionnaire, a 90-minute lab session in which you will solve complex puzzles, etc.*

Subjects: You are being asked to take part because *[explain in lay language the condition(s) or situation that makes the prospective subject eligible for the research. Example: We are asking you to take part in this study because you have anxiety. We want to see how this behavioral intervention helps people with anxiety.]*.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.]*. *[If extra credit is offered for participation, please state that an alternative assignment will be offered to students as a non-research alternative involving comparable time and effort to that which is involved in the research.*

*If subjects are employees, include as applicable:* Your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities*. If subjects are students, include as applicable:* Your decision to participate or not to participate will not affect your student status, course grade, recommendations, or access to future courses or training opportunities.*]*

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. [*If applicable:* There is no cost to participate.] You *[will /will not]* be compensated *[enter amount if compensated]* for your participation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

**Why are you being asked to take part?**

# *[Include additional information regarding the purpose of the study and why subjects are being asked to take part beyond what is included in the Overview section.]*

# Study Procedures:

*Explain in lay terms what will happen during the study. Make sure your explanation addresses what is being performed as standard of care and what is being performed strictly as part of the research. Explain what may happen at each study visit and at what intervals study visits will occur. Explain the study visit timetable – you may want to complement this description with a table or timeline*. *Explain what the subject will need to do before the first study visit, if anything.*At each visit, you will be asked to:

* *Describe the tests and procedures that will need to be performed, including the purpose of each. If there are multiple visits with different procedures occurring at each visit, it is suggested to list each in a separate paragraph and/or as bulleted items.*
* *Explain the questions that will be asked and/or interviews/surveys that may be conducted.*
* *If audio- or videotaping will be used, the subject must be informed of taping and, if applicable, given the option to agree to the recording. Explain who will have access to these tapes, whether the information will be identifiable, how long the tapes will be maintained, (noting our policy is 5 years after the Final Report is submitted to the IRB) and when the time comes, when and how they will be destroyed*.

# Total Number of Subjects

About *[number of subjects]* individuals will take part in this study at MGS. [*If the study includes multiple sites, add the following statement:* A total of *[number of subjevts]* individuals will participate in the study at all sites.]

# Alternatives / Voluntary Participation / Withdrawal

*[Use whichever statement is applicable:]*

You do not have to participate in this research study. *[This statement is sufficient if there are no alternatives for the subject.]*

*[Or]*

Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.]*You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. *[If subjects are students or employees, include as applicable: decision to participate or not to participate will not affect your student status (course grade) or job status.]*

# Benefits

*[Use whichever statement is applicable:]*

You will receive no benefit(s) by participating in this research study.

*[Or]*

We are unsure if you will receive any benefits by taking part in this research study.

*[Or]*

The potential benefits of participating in this research study include:

*[List and explain any anticipated benefits the person may have from taking part in this study. Please note that compensation for participation IS NOT considered a benefit.]*

# Risks or Discomfort

*[Use whichever statement is applicable:]*

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

 *[Or]*

The following risks may occur:

* *List and explain the physical, psychological, and social risks/discomforts and when known, indicate the relative chances of occurrence for each.*
* *When applicable, explain any risks that might be associated with a breach of confidentiality, including risks to employability, insurability, and/or criminal and civil liabilities.*

# Compensation

*[If compensation for participation is available, include the dollar amount per visit and payment upon study completion of study activities. Please note raffles/random drawings of chance is not permitted.]*

You will be compensated *[enter amount]* if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be compensated *[enter $ amount here]* for each study visit you complete.

*[MGS investigators must include the following for studies where compensation is more than $75 per payment or $300 per calendar year:]*

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

##### *[If subjects are faculty/staff of MGS who will be compensated please include the following language:]*

If you do not want to complete the tax payer ID form you can still participate in the study, however if the form is not completed you will not be compensated.

##### *[If no payment for participation is available, include the following:]*

You will receive no payment or other compensation for taking part in this study.

*[If commercial development is expected to arise from the study, include the following:]*

The findings from this research, which may include your biospecimens (even if identifiers are removed), may result in and be used for the future development of products that are of commercial value and/or profit. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

# Costs

*[Use only the following statements that apply to your research]*

It *[will / will not]* cost you *[amount / anything]* to take part in the study.

*[If the costs of the research are being paid by the study sponsor the following statement is required:]*

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

*[If there are costs associated with the study:]*

You or your insurance company will be expected to pay the costs for the following: *[list all procedures which will be the responsibility of the subject outside of routine care.]*

# Conflict of Interest Statement

*[Include the language outlined in your COI Management Plan.]*

# Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

* The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff. *[Modify to match your study. Do not list the actual names of individuals, just their job class.]*
* Certain government and graduate school people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
* Any agency of the federal, state, or local government that regulates this research. This includes *[List all federal, state, or local agencies/individuals authorized to access records including:* the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).*]*
* The MGS Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in MGS Research Integrity and Compliance.
* *[Include the name the sponsor(s) or others. If not applicable, please delete this item.]*

*[Please include one of the following statements if the research involves the collection of identifiable private information or biospecimens.]*

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative. We will do our best to protect
your data and samples during storage if they are shared. However, there remains a possibility that
someone could identify you. *Or;*

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

*[Use the mandatory statement below if conducting an online survey:]*

If completing an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

 *[For study sites located in the European Union (EU) or studies that will enroll European Union subjects, include the green language in the following five paragraphs through “…with the data supervisory authority in your country.”]*

Data collected for this research will be stored at the *[insert name of MGS study site, e.g. the Alzheimer’s Disease Neuroimaging Initiative Data Coordinating Center]*, located at the University of South Florida in the United States.

***The following information may be used and disclosed to others:***

* Your research records
* All of your past, current or future medical and other health records held by your study site
* Your contact information, including your name, e-mail address and your mailing address
* *[Insert any other personal data that will be collected from EU subjects, including, for example, information about subjects’ ethnic or racial background, sexual history or sexual orientation, or political or religious beliefs.]*

Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: *[Insert appropriate business address.]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by MGS policies.

If you have concerns about the use or storage of your personal information, you have a right to lodge a complaint with the data supervisory authority in your country.

*[If applicable (i.e., for studies involving surveys or interviews in which sexual violence or sexual harassment may be disclosed by a MGS faculty, staff or student), include the following language.]*

A federal law called Title IX protects your right to be free from sexual discrimination, including sexual harassment and sexual violence. MGS’s Title IX policy requires certain MGS employees to report sexual harassment or sexual violence against any MGS employee, student or group, but does not require researchers to report sexual harassment or sexual violence when they learn about it as part of conducting an IRB-approved study. If, as part of this study, you tell us about any sexual harassment or sexual violence that has happened to you, including rape or sexual assault, we are not required to report it to the University. If you have questions about Title IX or MGS’s Title IX policy, please call MGS’s Office of Diversity, Inclusion & Equal Opportunity at (813) 974-4373.
 *[If applicable (i.e., for studies involving focus groups), include the following language.]*

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow subjects and not repeat what is said in the focus group to others.

*[If your research is NIH funded and you are conducting research involving sensitive, identifiable information, you have automatically received a certificate of confidentiality as a part of the terms and conditions of the award and are required to include this language. If your research is not NIH funded and you have applied for a certificate of confidentiality, insert this language as appropriate.]*

To help us protect your privacy, *[we will obtain/we have obtained]* a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the 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 researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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).

You should understand that 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 Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a subject in the research project under certain circumstances. The investigative team will voluntarily comply with Florida Statutes and federal regulations, which may mandate or permit certain disclosures of protected information by the investigative team to appropriate individuals.

*[If this is an NIH funded study, the* [*Data Sharing policy*](https://sharing.nih.gov/data-management-and-sharing-policy) *requires a sharing plan. Add a statement here to indicate how you will share individual subject level data. E.g., “Per NIH’s required data sharing policy, data from this research will be shared with other researchers via an open-source database. This website will not include information that can identify you, but* *no guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this database involves risks similar to a person’s everyday use of the Internet. If you complete this study and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.”]*

*[If this is a clinical trial add:]* A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. 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.

**What if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

*[Please include a statement regarding whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so under what conditions.]*

*[If clinically relevant results will be returned, insert the following:]* We may learn things about you from the study activities that could be important to your health or to your treatment. 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 subjects will be provided research results, and how subjects will be notified.]* The results will not be placed in your medical record. 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.

*[If clinically relevant results will not be returned, insert the following:]* When *[data/biospecimens/images]* are collected and analyzed, there is the chance of finding something unexpected. The results from the *[data/biospecimens/images]* we collect in this research study may not be the same as what you would receive as a part of your regular health care. Because of this, you will not be informed of any unexpected findings. The results of your *[data/biospecimens/images]* will not be placed in your medical record. If you believe you are having symptoms that may require care, you should contact your primary care physician.

# You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call *[name of principal investigator]* at *[telephone #]*. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the MGS IRB at (813) 974-5638or contact by email atRSCH-IRB@MGS.edu. *[Research conducted at MGS Affiliates should insert Affiliate contact information here.]*

# *[The following information can be deleted if you are not part of a covered entity, which must adhere to the HIPAA Privacy Rule Regulations. Otherwise, the following MGS approved authorization language MUST be included in your informed consent document.]*

# Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than MGS who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research *[delete bullets as applicable]*:

* The medical staff that takes care of you and those who are part of this research study;
* Each research site for this study including *[list all sites who will use and share PHI for this research study]*;
* Any laboratories, pharmacies, or others who are part of the approved plan for this study;
* The MGS Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in MGS Research Integrity and Compliance and the MGS Health Office of Clinical Research;

 *[Delete additional bullets as applicable:]*

* All designated review committees such as *[Add all that apply e.g. VA Research Services; etc.]*;
* Data Safety Monitoring Boards or others who monitor the data and safety of the study;
* There may be other people and/or organizations who may be given access to your personal health information, including *[List any other persons, classes of persons, and/or organizations (including Tampa General Hospital, Moffitt Cancer Center, etc.). Do not list persons who are likely to change over the course of the study, instead list them by title or category only.]*

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, MGS may collect, use, and share the following information *[Modify to match what data will be collected and used in your study]:*

* Your research record
* All of your past, current or future medical and other health records held by MGS, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.
* *[List any other needed information not included above. The descriptions should have enough detail that one (or an organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.]*

You can refuse to sign this form.  If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

* You will no longer be a subject in this research study;
* We will stop collecting new information about you;
* We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
* Staff may need to follow-up with you if there is a medical reason to do so.

To revoke your authorization, please write to:

Principal Investigator

For IRB Study # *[Insert your Study #]*

*[Insert complete business mailing address]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by MGS policies.

# Consent to Take Part in Research

# *[If applicable:]* and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study[*If applicable:* and authorize that my health information as agreed above, be collected/disclosed in this study].I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

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Signature of Person Taking Part in Study Date
[*If applicable:* /Authorization]

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Printed Name of Person Taking Part in Study

# Statement of Person Obtaining Informed Consent andResearch Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

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

Signature of Person Obtaining Informed Consent Date

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Printed Name of Person Obtaining Informed Consent