



Originally Issued: September 6, 2016  
Reviewed: January 2019

## **INFORMED CONSENT**

### **Authorization to Participate in Research**

#### **I. Introduction**

You are being asked to participate in a research study that is being facilitated by who is the Principal Investigator (PI) and [Title of PI], from the [College or Department]

This research is studying

[purpose of the study].

You are being asked to participate in this study because [inclusion and exclusion criteria]

{# of participants} people will take part in this study here at Athens State University. [Funder's Name] is funding this study.

This form will not only describe the research study but will also explain any possible risks and/or possible benefits that could occur from your participation. We recommend that you to talk with your family and friends before you decide to participate in this research study. If you have any questions pertaining to this study and/or your participation in this study, please ask one of the study investigators.

#### **II. What will happen if I decide to participate?**

If you agree to participate in this study, the following things will happen:

#### **III. How long will I be in this study?**

Your participation in this study will take a total of \_\_\_\_\_ hours over a period of \_\_\_\_\_ [how long each activity/session will take]

also include about how many participants will be involved in the study.



Originally Issued: September 6, 2016  
Reviewed: January 2019

#### **IV. What are the risks or side effects of participating in this study?**

Describe any risks study, please include any risks to confidentiality. Note: There could be risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participation in any study. Need to add explanation as to whether medical treatments are available, if injury occurs, what they consist of, and where information can be obtained.

#### **V. What are the benefits to being in this study?**

Discuss, in detail, any benefits that the participant might experience from participating in this study. Note: If there are no benefits to participant, simply state: There will be no benefit to you from participating in this study. It is our hope that the information we gain from this study will help [elaborate on how participating in this study would benefit society].

#### **VI. What other choices do I have if I do not want to be in this study?**

Explain other choices participants might have, if any. For example, if offering extra credit in a classroom setting for participating in research, you will need to state what other alternative to participation in the study would be available. (Note, alternative must offer the same amount of extra credit/compensation and be equal to the amount of time a participant would spend on the research study. Some examples are: There are no penalties if you choose not to take part in this study, OR You are not obligated to participate in this study for extra credit and for any reason you do not feel comfortable or do not wish to participate, you can receive the same amount of extra credit by [task].

#### **VII. How will my information be kept confidential?**

We will take necessary measures to protect the security of all of your personal information but cannot guarantee confidentiality of all data within the study. Information that is contained within this study will be used by study staff. The Athens State University Institutional Review Board (IRB) that oversees human subject research and/or other entities may be permitted to access your records. Also, there may be times when we are required by law to share your information but your name will not be used in any published reports about this study. Detail the steps that will be taken to ensure confidentiality (e.g., where data will be stored and transferred, and when data will be de-identified, security of storage (locked filing cabinet, online, etc.)



Originally Issued: September 6, 2016  
Reviewed: January 2019

### **VIII. What are the costs of taking part in this study?**

Describe any and all costs to participants for being involved in this study.

### **IX. Will I be paid for taking part in this study?**

Compensation is considered taxable income so amounts of \$600 or more will need to be reported by Athens State University to the Internal Revenue Service (IRS).

Explain the compensation, if any, that participants would receive. Example statement: For your participation in this study and any inconvenience you experienced, you will be paid [amount] for each visit, for a total of [amount]. For those who have not fully completed the study, you will be paid [amount] for each visit that you completed.

### **X. How will I know if you learn something new that may change my mind about participating?**

Detail the procedures that you will take to inform and update participants that may impact their decision to participate. Example statement: Please be aware that you will be informed of any significant new findings that may become available during the course of this study such as changes in the risks and/or benefits that result from your participation in the research.

### **XI. Can I stop being in the study once I begin?**

Explain that participation in this study is voluntary and the process for participants to withdraw once the study has begun. Include details on how participants can request that their data not be included. Also, include information and/or example of how/why the investigator will withdraw a participant.



Originally Issued: September 6, 2016  
Reviewed: January 2019

**HIPPA Authorization is applicable in this study.**      **Yes**      **No**

**HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)**

As part of this study, we will be collecting your health information and sharing it with others. This information is protected because it is identifiable or connected to you.

**Protected Health Information (PHI)**

You understand that by signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include but not limited to medical history, body mass index, etc.

You are also informed that both researchers, staff at Athens State University, and others listed on this form, may share your health information (re-disclosed) outside of the research study and would no longer be protected by federal privacy laws. Some examples for disclosures would be law enforcement, judicial proceedings, health oversight activities and public health.

**Right to Withdraw Your Authorization**

This authorization you have signed for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used and/or disclosed as long as it is needed for this study but you may withdraw your authorization at any time provided you notify the ASU investigators in writing. Please send a letter notifying the Principal Investigator and the IRB Training Administrator of your withdrawal to:

Click here to insert Principal Investigator Name.  
300 North Beaty Street  
Athens, AL 35611

Click here to insert IRB Administrator Name  
300 North Beaty Street  
Athens, AL 35611

Please be aware that the research team will not be required to retrieve any of your health information or destroy any information that has already been used or shared before your withdrawal is received.



Originally Issued: September 6, 2016  
Reviewed: January 2019

### **Refusal to Sign**

Please understand that you *will not* be allowed to participate in this research study, if you choose not to sign this consent form and authorization for the use and disclosure of your Personal Health Information (PHI).

### **Whom can I call with questions or complaints about this study?**

Please be aware that if you have any questions, concerns or complaints at any time concerning this research study, please contact the Principal Investigator at [Click here to insert contact information of Principal Investigator.](#)

If you need to speak with someone other than the research team, please contact the IRB Training Administrator at [Click here to insert contact information of IRB Training Administrator..](#)

### **Whom can I call with questions about my rights as a research participant?**

If you have any questions pertaining to your rights as a research participant, please contact the IRB Training Administrator at [Click here to insert contact information of IRB Training Administrator..](#)

The IRB is a committee, reporting to the Provost/Vice President for Academic Affairs, established to ensure that the University follows federal and state guidelines on the protection of human subjects involved in research.

## **CONSENT AND AUTHORIZATION**

By signing this document, you are making a decision whether to participate (or to have your child participate) in this study. Your signature below indicates that you/your child read the information provided (or the information was read to you/your child). By signing this consent form, you are not waiving any of your (your child's) legal rights as a research participant.

You have had the opportunity to ask questions and all questions have been fully answered to your satisfaction. You (or your child) agree, by signing this consent form, to participate in this study. A copy of the consent form will be provided to you.

---

(PRINT) Name of Adult Subject  
OR Child enrollment, Name of Parent/Child's Legal Guardian



Originally Issued: September 6, 2016  
Reviewed: January 2019

X

---

Signature of Adult Subject

OR for Child enrollment, Signature of Parent/Child's Legal Guardian

---

Date

**INVESTIGATOR SIGNATURE**

I have explained the research to the participant and answered all questions. I believe that the participant fully understands the information described within this consent form and freely consents to participate in this study.

---

(PRINT) Name of Investigator/Study Team Member

X

---

---

Date