**UNIVERSITY OF GEORGIA**

**CONSENT FORM**

**ADDITIONAL ELEMENTS**

**Instructions:** The sections below may be required when a project involves certain procedures or when it is determined to involve more than minimal risk. Recommended or sample language appears in black font; it may be modified to fit your study. Remove italicized directions/guidance (in this red font) before inserting into your consent document.

**Incentives/compensation for participation**

*Indicate whether the participant will receive any incentive (monetary or non-monetary) for being in the study. Describe how/when payment will be made, if any information must be recorded to track the payment, and identify any office/organization that tracking information will be shared with.*  You will receive $30 after the first session, $70 after the second, and $100 after the third session. You will be asked to complete a receipt for each check payment provided including your name and address. This will be shared with the investigator’s departmental business office.

*If the incentive/compensation is disseminated via a drawing and local/state law does not allow such schemes without a lottery license (e.g., Georgia), explain that participation in the research is not required to enter the drawing. Describe a method for entering the drawing without enrolling in the research or completing any research procedures.* For your participation, you will be entered into a drawing for a $50 gift card to Wal-Mart. You do not have to be in the study to enter the drawing. Send an email to xxxx@uga.edu to enter the drawing if you do not want to be in the study. Your name will be provided to the investigator’s departmental business office for tracking purposes if you win.

*If extra credit is offered as an incentive (e.g., UGA research pool is used), include a statement describing the non-research alternative to participation that is available to earn the credit. This must specify that the non-research alternative is equivalent in effort or duration.*

**Audio/Video Recording/Photographs**

*If photographs will be taken or audio and/or video recording devices will be used, explain why the recordings are needed for the research and what will be done with them upon completion of the research (e.g., kept indefinitely, archived after transcription, destroyed after X years).*

*If the recording or photograph is optional for participation, provide a separate line on the consent form for the participant to signify agreement to be audio/video recorded. For example:*

Please provide initials below if you agree to have this interview *(specify audio or video)* recorded or not. You may still participate in this study even if you are not willing to have the interview recorded.

 I do not want to have this interview recorded.

 I am willing to have this interview recorded.

*If you plan to take photographs or make audio, video, or other types of recordings, and you want to use the photographs/record for activities beyond research analysis (e.g., in publications, presentations, or other promotional purposes), you will need to include a section that informs the participant that you are making a [type(s) of media used] recording in which the person’s name, likeness, image, and/or voice will be included. The same signature line above may be used for this performance release information.*

**Detailed Description of Procedures and Visits**

*Describe succinctly and in chronological order the procedures for this study. It is not necessary to describe in detail procedures that are routine care and not required by the protocol. However, DO describe procedures that are different in any way from what the subject would receive if not participating in the study, even if the study procedures are standard of care.*

*Clearly indicate which, if any, procedures are optional and state that subjects will be able to indicate their choice at the end of the form.*

*State how much time the visits and procedures will require. If studies are complex, use a simple table showing what procedures will occur at each study visit. In most cases, tables provided by the sponsor in the study protocol are too complex for most subjects. Example:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Visit 1Day 1 | Visit 2Day 14 | Visit 3Month 3 | Visit 4Month 6 | Visit 5Month 12 |
| Consent Discussion, Screening tests and medical history  | X |  |  |  |  |
| Urine Collection | X | X | X | X | X |
| Quality of Life Questionnaire | X |  |  | X | X |
| Total time | 4 hours | 30 minutes | 30 minutes | 3 hours | 3 hours |

*If questionnaires, surveys, diaries, or other data collection materials are being used, mention what kinds of questions will be asked and how long the tasks will take to complete.*

*If the subject’s medical records will be reviewed, state this and summarize the information to be collected. UGA recommends a stand-alone HIPAA Authorization form.*

**Additional Risks and Discomforts**

*Describe any additional risks associated with the detailed procedures/visits along with measures to minimize these.*

**Participant relationships with Researchers**

*If there is a working relationship between any researcher and the subjects or if recruitment takes place where services are provided, state that the decision whether or not to participate will not affect the services. If students are the targeted population, include a statement that the decision to take part or not to take part in the research will not affect grades or class standing.* *If there is a working relationship between any researcher and the subjects or if recruitment takes place where services are provided, state that the decision whether or not to participate will not affect the services. If patients are the targeted population, include a statement that the decision to take part or not to take part in the research will not affect their treatment or health care services. If employees at the recruitment site are targeted, include a statement that the decision to take part or not to take part in the research will not affect their employment or employee evaluations.*

**Internet Data Collection**

*As the security of online transmissions may not be guaranteed, include a statement which describes the limits to confidentiality*. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. OR This research involves the transmission of data over the Internet. Every reasonable effort has been taken to ensure the effective use of available technology; however, confidentiality during online communication cannot be guaranteed.

**Focus Groups or Other Group Activities**

*When the project involves data collection via a focus group or other group activity, explain that protection of confidentiality may be limited.* Even though the investigator will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future.

**Sponsored Research**

*When the project has external support (funding), identify the source of funding and, if applicable, explain that the sponsor may inspect research records.*

**Conflict of Interest**

*Disclosure of conflict of interest is required if the Principal Investigator or anyone else on the research team has a conflict of interest in the study. Specifically, the researcher must disclose to the potential participants the nature of any financial or proprietary interests in the research.*

**UGA Health Center involvement**

*If the study involves subjects who are current or potential UGA Health Center (UHC) patients, and UHC is a participant in the study, in order to satisfy UHC’s JCAHO accreditation requirements include the following:* This study will be performed, in part, at the University Health Center (UHC). Refusal to participate or decision to stop participating at any time will not compromise your access to care, treatment, and UHC services not related to the research, if you otherwise have such access. If you have a health record at UHC, your participation in this project will be noted on the summary list unless you specifically request that it not be added.

**Clinical Trial**

*If the study qualifies as an “applicable clinical trial”, include a statement such as the following:* 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. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. You can search this Web site at any time.

**Unforeseeable Risks**

*When treatment or procedures involve risks to participants, or to the embryo or fetus should the participant become pregnant during the study, state the possibility.* The study involves DXA which produces a small amount of radiation. The effect of this radiation on a fetus is unknown. Please let the researchers know if you think you may be pregnant.

**Termination of participation by the researcher**

*If there are any, describe the anticipated circumstances under which participation will be terminated by the investigator without regard to consent.* If your blood pressure or heartrate is high on the day of testing, the investigator will not conduct the exercise portion of the study and you will be withdrawn from further activities.

**Costs associated with the study**

*If any additional costs to the participant may result from the study, describe these in sufficient detail.* Transportation to the testing site will be your responsibility.

**Withdrawal from the research study**

*For research that is not subject to FDA regulations or the HIPAA Privacy Rule, the investigator should inform subjects whether the investigator intends to either: (1) retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or (2) honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.* Use **one** of the following statements: (1) If you decide to stop or withdraw from the study or the investigator terminates your participation, the information/data collected from or about you up to the point of your withdrawal will be kept as part of the study and may continue to be analyzed. **OR** (2) If you decide to withdraw from the study or the investigator terminates your participation, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information.

**New Information**

*Include a statement that any significant new findings during the research study that may relate to a participant’s willingness to continue will be provided to the participant.*

**Number of Participants**

*There are many reasons why a person may want to know how many people will be enrolled in a study. For example, when a study involves a small group or a group with special characteristics and it is reasonable that a person may be concerned about being identified via dissemination of their information, provide the number of participants for consideration. If there are many exclusion criteria, it may be important for people to understand how likely it is that they will be selected for participation. When treatment is randomly assigned, people may want to know how many people will get the treatment and how many will receive a placebo.*

**Commercial use of biospecimens**

*If the project involves collection of biospecimens with a purpose of using them for commercial profit (even if they are de-identified), inform the participants whether they will or will not share in the commercial profit.*

**Return of clinically relevant results**

*If it is likely that clinically relevant information will be obtained during the course of the project, inform the participant whether or not this information will be disclosed and, if so, under what conditions.*

**Certificate of Confidentiality**

*If the project is supported by NIH and involves collection and use of identifiable sensitive information, NIH automatically grants a Certificate of Confidentiality (CoC) for the project. Non-federally funded researchers may also request a Certificate of Confidentiality. If a CoC applies to the study, the consent document should provide a description of this protection and any exceptions that the researcher chooses to make such as voluntary disclosure in the case of child abuse. This disclosure would have to be with the consent of the subject as in the sample below.*

Sample: To help us protect your privacy, we [choose one: will obtain or have obtained] a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can refuse 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 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.

However, if we learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, we will report that to the proper authorities.

**Genetic Information**

*For research involving biospecimens, state whether the research will (if known) 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).*

*If the genetic information nondiscrimination act or GINA applies to the study, include language about the protections it offers:* In the event of an unexpected breach of confidentiality, a recent federal law (Genetic

Information Non-Discrimination Act or GINA) will help protect you from health insurance or employment

discrimination based on genetic information obtained about you through research such as this*.*

**Data Sharing**

*If required by sponsor, agency, regulation, or if the project includes plans to share the data publicly for any reason, customize as applicable:*

Our funding agency requires us to make our dataset public so other researchers can use it. The public dataset will only include:

• Aggregate (grouped) data

• De-identified (no names, birthdate, address, etc.)

• Quotes using a pseudonym (fake name)