

## **Attachment A**

### **What about Confidentiality of Records and Authorization to Use/Share Protected Health Information for Research?**

If you agree to participate in this research, identifiable health information about you will be used and shared with others involved in this research. For you to be in this research we need your permission to collect and share this information. Federal law protects your right to privacy concerning this information.

When you sign this consent form at the end, it means that you have read this section and authorize the use and/or sharing of your protected health information as explained below. Your signature also means you have received a copy of \_\_\_\_\_ (covered entity) Notice of Privacy Practices. *The Notice of Privacy Practices should be given to each subject at the time consent for participation in the study is obtained.*

Individually identifiable health information under the federal privacy law is considered to be any information from your medical record, or obtained from this study, that can be associated with you, and relates to your past, present, or future physical or mental health or condition. This is referred to as protected health information.

Your protected health information will be kept confidential. Your identity will not be revealed in any publication or presentation of the results of this research.

*For research activities, where a certificate of confidentiality (COC) has been obtained, insert the COC language here.*

*If the study involves use of video/audio taping of the subject, include a statement specifically addressing for what purposes the tapes will be used, who has access to the tapes, how they are stored, and what happens to the tapes once the study is ended (i.e., Are they erased after all the necessary information is collected from them? Are they kept for archival purposes, educational purposes?).*

#### **Why is it necessary to use/share your protected health information with others?**

The main reason to use and share your health information is to conduct the research as described in this consent form. Your information may also be shared with people and organizations that make sure the research is being done correctly, and to report unexpected or bad side effects you may have.

In addition, we may be required by law to release protected health information about you. For example, if a judge requires such release in a lawsuit, or if you tell us of your intent to harm yourself or others.

#### **What protected health information about you will be used or shared with others as part of this research?**

We may use and share the results of tests, questionnaires, and interviews. We may also use and share information from your medical and research records. We will only collect information that is needed for the research.

### **Who will be authorized to use and/or share your protected health information?**

The researchers, their staff and the staff of \_\_\_\_\_ (name of covered entity) participating in the research will use your protected health information for this research study. In addition, the SUNY New Paltz Human Research Ethics Board (HREB), a committee responsible for protecting the rights of research subjects, and other SUNY New Paltz staff who supervise the way the research is done may have access to your protected health information.

The researchers and their staff will determine if your protected health information will be used or shared with others outside of \_\_\_\_\_ (name of covered entity) for purposes directly related to the conduct of the research.

### **With whom would the protected health information be shared?**

Your protected health information may be shared with:

- *The sponsor(s) of this study, specific name;*
- *The Contract Research Organization (CRO), specific name, a company hired by the sponsor to run the study;*
- *The Data Safety Monitoring Board reviewing the safety of this study, Add name of organization;*
- *Federal agencies that supervise the way the research is conducted, such as the Department of Health and Human Services' Office for Human Research Protections, the Food and Drug Administration (FDA), the National Institutes of Health, or other governmental offices as required by law.*
- *Your insurance company (only add if third party payers are expected to pay for any procedure/treatment or test performed in the course of the research).*

*Add or delete additional entities as necessary (e.g., collaborating research sites, outside laboratories, cooperative study groups, etc). Note that if an entity is not listed, that entity CANNOT legally receive the subject's health information.*

All reasonable efforts will be used to protect the confidentiality of your protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once your protected health information is disclosed (leaves covered entity), the Federal privacy law may not protect it.

### **For how long will your protected health information be used or shared with others?**

There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

**Can you withdraw your authorization to collect/use/share your protected health information?**

You always have the right to withdraw your permission (revoke authorization) for us to use and share your health information, by putting your request in writing to the investigator in charge of the study. This means that no further private health information will be collected. Once authorization is revoked, you may no longer participate in this research activity, but standard medical care and any other benefits to which you are entitled will not be affected. Revoking your authorization only affects uses and sharing of information obtained after your written request has been received, but not information obtained prior to that time.

Even after you withdraw your permission, \_\_\_\_\_ (covered entity) may continue to use and share information needed for the integrity of the study; for example, information about an unexpected or bad side effect you experienced related to the study.

**Can you have access to your health information?**

At the end of the study, you have the right to see and copy health information about you in accordance with the \_\_\_\_\_ (covered entity's) policies; however, your access may be limited while the study is in progress.