THE FOLLOWING DOCUMENT, WHICH WAS ADAPTED FROM THE NIH CONSENT LIBRARY PROVIDES EXAMPLE LANGUAGE THAT CAN BE USED FOR A NUMBER OF SPECIFIC CIRCUMSTANCES.

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CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

CLINICAL TRIAL

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

COMMERCIAL PROFIT

Your biospecimens may be used for commercial profit. You [*will or will not*] share in this commercial profit.

FOCUS GROUP

Procedure: You will be asked to take part in a focus group discussion led by one of the investigators. The focus group will have about [*specify #*] members. The discussion will last for about [*specify duration of time*]. During that time, you and the other group members will be asked questions about your opinions and experiences with [*specify topic about which data are being collected*]. We ask you to keep what is said during the group discussion confidential between the focus group members only.

Risks: See "**INVASION OF PRIVACY/BREACH IN CONFIDENTIALITY**" below.

INTERVIEW

Procedure: We will interview you in a private location for *[about X time]*. We will ask you questions about your experiences with [*specify topic(s)*].

Risks: Some of the questions may be upsetting or make you feel uncomfortable. You do not have to answer any questions you do not want to answer. You can stop the interview at any time.

*Also see "**INVASION OF PRIVACY/BREACH IN CONFIDENTIALITY**" below.*

INVASION OF PRIVACY/BREACH IN CONFIDENTIALITY

Risks: Because we will collect personal, identifiable information about you, it is possible that people who are not supposed to see your information might somehow get access to it. We will take precautions to prevent this, but we cannot ever be certain that it won't happen. To minimize this chance, we will label your information with a study number instead of labeling it with your name [*or medical record number].* All the information we collect about you will be securely stored, such as in a locked cabinets or password protected computer files.

NEW INFORMATION

If, during the study, significant new information becomes available which may influence my willingness to continue to participate, the investigator will provide this information to me.

QUESTIONNAIRES

Procedures: We will ask you to answer [*specify number*] questionnaires that will take about [*specify duration of time*] to complete. The questionnaires will ask you about [*Add relevant information here. For ex: the symptoms you're experiencing, your ability to complete everyday activities and will test your memory and concentration.*]

Risks: Some of the questions in the questionnaire may be upsetting or make you feel uncomfortable. You can skip any of the questions you do not want to answer. You can stop at any time.

Also see "**INVASION OF PRIVACY/BREACH IN CONFIDENTIALITY**" above.

SHARING OF CLINICALLY RELEVANT RESEARCH INFORMATION

If we learn information about you in this study that is relevant to your health, we [will or will not] share this information with you.

UNFORESEEABLE RISKS

It is possible that there are unknown risks to you and/or to an embryo of fetus, should you become pregnant while participating in this study.

WITHDRAWAL/EARLY TERMINATION

The researcher may withdraw me from the research at his/her professional discretion.