FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
1040 Park Avenue, Suite 103
Baltimore, Maryland 21201
410-837-3977 (phone) 410-752-4218 (fax)

Supplementary Application for Research Involving DNA/Tissue/Sample Banks

Name of Investigator: IRB Study #:

Title of Protocol: Date of Submission:

Please complete only if applicable to your project and attach to the Application for Study Review.

1. Describe the source and the samples/data that will be obtained.	
2. Describe the purposes of storing the samples/data.	
a. How will the samples/data be identified? i. ☐ Direct Identifier (e.g., participant name, address, social security number, medical record number, etc.) ii. ☐ Indirect Identifier (e.g., an assigned code used to track specimens) iii. ☐ No identifier (e.g., no identifiable link between the participant and the data)	
b. Will the samples/data be destroyed after these purposes are served? ☐ Yes ☐ No	
i. If no, how long will the data be stored?	
ii. If no, where will the samples/data be stored?	
iii. If no, how long will the samples/data be stored?	
3. Will the participants be provided with any info about additional analysis conducted on the sample? ☐ Yes ☐ No	
4. Who will "own" the samples/data?	
5. Will the investigator of this research remain in control of the samples/data? ☐ Yes ☐ No	
a. If no, will the samples/data be shared with other investigators? ☐ Yes ☐ No	
b. If yes to 5a, list the investigators, indicate if they are affiliated with FRI, and how the samples/data will be shared.	

For research involving DNA/Tissue and Cell Lines, the following paragraphs should be inserted into the standard informed consent template, as appropriate.

POSSIBLE COMMERCIAL PRODUCTS

(Note: Please insert the following paragraph if you intend to collect tissue and/or fluid samples as part of the research. Please insert both the first and second paragraph if a cell line will be developed from tissue and/or fluids. If this section does not apply to your research, please omit this entry and delete the heading.)

Suggested text:
All tissue and/or fluid samples are important to this research study. Your sample will be owned by FRI or by a third party designated by FRI (such as another university or a private company). If a commercial product is developed from this research project, FRI or its designee will own the commercial product. There are no plans to provide financial compensation to you should this occur.

Please insert the following paragraph only if you plan to create a cell line:
Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one that will grow indefinitely in the

laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

Guidelines:

⇒ If any human materials (tumor tissue, bone marrow, blood, etc.) are used for establishing a cell line which may be shared with other researchers and which may in the future be of commercial value, the subject/participant must be informed of the fact in the consent form. The above statement must be included verbatim.]

SAMPLE REMAINING AT THE END OF THE STUDY

(Note: Please insert the following paragraph if you intend to collect tissue and/or fluid samples as part of the research. If this section does not apply to your research, please omit this entry and delete the heading.)

On the checklist at the end of this consent form, you will be asked to indicate if you would permit part of this sample to be shared with other researchers. If you agree to have your sample shared with other researchers and later decide to withdraw, we may not be able to retrieve any or your entire sample from other researchers. The researcher is not required to store your sample(s) indefinitely.

INFORMATION ABOUT YOUR SAMPLE

(Note: Please insert the following paragraph if you intend to collect tissue and/or fluid samples as part of the research. If this section does not apply to your research, please omit this entry and delete the heading.)

On the checklist below, you are asked to let us know if you would like to receive information about the results of this study. There are two types of information you may receive:

1. General information about what this study found (or conclusions of the study);
2. Specific information about what the study found about your sample.

You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

PRIVACY AND CONFIDENTIALITY

(Note: Please insert the following paragraphs if you intend to collect tissue and/or fluid samples as part of the research. If these paragraphs do not apply to your research, please omit these paragraphs.)

Each tissue and fluid sample contains genetic information about your parents and ancestors such as the information contained in DNA, RNA, or protein. It may be helpful to study members of your family. Your relatives will not be contacted without your permission.

Genetic Information in your Sample: Possible Limits to Individual Confidentiality

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggesting different parentage is obtained during research. We do not plan to report such findings to participants.

Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information.

SIGNATURE OF RESEARCH SUBJECT/PARTICIPANT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject/Participant

_____ _____
Signature of Subject/Participant Date

SHARING OF SAMPLES

(Note: Please insert the following paragraph if you intend to collect tissue and/or fluid samples as part of the research. If this section does not apply to your research, please omit this entry and delete the heading.)

Please check the appropriate box below and initial:

☐ _____I agree to have my tissue/fluid sample shared with other researchers.

☐ _____I do not want my tissue/fluid sample shared with other researchers.

INFORMATION ABOUT MY SAMPLE

(Note: Please insert the following paragraph if you intend to collect tissue and/or fluid samples as part of the research. If this section does not apply to your research, please omit this entry and delete the heading.)

Please indicate by checking and initialing the category below what type of information you want to receive. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators."

☐_____ General Information about what the study found

☐_____ Specific Information about what the study found about me

☐_____ I do not want any information about my sample

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject/participant or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's/participant's)

SIGNATURE OF WITNESS (If an oral translator is used.)

My signature as witness certified that the subject/participant or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

_____

Name of Witness

_____ _____

Signature of Witness Date (must be the same as subject's/participant's)