We the UF Diabetes Institute are asking permission from you, ______________, to store some of your tissue/blood sample that is not needed for your medical treatment in order to use it for future research.

The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will describe this tissue/blood sample bank to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, please read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits that you would otherwise be entitled to.

1. **What are we asking to store?**

If you agree, one or more of the following tissue/blood sample(s) will be collected and stored in the tissue bank: blood, stool, saliva, cord-blood, and urine.

2. **Reason for Storing Your Tissue:**

We wish to store your tissue/blood sample and potentially use it in future research. Many different kinds of research uses tissue/blood sample. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your tissue/blood sample may look for genetic causes and signs of disease.
Many medical problems may arise due to the environment or from genetic factors. Your medical condition may come from one or both of these causes. Genetic factors are those that people are born with and that can affect other family members. There may be genetic testing done in the future that would provide information about traits that were passed on to you from your parents or from you to your children. Because the nature and value of any future testing or research cannot be known at this time, this genetic information and any other results obtained from using your tissue/blood may not be given to you or your doctor.

3. Can you change your mind?

If you decide that your tissue/blood sample can be kept for future research but you later change your mind, you can contact the UF Diabetes Institute at 352-273-8278 who will remove and destroy any of your tissue/blood sample that he/she still has. Otherwise, the samples may be kept until they are used up, or until the University of Florida decides to destroy them. You have the right to see and copy the information that is collected from you and stored in the medical information/tissue bank. There will be no cost to you for any tissue/blood collected and stored.

4. Where will your tissue/blood sample be stored?

Your tissue will be kept in a secure location in a tissue bank/blood sample called The UF Diabetes Institute Tissue Bank so that it may be used in future research to learn more about your medical condition and other medical problems. The tissue/blood sample will be stored in a de-identified fashion.

5. Are there any benefits to your participation in this tissue/blood sample bank?

There is no direct benefit for your participation in this tissue/blood bank. Even though the research that is done on your tissue/blood cannot be used to help you, it might help other people who have a similar medical condition or other medical problems.

6. Are there any risks to your participation in this tissue/blood sample bank?

The sample will be issued a code at the time of collection. The key to break this code will only be available to what is called the gatekeeper. Your tissue or any personal information will only be supplied to IRB approved studies. Therefore the risk is minimal.

Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may obtain your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to a third party.
If you were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party learned the results, there is a risk of social stigma and of the unpredicted disclosure of this information to others.

There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/quina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

7. Will your tissue\blood be shared with others?

The UF Diabetes Institute and/or their successors will be allowed to collect, use and/or give out your tissue/blood sample. They may give your tissue/blood to other researchers whose research is approved by an Institutional Review Board (IRB) (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). They may also give your tissue/blood to a study sponsor, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections, or other Government agencies. Your tissue/blood, whichever is appropriate may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the University of Florida’s costs of sharing your tissue/blood. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by the law.

8. How will the researchers benefit?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. It is possible that new treatments, medicines, therapies or products could be created from studies that use your tissue or medical information. If that happens, the Principal Investigator and the University of Florida could receive significant financial benefits. You will not be offered any payment or any other financial benefit.
9. Signatures:

As an investigator or the investigator’s representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant’s protected health information will be collected, used, and shared with others:

_________________________________________________ ______________
Signature of Person Obtaining Consent & Authorization Date

Consenting Adults. You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_________________________________________________ ______________
Signature of Adult Consenting & Authorizing for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_________________________________________________ ______________
Consent & Authorization Signature Date
of Parent/Legal Representative

Print:  Name of Legal Representative Print:  Relationship to Participant: ____________________________
______________________________________________

Print:  Name of Subject:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

______________________________________________ __________________
Assent Signature of Participant Date