UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow us to collect research information about your child.

If you are an adult participant reading this form, the word "you" refers to you.

We (UF Diabetes Institute (DI)) are asking permission from you,

_____

Printed name of study participant ("study subject")

to store some of your medical and contact information in order to talk to you at a later time about our on going or future research studies. In addition to being able to offer you information about our research studies on diabetes we will also share with you information about seminars on diabetes and send you a periodic electronic newsletters (e-newsletter).

The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator (PI) will describe this information bank to you and answer all of your questions. You may also call the PI, Dr. Michael Haller at 352-273-9264 or Miriam Cintron at 352-273-5580. 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 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, the following medical and contact information will be collected and stored in a data bank or contact registry: Name of adult or parent, name(s) of child(ren), email address, telephone number, type of diabetes, date of birth, date of diagnosis, and your responses to a questionnaire completed by you.

2. Reason for Storing Your Medical and Contact information:

We wish to store your medical and contact information in a data bank to use it to contact you about on going and future research in diabetes. You will be contacted if your information shows that you match the requirements for a current or a future diabetes study. Many different kinds of research use data banks to contact people who are interested in taking part in research studies. 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). Some research done with medical information 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 medical information may not be given to you or your doctor.

3. Can you change your mind?

If you decide that your medical or contact information can be kept for future research but you later change your mind, you can contact Dr. Haller at 352-273-9264 who will remove and destroy any of your medical or contact information that he still has. Otherwise, the information may be kept 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 data bank. There will be no cost to you for any medical or contact information collected and stored.

4. Where will your medical information be stored?

Your medical and contact information will be kept in a secure, computerized database called REDCap (Research Electronic Data Capture). You may be contacted if your information shows that you match the requirements for a current or future research study or to attend one of the seminars offered by the UF Diabetes Institute group. You will not be contacted more than four times a year regarding your possible participation in a current or future research study.

The collection of this information will be done entirely through the internet on the UF Diabetes Institute website. Your consent to take part will also be obtained through the internet in the process explained below.

- You must read this informed consent before you register to take part.

- After you read this informed consent, you can take part in this contact registry by checking the proper box on the web survey.
- You agree to take part by choosing, **Yes**. When you choose **Yes,** you are giving your consent or permission to have your data collected.
- After agreeing to participate, you will be instructed to provide some basic information (name and email address).
- You may download a copy of this informed consent for your records.
- If you choose **No**, t a menu box will appear. Clicking the button "end the survey now" will return you back to the UF Diabetes Institute website.
- You will complete the registry form by answering several questions.
- If you do **not** have diabetes, only answer the first 6 questions.
- When you have finished answering these questions click submit.
- This will complete your registration for this contact registry.

5. Are there any benefits to your participation in this medical and contact information bank?

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

However, taking part in the data bank will allow us to contact you and share information about research trials that are being done by the UF Diabetes team. We offer many research trials through TrialNet, The Juvenile Diabetes Research Foundation (JDRF) and The Helmsley Foundation, to name a few. Any research study offered to you will have a separate informed consent and will contain information specific to that research. These research studies have been approved by an Institutional Review Board (IRB).

Another possible benefit to taking part will be the periodic e-newsletters sent to you at your email address. The e-newsletter contains articles of interest on diabetes. Such as, educational news on diabetes care, information on upcoming seminars, and the latest topics in the news concerning diabetes. The seminar series offered by the DI provides you the opportunity to come and listen to talks given by experts in the field of diabetes on a variety topics related to diabetes. These seminars are free.

6. Are there any risks to your participation in this medical and contact information bank?

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 information could be linked to your identity and inadvertently disclosed to a third party.

7. Will your medical and contact information be shared with others?

Dr. Haller and/or people working on his staff or their successors will be allowed to collect, use and/or give out your medical information. They may give your medical information 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 medical information 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 medical information 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 medical information. 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 gotten by your participation in a current or future study are presented at scientific meetings or in scientific journals. **I**t 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. Authorization

A record of your agreeing to take part will be kept and recorded in REDCap. You can communicate with the Principal Investigator (Dr. Michael Haller) or a representative of this contact registry for further explanation to the purpose of taking part in this data bank. You can call them at 352-273-9264 or 352-273-5580 or email cintrm@peds.ufl.edu. You are encouraged to download a copy of this informed consent for your records. You voluntarily agree to the collection and storage of your: name, your children's name, email address, telephone number, type of diabetes, date of birth, date of diagnosis, and your responses to the questionnaire completed by you. By agreeing to participate in this registry, you are not waiving any of your legal rights.