INTRODUCTION

Name of person seeking your consent:

Place of employment & position:

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")
2. **What is the Title of this research study?**

   Immune Function and the Progression to Type 1 Diabetes: Project 1; Project 2; Core A; Core B

3. **Who do you call if you have questions about this research study?**

   Principal Investigator: Mark A. Atkinson (352-273-8278)

   Other research staff: Other UF Diabetes Institute Study Staff and Investigators (352-273-8278)

4. **Who is paying for this research study?**

   The sponsor of this study is the National Institutes of Health.

5. **Why is this research study being done?**

   The purpose of this research study is to learn more about the genetics and immune function of blood cells, and viruses in insulin dependent diabetes. We believe the collection of such information will lead to improved ways of treating insulin dependent diabetes as well as a possible cure or prevention.

   You are being asked to be in this research study because the progression of T1D is dependent on multiple factors both genetic and environmental. It can occur at any stage of life but is markedly more incident at younger ages.

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**WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?**

6. **What will be done as part of your normal clinical care (even if you did not participate in this research study)?**

   Participation in this research study or lack of participation will in no way affect your clinical care. The Clinical plan your physician has determined best will be followed.

7. **What will be done only because you are in this research study?**

   Experienced personnel will draw a blood sample from you at the time you consent to the study. The amount of blood to be drawn from you will be determined by age and body weight according to guidelines established by the National Institutes of Health. Regardless of age and/or eight never more than 75 cc (which is equivalent to about 9 tablespoons) will be drawn at any given time.
Some individuals will be asked to provide stool, urine or saliva samples. If you are participating in the saliva portion of this study you will be asked to spit into a collection tube until the tube is full.

If you are participating in the stool sample portion of this study you will be provided with an at home kit to collect the stool. You would then be asked to return the sample in a self-addressed postage paid envelope.

Some individuals undergoing surgical procedures may be asked to donate tissues that otherwise would have been discarded. Examples of these procedures would be tonsillectomy and adenoidectomy.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Your sample will be stored and utilized until completion of the study.

9. How many people are expected to take part in this research study?

Approximately 800 subjects will be enrolled in this on-going study.

**WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?**

10. What are the possible discomforts and risks from taking part in this research study?

The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and uncommonly, faintness from the procedure.

Other possible risks to you may include: This is a laboratory study consisting of a blood draw only, so it poses no health risk to you, other than the minimal risks associated with drawing blood. All blood draws will be performed by trained personnel.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.
Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit for participation in this study. The indirect benefit could be knowledge gained could change the way Diabetes is treated.

11b. How could others possibly benefit from this study?

One possible overall benefit of this study would be a better understanding of diabetes and why some have it. Ultimately a cure and/or vaccine could be found as a result of participation in this study.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. Your consent is totally voluntary. If you do not want to take part in this study you should tell the Principal Investigator or the study representative and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.
13b. If you withdraw, can information about you still be used and/or collected?

If you request to withdraw from the study all of your remaining stored sample will be properly destroyed as well as any personal information deleted.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The study is cancelled by the National Institutes of Health or for other administrative reasons. Ask the Principal Investigator or study representative if you would like more information about this.

**WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?**

14. If you choose to take part in this research study, will it cost you anything?

The Sponsor will pay for all services required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Mark A. Atkinson (352-273-8278).

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

You will be given a $20 gift card at the time of your blood-draw.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the
University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Sex
- Race
- Ethnicity
- Date of Birth
- Weight
- Do you have diabetes
- Does a relative have diabetes
- Any illness at the time of consent

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.
18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- The purpose of this research study is Diabetes. The progression of Diabetes is dependent on multiple factors both genetic and environmental. It can occur at any stage of life. We believe the collection of this information will lead to improved ways of treating insulin dependent diabetes as well as a possible cure or prevention.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida 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).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies that are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- Your insurance company for purposes of obtaining payment
Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the person or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.
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.

_____________________________ Date
Assent Signature of Participant