Consent Document for Participant with Diabetes (age over 18)

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Adolescents with and without Diabetes: Transition to Emerging Adulthood

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Why is this research being done?

The purpose of this study is to examine the difficulties young people (ages 17-20) face in dealing with diabetes during the transition to young adulthood. During this time many changes in life situations occur, such as attending college, working, or living away from home. We will examine changes in life situations; how young people take care of their diabetes; relationships with family and friends; and health behaviors, such as diet, exercise, smoking, and alcohol use. The study will take place over a 3-year period spanning the senior year of high school and the first two years after graduation.

Who is being asked to take part in this research study?

You are being asked to participate in this study because you were enrolled in the original study titled “Psychosocial Factors in Adolescent Adjustment to IDDM” that took place between July 2002 and June 2007. In order to participate in the current study, you must have been enrolled in the original study, have type 1 diabetes, and be in your senior year of high school during the first year of the study. A total of 260 young people were enrolled in the original study and will be invited to participate in the current study.

What procedures will be performed for research purposes?

There are three parts to the research study. If you decide to take part in the study, you will complete the following procedures:

1. The first part involves an on-line questionnaire that you will complete over the internet once a year for the three years of the study. If you do not have access to the internet, you can complete the questionnaire on paper. The questionnaire takes 45 minutes or less to complete. You will be asked questions about your current life situation (i.e., attending school, working, living with family or away from home), how you take care of your diabetes, your relationships with family and friends, and health behaviors, such as diet, exercise, smoking, and alcohol use. You will complete the first questionnaire during your senior year of high school, the second questionnaire one year later, and the third one year after that.

2. The second part of the study involves 3 phone interviews conducted once every 2 weeks over the 6 weeks that follow the on-line questionnaire. Each interview lasts between 15 and 20 minutes. You will be asked to review your day from beginning to end, detailing what you have eaten and how you have spent your time. These interviews will take place in the first two years of the study.

3. The research staff will also review your medical records over the three years of the study to obtain height and weight and measures of metabolic control (HbA1c) performed at routine physician visits.

What are the possible risks and discomforts of this research study?

The questions asked in this study pose minimal risk. Most of the questions were used in the previous research study in which you participated. The only foreseeable risk is that you could become distressed by
a question. From our experience, we believe this risk to be minimal. If you object to any of the questions, you may refrain from answering and/or discontinue participation in the study.

**What are possible benefits from taking part in this study?**

You will likely receive no direct benefit from taking part in this research study. The results of the study will benefit health care professionals by providing an increased understanding of how young people with and without diabetes fare during the transition to young adulthood.

**Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?**

No treatments or interventions are being performed for this research study. Neither you, nor your insurance provider, will be charged for any costs. You will be charged, in the standard manner, for any procedures performed for your routine medical care (e.g., the HbA1c test which is performed at your routine physician visits).

**Will I be paid if I take part in this research study?**

You will be paid $50 for each of the three on-line questionnaires, for a total of $150 over the three years of the study.

You will also be paid $25 for each of the three 24-hour recall phone interviews with an additional $25 bonus upon completion of all three, for a total of $100 each year. These phone interviews take place during the first 2 years of the study. This results in a total payment of $200 if you complete all phone interviews over the two years.

**Who will know about my participation in this research study?**

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet or in a password-protected computer file in Dr. Helgeson's offices. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records in a password-protected database. You will not be identified by name in any publication of the research results.

**Will this research study involve the use or disclosure of my identifiable medical information?**

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to metabolic control (HbA1c) and the frequency of diabetes-related hospitalization (e.g., for DKA). From this information, case report forms will be prepared so that your medical information can be compared to that of other people in the study. These forms will be sent to Dr. Vicki Helgeson. Your identity on these
forms will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records in a password-protected database.

**Who will have access to identifiable information related to my participation in this research study?**

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of the sponsor of this research study, the National Institutes of Health, may review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.

**For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?**

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of five years after final reporting or publication of a project.

**Is my participation in this research study voluntary?**

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you
will not be allowed to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If your doctor is involved as an investigator in this research study, he or she will be interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

**May I withdraw, at a future date, my consent for participation in this research study?**

You may withdraw, at any time, your consent for your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study, Dr. Vicki Helgeson, at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

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University Of Pittsburgh
Institutional Review Board
Approval Date: 4/12/2007
Renewal Date: 4/11/2008
IRB #: PRO07030077
Version: 1.00
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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigators listed on the first page of this consent document at the telephone numbers given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office at the University of Pittsburgh (1-866-212-2668) or the Chair of Carnegie Mellon University’s Institutional Review Board (412-268-1901 or 412-268-4727) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

______________________________
Participant’s Name (Print)

______________________________  __________________________
Participant’s Signature  Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

______________________________  __________________________
Printed Name of Person Obtaining Consent  Role in Research Study

______________________________  __________________________
Signature of Person Obtaining Consent  Date