INTERVIEWING INSTRUCTIONS

TABLE OF CONTENTS

I. EXAM FORMS OVERVIEW

This section of the *Type 1 Diabetes Genetics Consortium (T1DGC) Manual of Operations* provides the instructions for the administration of all data forms that are used during the examination. See **Chapter II,** *Guidelines,* for a summary of the exam forms, when they are administered, and to whom.

Before a participant comes into the clinic, prepare and review the forms for the exam. For affected sibling pair (ASP) and trio families, these forms include: the *T1DCG Consent Summary Form* (one for each family); the *Informed Consent* (one for each participating family member); the *T1DGC Exam Form* (one for each participating family member); and the *T1DGC Blood Collection Form* (one or each participating family member). In the North American Network, the *Trio Pre-eligibility* form is required.

For cases and controls, the forms include the *Informed Consent*, the *T1DGC Consent Record (Addendum to Layered Consent)*, and the *T1DGC Blood Collection Form*. For cases only, the *T1DGC Exam Form* is completed. There is no *T1DGC Consent Summary Form* for the case-control collection.

See Appendices A-E for comprehensive instructions (Q x Qs) for the *T1DGC ASP Consent Summary Form* and each *T1DGC ASP Exam Form*. See Appendices F-H for comprehensive instructions (Q x Qs) for the *T1DGC Trio Consent Summary Form* and each *T1DGC Trio Exam Form.* See Appendix I for comprehensive instructions (Q x Qs) for the *T1DGC Consent Record (Addendum to Layered Consent)*. See Appendix J for comprehensive instructions (Q x Qs) for the *T1DGC Case Exam Form.* See **Chapter VI**, *Blood Collection and Processing,* for the instructions to complete the *T1DGC Blood Collection Form*s.

If the *T1DGC Exam Form* is completed over the phone prior to the participant signing the *Informed Consent*, when the participant comes into the clinic for blood collection and to sign the *Informed Consent*, the responses on the *T1DGC Exam Form*

should be reviewed with the participant and the date of interview changed to the date the participant was seen in the clinic.

For certain networks, it is necessary for the interviewer to translate the questions on the forms to another language in order for the participant to understand the questions. It is critical that the meaning and intent of questions be maintained. The interviewer must be fluent in both the participant's native tongue and English to ensure that correct responses are elicited and recorded.

II. INTERVIEWING PRINCIPLES AND PROCEDURES

Interviewing, in part, is a science and also an art. There are definite rules that produce valid results and general guidelines to follow, but much depends on the sensitivity of the interviewer. The procedures and techniques that follow will help you to conduct interviews that yield valid data.

A. Developing a Good Interviewing Relationship

Interviewing is a major component of the T1DGC study, and therefore it is crucial that interviewers present questions appropriately and record participant responses precisely and accurately. In order to maintain an objective information-gathering atmosphere, the interviewer must convey that he/she is an understanding person capable of accepting information in a non-judgmental manner and convey an interest in what the participant is saying. The participant must find satisfaction in talking to a receptive person without the fear of appearing inadequate.

It is the interviewer's responsibility to obtain full and accurate information by eliciting cooperation from participants, establishing and maintaining rapport, and encouraging active participation in a strictly neutral way. Interviewers are skilled professionals. Their skills make it possible for participants to give frank, complete, and relevant answers to questions.

In general, the majority of participants are willing to be interviewed. A confident, enthusiastic approach that assumes people are willing to be interviewed is the most effective technique.

To increase the participant's cooperativeness, be prepared and know the material. Participants need to feel that the interviewer is interested in the study and in their responses. Be an active listener and establish comfortable eye contact with the participant. Offer convincing statements about the purpose of the study. Discuss how the participant was selected. Describe the beneficial uses of the research findings to both the participant and to the community.

B. Type of Questions

1. *Pre-coded Questions:* With pre-coded questions, mark an "X" in the correct response box. In addition to marking a box, it is very important that you record the participant's verbatim response on the form whenever there is uncertainty about which code is appropriate.

2. *Multiple Answer Questions:* With multiple answer questions, mark an "X" in all correct response boxes. If the participant is unsure about any or all of the information, only the "Don't know" box should be marked. In some cases a "None of the above" choice can be marked if none of the responses are correct.

3. *Fill-in-the-Box Questions:* With fill-in-the-box questions, the correct numbers should be recorded in the corresponding boxes. If there are two boxes, and the digit is a single-digit number, a leading "0" (zero) is placed in the first box. **Each box must contain a numerical value.**

C. Interviewer Administered Questionnaires

There are several standard procedures for reading questions. Read in a natural conversation rhythm and in a normal tone of voice. Be cautious about reading questions too rapidly. The participant may not feel comfortable asking that questions be repeated and consequently the answer will not reflect his/her true thoughts on the issue.

Be aware of the participant's facial expressions (*e.g.,* puzzled, confused). Repeat the question if it is answered inappropriately, but repeat it exactly as written. Show no impatience when asked to repeat a question.

Each question must be asked of each participant in the same way and in the same order to ensure that comparable information is being obtained from all participants in the study.

1. Interview instructions are provided throughout the interview on the forms. These instructions are not to be read to participants but are intended to give the interviewer direction. The interviewer instructions appear in all capital letters.

2. Read only those choices that appear in the question and those you are instructed to read.

3. Ask the questions exactly as worded and in the same order as they appear in the questionnaires. Minor changes in wording can completely change the meaning of a question. Unless each interviewer asks the questions exactly as shown, the answers are not valid. Similarly, follow the sequence of questions. Do not ask questions out of order.

4. Ask every question. It is the interviewer's responsibility to ask every question. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. Do not omit questions and do not assume you know the answer to the question.

5. Follow skip patterns. For several questions, answering a question by responding in one way makes one or more questions after this question irrelevant. Throughout the forms, the interviewer may be directed to skip to another question. Questions that are skipped should not be answered.

D. How to Get Satisfactory Answers

1. Learn the purpose of each question. In order to interview well, you need to understand the type of information we are trying to capture with each particular question. Unless you understand its purpose, you may not be able to judge when a response is adequate and when you must probe for clarification or for additional information.

2. Do not attempt to interpret or explain the question; maintain neutrality. If a participant does not seem to understand a question, repeat the question slowly and clearly. Give the participant time to think about the question (while simultaneously being aware of time allowed for administering the form). Unless there are other instructions about handling specific questions, the acceptable reply for a participant who wants to know what a question means is "whatever it means to you". Do not attempt to explain the purpose of a question.

3. Do not define terms used in questions. Some participants may ask what is meant by a word used in a question. Leave the matter of definition to the participant, suggesting "whatever you think _____ means" or "however you use the term _____".

4. Do not leave a question until you have an adequate answer or have determined that a participant cannot give a clear answer.

E. How to Record the Interviews

1. In order to best record participants' responses, the following suggestions are recommended:
   a. Be prepared to write.
   b. Periodically establish eye contact with the participant while writing.
   c. If you question whether you marked the correct response, be sure to record the participant's verbatim response on the form.
   d. If you make a recording mistake, cross out the error with two horizontal lines. Then circle, initial, and date the correct answer. **Never use white**

out to erase a mistake. All corrections must be documented as described above.

2. The form sets are FAXed or photocopies are mailed to the Regional Network Center for data entry. Therefore, the following recording techniques are mandatory to ensure clarity and quality of the answers on the forms:

   a. Mark a response box with an "X," not a check. Otherwise, the data editor will have to re-mark the answers before sending the form set.

   b. A black, medium-tip ballpoint pen must be used to record answers. Pencils are never used to complete data forms.

   c. If a wrong answer is inadvertently marked, draw two horizontal lines through the wrong answer. Mark an "X" in the correct response box, circle the correct response box, and write your initials and the date next to the correct response. **Never use white out on any form. All corrections must be documented as described above.**

   d. If no answer is given and there is not an appropriate response box, mark the "Not applicable" or "Question not asked" box.

   e. Numerals must be printed clearly and legibly. It is requested that the following numerals be recorded in this manner:

      i. zero has a line drawn through it (Ø);

      ii. one is written as a single vertical line (|); and

      iii. seven has a line drawn through the stem (7̸).

III. USING THE CUE CARDS

There are a number of cue cards to assist you and the participant in completing the exam forms. Some of these cue cards contain information that are read to the participant before the participant answers the questions. Other cue cards are handed to the participant so that they may select any correct responses. If a participant cannot read English, the interviewer may need to read all cue cards to the participants.

The cue cards that are read to the participant do not have to be read exactly as written. These cue cards are meant to help you when there is doubt about what to say. Although the cue card does not have to be read exactly as written, the information on the cue card must be conveyed to the participant to capture the correct response(s). The cue cards that are handed to the participant usually contain a list of choices from which a participant may select. Table 1 provides a summary of the cue cards, outlining when and how they are used. Cue cards are network-specific, listing only the relevant responses. The cue cards provided in Appendix K list all applicable responses and should be referenced if the interviewer believes the participant will benefit from seeing the complete list.

Table 1. Summary of Cue Cards and Intended Use

Cue Card	Cue Card Title	When Used	Interviewer or Self-Read
1	Genetic Studies	Eligibility Form	Self-Read
2	Exclusion Disorders	Eligibility Form	Self-Read
3	Description of Study	Eligibility Form	Interviewer Read
4	Race/Ethnic Origin	Exam Form	Self-Read
5	Diseases or Disorders	Exam Form	Self-Read
6	Previous Studies	Exam Form	Self-Read
7-8	Pedigree	Exam Forms	Interviewer uses to identify family members
9	Definitions for North American (NA) Network Only	NA Trio Pre-Eligibility and Case-Control Eligibility Forms	Interviewer uses to clarify definition of ethnicity/race
10	Region/Tribe	Case- Control Eligibility Forms	Self-Read

The *Classification of Cultural and Ethnic Groups* (Appendix L) will be used to develop the network-specific ethnicity cue card (Cue Card 4) in the North American and United Kingdom Networks; the entire list may be referenced if a participant does not identify with categories on the network-specific cue card. In the Asia-Pacific and European Networks, the entire list will be used rather than a cue card.

Categories listed as “no further designation” mean that a participant does not identify with one of the smaller, more definitive categories (*e.g.*, a participant is British, but not English, Scottish or Welsh). For North American trio family participants it is important to use a designation other than “810, North American, no other designation” because this does not provide sufficient information regarding race or ethnic origin. For further information regarding this, refer to **Chapter III,** *Recruitment*, and **Chapter IV**, *Eligibility*.

Categories listed as “not elsewhere classified” mean that a participant identifies with the primary classification, but is part of a smaller group of people within that category (*e.g.*, Inuit).

Cue Card 6 contains a list of regional, national, and international studies that are funded by either the National Institutes of Health (NIH) or by the Juvenile Diabetes Research Foundation (JDRF). Participation in any of these studies is not an exclusion criterion; however, the T1DGC is interested in compiling information regarding overlap of participants between the T1DGC and these studies. If a participant is uncertain about participation in one of these studies, the descriptions provided below may be used.

DPT-1 (Diabetes Prevention Trial – Type 1): An international multi-center trial looking at whether antigen treatment (either injected or oral insulin) could delay or prevent the onset of type1 diabetes in those at risk for type 1 diabetes.

TrialNet (Type 1 Diabetes TrialNet): Based upon the clinical trial network created for DPT-1. TrialNet conducts large scale trials aimed at preventing type 1 diabetes and preserving beta cell function in patients with recent onset type 1 diabetes.

TEDDY (Consortium for Identification of the Environmental Determinants of Diabetes in the Young): An international consortium to identify infectious agents,

dietary factors, or other environmental factors which may trigger type 1 diabetes in genetically susceptible individuals from birth.

SEARCH (SEARCH for Diabetes in Youth): An epidemiological study focusing on children and youth in the United States who have diabetes. The study goals are to identify the number of children and youth under age 20 who have diabetes and learn how type 1 and type 2 diabetes differs. Additionally, researchers will learn about complications, the different types of medical care received, and how diabetes affects the lives of children and youth who have diabetes.

GoKinD (Genetics of Kidneys in Diabetes): A multi-clinic study across the United States and Canada striving to investigate the role genes play in causing nephropathy in people with type 1 diabetes. The fundamental aim of GoKinD is to facilitate investigator-driven research into the genetic basis of diabetic nephropathy by collecting the necessary DNA samples to determine if there are genetic differences between people who do and do not develop diabetic kidney disease.

TRIGR (Trial to Reduce IDDM in the Genetically at Risk): An international trial to determine whether delayed exposure to intact food proteins will reduce the chances of developing type 1 diabetes in babies genetically at risk for the disease.

EDIC (Epidemiology of Diabetes Interventions and Complications): A multi-center, longitudinal, observational study designed as follow-up to the Diabetes Control and Complications Trial (DCCT). Data collection focuses on nephropathy and macro vascular complications.

FIND (The Family Investigation of Nephropathy and Diabetes): A multi-center consortium established to identify the genes responsible for diabetic

nephropathy. Participants have cell lines created, and a repository containing stored urine and serum samples has been developed.

ENDIT (European Nicotinamide Diabetes Intervention Trial): Randomized controlled trial assessing the effect of nicotinamide treatment on the development of type 1 diabetes in non-diabetic autoantibody-positive (ICA) first-degree relatives of patients with type 1 diabetes.

*PANDA (Prospective Assessment in Newborns for Diabetes Autoimmunity): S*tudy attempting to define the interactions of genes and environmental factors that initiate or protect children from type 1 diabetes. Newborns at high genetic risk are being followed prospectively to identify dietary factors, infectious agents or other environmental factors that may trigger autoimmunity.

Australian Type 1 Diabetes Repository: A repository that aims to identify genes and immune markers that predispose to type 1 diabetes. A blood sample is collected from family members of a person with type 1 diabetes (including the person with type 1 diabetes). The repository stores samples of cells or DNA and keeps information about the genetic and other relevant tests in a data base for ongoing and future diabetes research.

EURODIAB TIGER: Prospective, international register which included children with onset of diabetes before age 15, in 36 different centers throughout Europe. This study has provided interesting epidemiological information about geographical and seasonal variations in incidence of the disease.

BOX (Bart's Oxford Family Study of Childhood Diabetes): A longitudinal study aiming to enroll the families of all people living in the Oxford region who develop diabetes before the age of 21 in order to investigate the genetic and environmental factors contributing to the development of diabetes.

Cue Cards 7 and 8 (Pedigree) are not referred to in the exam forms as are the others. These may be useful in identifying family members, but use of them is optional.

Cue Card 9 is not referred to on the *North American Trio Pre-Eligibility Form* or the case-control eligibility forms but is provided to clinic staff in order to quickly allow clinic staff to review the definition of ethnicity/race for North American trios, cases and controls.

Cue Card 10 will be used only in India and Cameroon and provides the region and tribe categories for the case-control collection.

IV. FOLLOWING TRAINING

Familiarize yourself with the questionnaires. Read the instructions carefully. Administer questionnaires to yourself just as you would a participant and probe yourself if an answer to a question is uncodable or otherwise inadequate. Complete the interview with a co-worker or family member. Re-read the instructions watching for any errors you make so that you do not repeat them on subsequent interviews. Study the comprehensive instructions (Q x Qs) thoroughly, so that you understand the purpose of the questions. You may wish to re-read this manual following the conduct of interviews. It may provide a different perspective and reinforce what you have experienced. Complete the pilot study and carefully note the specific feedback from the Regional Network Center.

V. CONFIDENTIALITY BETWEEN PARTICIPANT AND INTERVIEWER

Participants may be hesitant to participate or disclose personal information if they are unsure where this information is going or what is done with the information they disclose. In order to help participants feel at ease, confidentiality practices must be explained fully.

A. How to Explain the Flow of Information

1. Be familiar with where participant information and laboratory samples are sent.

2. The identifier that allows the clinics, the Regional Network Center, the Coordinating Center and the laboratories to identify a participant is an ID that contains a network identifier, family identifier and personal identifier. The only individuals who know the identity of participants are the clinic staff.

3. Information is not disclosed to other family members or any other participants in the study.

4. Information is seen only by the Clinic Coordinator and other clinic staff.

5. Information received from questionnaires is sent to the Regional Network Center, using only the participant's ID number, where a data entry coordinator views the answers while entering them into a computer.

6. These data are transmitted to the Coordinating Center where it is analyzed. There also are data edits for incomplete or incorrect information that are corrected by the Regional Network Center and the clinics.

7. Blood samples are sent to regional laboratories for storage and analysis. A cell line sample, DNA aliquots, and storage samples (serum and plasma) are sent to a Central NIDDK Repository for storage. DNA aliquots are sent to genotyping facilities around the world for study-directed genotyping projects.

8. Members of the Type 1 Diabetes Genetics Consortium and the scientific community at large can request cell lines and blood samples. These scientists are from all over the world.

B. Participant Confidentiality

All information regarding a participant is confidential. Participant files and study documents are kept secure using the same protocol as is used by individual clinics for patient charts. Information sent to the Regional Network Center, the Coordinating Center, and the laboratories has no personal identifiers.

VI. ANSWERING DIFFICULT QUESTIONS

Being familiar with the information is not enough when participants ask you difficult questions that you may or may not be able to answer. The following contains appropriate answers to difficult questions that participants may ask. However, if you are unsure of how to respond to a participant's question, be familiar with other resources you can access or where to direct the participant (*e.g.,* Principal Investigator, physicians, etc.).

A. How was I chosen for this study? How did you get my name?

The answer to this question varies by network and/or clinic and the mode of recruitment. Some possible answers include:

1. *We received your name from the national registry.*
2. *Another study put us in contact with you.*
3. *Your child (or brother/sister) participated in another study with us, and now we would like to get his/her biological family's information.*

B. Will I be informed of the paternity for myself (or my sibling or my children)?

Although the Coordinating Center in Winston-Salem, North Carolina, United States of America, will know the paternity of you, your siblings, and your children, this information is not transmitted to the Regional Network Center or the clinics. I will not know this information nor can I obtain this information. Further, information at the Coordinating Center is stored only by participant ID; they will not know your name.

C. Why I am ineligible to participate in this study?

You do not meet the study criteria for a person with type 1 diabetes. I am not disagreeing with your doctor's opinion, but you do not meet the criteria for this study. If you have any questions about your diabetes, I will try to help or you can talk to your physician.

D. Why isn't my other sibling able to participate as well?

This particular study is only interested in the children that have type 1 diabetes, and only up to two children who do not have diabetes in a family are able to participate. Since this is a genetic study, we are able to obtain more information from those siblings that have type 1 diabetes than those who do not.

E. Who will receive my genetic information?

Clinics should have on hand a list of the Regional Network Center, regional laboratories, and the Coordinating Center so that it is readily available if a participant asks for this information. If the participant wants a verbal answer only, the following will probably satisfy his/her curiosity.

Your blood samples will go to two different laboratories, one for analysis and one for creation of a cell line. The results from the laboratory will be sent to the Coordinating Center in Winston-Salem, North Carolina, United States of America for analyses. The group of scientists who are participating in this study can apply to the Coordinating Center to obtain your information, although this does not always mean they will receive it. These scientists are kept from knowing your identity.

F. Why should I participate in this study?

You will be part of an important research program to help understand the causes of type 1 diabetes. This project is different from previous studies of genes related to type 1 diabetes because it is much larger and because we can now apply new tools to genetic analyses.

G. What happens if I decide not to participate or to withdraw?

Nothing will change. We will still continue to treat you to the best of our ability. Participation is strictly voluntary.

H. Can my cell line be used to clone me?

Copies of your blood cells will be made to make a marker in order to identify potential genes that may lead to type 1 diabetes. However, no one will use your DNA to make another person.

APPENDIX A
ASP CONSENT SUMMARY FORM:
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is completed as members of the family consent, assent, sign authorization, and/or refuse to be included in this study. In order for a family to be included, two affected siblings must consent to participate or parents consent to his/her participation in this study. As family members sign the *Informed Consent*, clinic staff assigns individual Participant ID Labels and records the appropriate information.

A child or a guardian can sign the *Informed Consent*. If the child is not old enough to consent for himself/herself, at least one guardian must sign the *Informed Consent*. Consult your local IRB or Ethics Committee for specific requirements. Assent is an agreement with a child who is not old enough to sign a consent form, stating that he/she is willing to participate in the study and understands what the study entails. This can be verbal or written. Certain IRBs or Ethics Committees may require both guardians to sign a consent form and the child to consent or assent. Written authorization is required in the United States **only**, and may be embedded within the *Informed consent*. However, any North American clinic and those clinics within Puerto Rico must have the "Consent and written authorization" or "Consent, assent and written authorization" box marked in order for a participant to enroll in the study.

If a non-essential family member (*i.e.,* either biological parent or either unaffected sibling) refuses or is not available, the question should not be completed.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first

box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950).

Question by Question Instructions

The interviewer affixes the Family ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

1. Proband (AS1)

This person **must** consent in order for the family to be included. Once he/she consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed and affix the Proband ID Label in the box.

The interviewer marks "Consent" if the proband or his/her guardian(s) signs the *Informed Consent*. The interviewer marks "Refused" if the proband does not want to participate in this study. This form is not completed further if "Refused" is marked, unless there is another affected child in the family. For some clinics, the guardian(s) must sign the *Informed Consent*, and the proband must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the proband is unable to be reached. This form is not completed further if "Not available" is marked, unless there is another affected child in the family.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the proband must assent to participation. Only one date is required.

2. Affected Sibling (AS2)

This person **must** consent in order for the family to be included. Once he/she consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed and affix the Affected Sibling ID Label in the box.

The interviewer marks "Consent" if the affected sibling or his/her guardian(s) signs the *Informed Consent*. The interviewer marks "Refused" if the affected sibling does not want to participate in this study. This form is not completed further if "Refused" is marked, unless there is another affected child in the family. For some clinics, the guardian(s) must sign the *Informed Consent*, and the affected sibling must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the affected sibling is unable to be reached. This form is not completed further if "Not available" is marked, unless there is another affected child in the family.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the affected sibling must assent to participation. Only one date is required.

3. Father (FA)

This person does not have to consent in order for the family to be included. If the father consents, provides written authorization and/or assent, mark the consent status box, record the date the *Informed Consent* is signed and affix the Father ID Label in the box.

The interviewer marks "Consent" if the father signs the *Informed Consent*. The interviewer marks "Refused" if the father does not want to participate in this study. If the father is not able to sign the *Informed Consent* himself, the child must sign the *Informed Consent* and the father must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the father is unable to be reached. If the father refuses or is not available, this question should not be completed.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both the father and a child must sign the *Informed Consent*. Only one date is required.

4. Mother (MO)

This person does not have to consent in order for the family to be included. If the mother consents, provides written authorization and/or assent, mark the consent status box, record the date the *Informed Consent* is signed and affix the Mother ID Label in the box.

The interviewer marks "Consent" if the mother signs the *Informed Consent*. The interviewer marks "Refused" if the mother does not want to participate in this study. If

the mother is not able to sign the *Informed Consent* herself, the child must sign the *Informed Consent* and the mother must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the mother is unable to be reached. If the mother refuses or is not available, this question should not be completed.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both the mother and a child must sign the *Informed Consent*. Only one date is required.

5-6. Unaffected Sibling (UN1 and UN2)

This person does not have to consent in order for the family to be included. If the unaffected sibling consents, provides written authorization and/or assent, mark the consent status box, record the date the *Informed Consent* is signed and affix the Unaffected Sibling ID Label in the box.

The interviewer marks "Consent" if the unaffected sibling or his/her guardian(s) signs the *Informed Consent*. The interviewer marks "Refused" if the unaffected sibling does not want to participate in this study. For some clinics, the guardian(s) must sign the *Informed Consent*, and the unaffected sibling must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The

interviewer marks “Not available” if the unaffected sibling is unable to be reached. If the unaffected sibling refuses or is not available, this question should not be completed.

Record the date the consent is signed in the appropriate boxes. Two date fields for “Date informed consent signed” are provided for cases in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the unaffected sibling must assent to participation. Only one date is required.

Questions 7-9 are used for recording information on additional siblings if the initial contacts refused, were unavailable or if additional affected siblings are participating in the study. In addition to marking consent status, recording the date the *Informed Consent* is signed and affixing the label, the interviewer marks whether this is an affected sibling or an unaffected sibling.

7-9. Other Sibling(s)

The interviewer records whether the participant is an affected or unaffected sibling. If this participant is an affected sibling, he/she must meet T1DGC criteria for type 1 diabetes as determined by the *T1DGC ASP Eligibility Form* or the *T1DGC ASP Application for Additional Sibling* (see **Chapter IV,** *Eligibility*). If the participant does not have diabetes, the interviewer marks unaffected sibling.

If the sibling consents, provides written authorization and/or assent, mark the consent status box, record the date the *Informed Consent* is signed and affix the Additional Sibling ID Label in the box.

The interviewer marks “Consent” if the sibling or his/her guardian(s) signs the *Informed Consent*. The interviewer marks “Refused” if the sibling does not want to participate in this study. For some clinics, the guardian(s) must sign the *Informed Consent*, and the sibling must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks “Consent and assent” in cases such as these. For clinics within the

United States, a *Written Authorization* must also be completed, and the interviewer marks “Consent and written authorization.” The interviewer marks “Consent, assent and written authorization” for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks “Not available” if the sibling is unable to be reached. If this is an extra additional affected sibling, and the affected sibling refuses, or is not available, this question should not be completed.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for “Date informed consent signed” are provided for cases in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the sibling must assent to participation. Only one date is required.

Questions 10-12 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing, after editing, and after no further family members are expected to come into the clinic).

10. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC ASP Consent Summary Form*.

11. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

12. Close-out Date

This portion is recorded when the clinic staff has obtained informed consent from one or more members of the family. This date is updated as new members of the family sign the informed consent. The date should always match the date the last family member consented. Record the close-out date in the appropriate boxes.

APPENDIX B
ASP EXAM FORM (PROBAND):
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the proband or to the proband's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). The proband is the first child diagnosed with type 1 diabetes in the family. Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single

digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the proband's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the proband. The secondary ID is "AS1" and it is recorded on every page.

1. Interview Date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Who is completing this form? PROBAND IS THE FIRST CHILD DIAGNOSED WITH TYPE 1 DIABETES. IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.

The interviewer marks "Proband" if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the proband. The interviewer may ask the participant his/her relationship to the child, if it is not already known. The interviewer marks "Biological Father" if the man completing the interview believes himself to be the biological father of the proband. The interviewer marks "Biological Mother" if the woman completing the interview gave birth to the proband. The interviewer marks "Other Guardian" if the person completing this form is neither biological parent of the proband. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the proband.

4. *(Your child's)* Gender

The participant responds by giving his/her, or the child's, gender.

5. What is your *(child's)* date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 6. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

6. What is your *(child's)* current age?

The participant responds by giving his/her current age, or that of the child, at the time of the interview. If the information is abstracted from other sources and transferred

onto this form, the interviewer determines the proband's current age. The proband's age is recorded in years.

7a. Are you *(Is your child)* Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself, or the child, to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 7b.

7b. Which of the following best describes your *(child's)* race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her, or the child's, race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her, or the child's race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she, or the child, most identifies with and records that choice in the first set of boxes with the word "Primary" beside it.

8. Do you *(Does your child)* have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she, or the child, has any of the diseases listed on the card. If the participant reports that the proband has any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If

the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If the participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark "Don't know."

9. At the time you were *(your child was)* diagnosed with diabetes, would you consider your *(his/her)* body size as thin, medium or heavy?

The participant recalls the size of his/her, or the child's, body at the time of diagnosis. This is a subjective measure and is up to the participant's perception of thin, medium and heavy. If the participant cannot recollect the proband's body size, mark the "Don't know" box, continue with the form.

Family History.

In this section we wish to obtain information about living and deceased members of your *(child's)* family. We are only interested in your *(child's)* biological relatives.

QUESTION 10 REFERS TO THE PROBAND'S CHILDREN.

10. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.

The participant responds "Yes" if he/she, or the child, has any biological children and continues to Question 10a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the proband is old enough to have children. The interviewer skips to Question 11. The interviewer marks "Question not asked" if the proband is not old enough to have children and the interviewer does not ask the question and skips to Question 11. If the participant does not know this information, but the proband is old enough to have children, mark the "Don't know" box and skip to Question 11.

10a. How many children do you *(does your child)* have?

The participant responds by giving the number of biological children he/she, or the child, has.

10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological children he/she or the child has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

10c. How many of them have another type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or the number for whom he/she is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

11. Is your *(child's)* biological mother participating in this study?

The participant answers "Yes" if the biological mother of the proband has been contacted and is interested in participating in this study. If the child's mother is participating, she will answer these questions on the *T1DGC ASP Exam Form (Parent Data from Source.* The interviewer skips to Question 12. If the participant answers "No" or "Don't know," continue to Question 11a.

QUESTIONS 11a-11c REFER TO THE PROBAND'S MATERNAL RELATIVES.

11a. Which of the following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1 diabetes, as defined by the T1DGC. If the participant answers "Don't know" to any of the questions, continue with the form.

11b. Which of the following biological relatives have been diagnosed with another type of diabetes?

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

11c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* mother's side?

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her mother's side. These are the biological mother's full siblings. Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 12. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 11c1.

11c1. How many full aunts and uncles on your *(child's)* mother's side do you *(does your child)* have?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side.

11c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

11c3. How many of them have another type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

11c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 11c2, 11c3, and 11c4 add up to the answer given in Question 11c1.

12. Is your *(child's)* biological father participating in this study?

The participant answers "Yes" if the biological father of the proband has been contacted and is interested in participating in this study. If the child's father is participating, he will answer these questions on the *T1DGC ASP Exam Form (Parent Data from Source);* the interviewer skips to Question 13. If the participant answers "No" or "Don't know," continue to Question 12a.

QUESTIONS 12a-12c REFER TO THE PROBAND'S PATERNAL RELATIVES.

12a. Which of the following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1 diabetes, as defined by the T1DGC. If the participant answers "Don't know" to any of the questions, continue with the form.

12b. Which of the following biological relatives have been diagnosed with another type of diabetes?

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

12c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* father's side?

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her father's side. These are the biological father's full siblings. Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 13. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 12c1.

12c1. How many full aunts and uncles on your *(child's)* father's side do you *(does your child)* have?

The participant responds by giving the number of biological aunts and uncles he/she or the child has, on his/her father's side.

12c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological aunts and uncles he/she or the child has, on his/her father's side who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

12c3. How many of them have another type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

12c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 12c2, 12c3, and 12c4 add up to the answer given in Question 12c1.

13. How many full brothers and sisters do you *(does your child)* have? Full brothers and sisters are those that have the same biological mother and same biological father.

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has. Both living and deceased brothers and sisters are included in this count. Step-siblings, adopted siblings and half siblings are not included. Any siblings participating in this study are included in this count. This number should always be equal to or exceed the number of siblings participating in the T1DGC.

13a. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC. This number should always be equal to or exceed the number of affected siblings participating in the T1DGC.

13b. How many of them have another type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

13c. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. This number should always be equal to or exceed the number of unaffected siblings participating in the T1DGC. The interviewer performs a quick check to be certain the answers to Questions 13a, 13b, and 13c add up to the answer given in Question 13.

14. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* mother?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her mother's side; the interviewer continues to Question 14a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 15.

14a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* mother?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side.

14b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

14c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

14d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 14b, 14c, and 14d add up to the answer given in Question 14a.

15. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* father?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her father's side; the interviewer continues to Question 15a. Both living

and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 16.

15a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* father?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side

15b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

15c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

15d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 15b, 15c, and 15d add up to the answer given in Question 15a.

16. Have you *(Has your child)* participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she, or the child, has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 16a. If the participant answers "No" or "Don't know," skip to Question 17.

16a. In which studies have you *(has your child)* participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she, or the child, has participated. The interviewer records up to five study codes that correspond with the study(ies) the proband has participated in.

Questions 17-18 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).

17. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC ASP Exam Form*.

18. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX C
ASP EXAM FORM (AFFECTED SIBLING):
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the affected sibling or to the affected sibling's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). The affected sibling is the second child diagnosed with type 1 diabetes in the family. This form is also completed for any additional affected siblings approved to participate. Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records the appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single

digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the affected sibling's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and is recorded on every page.

The interviewer records the secondary ID for the affected sibling. The secondary ID is "AS2" and it is recorded on every page. Any additional siblings have a secondary ID of "AS3," "AS4," or "AS5."

1. Interview Date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Who is completing this form? AFFECTED SIBLING IS THE SECOND CHILD DIAGNOSED WITH TYPE 1 DIABETES. IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.

The interviewer marks "Affected Sibling" if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the affected sibling. The interviewer may ask the participant his/her relationship to the child, if it is not already known. The interviewer marks "Biological Father" if the man completing the interview believes himself to be the biological father of the affected sibling. The interviewer marks "Biological Mother" if the woman completing the interview gave birth to the affected sibling. The interviewer marks "Other Guardian" if the person completing this form is neither biological parent of the affected sibling. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the affected sibling.

4. *(Your child's)* Gender

The participant responds by giving his/her, or the child's, gender.

5. What is your *(child's)* date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 6. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

6. What is your *(child's)* current age?

The participant responds by giving his/her current age, or that of the child, at the time of the interview. If the information is abstracted from other sources and transferred

onto this form, the interviewer determines the affected sibling's current age. The affected sibling's age is recorded in years.

7a. Are you *(Is your child)* Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself or the child, to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 7b.

7b. Which of the following best describes your *(child's)* race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her, or the child's, race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her, or the child's race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she, or the child, most identifies with and records that choice in the first set of boxes with the word "Primary" beside it.

8. Do you (Does your child) have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she, or the child, has any of the diseases listed on the card. If the participant reports that the affected sibling has any of the diseases, mark the appropriate box. Leave boxes blank for negative

answers. If the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If a participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark the "Don't know" box.

9. At the time you were *(your child was)* diagnosed with diabetes, would you consider your *(his/her)* body size as thin, medium or heavy?

The participant recalls the size of his/her, or the child's, body at the time of diagnosis. This is a subjective measure and it is up to the participant's perception of thin, medium and heavy. If the participant cannot recollect the affected sibling's body size, mark the "Don't know" box, continue with the form.

Family History.

In this section we wish to obtain information about all of your *(child's)* biological children.

QUESTION 10 REFERS TO THE AFFECTED SIBLING'S CHILDREN.

10. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.

The participant responds "Yes" if he/she, or the child, has any biological children and continues to Question 10a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the affected sibling is old enough to have children. The interviewer skips to Question 11. The interviewer marks "Question not asked" if the affected sibling is not old enough to have children and the interviewer does not ask the question, and skips to Question 11. If the participant does not know this information, but the affected sibling is old enough to have children, mark the "Don't know" box and skip to Question 11.

10a. How many children do you *(does your child)* have?

The participant responds by giving the number of biological children he/she, or the child, has.

10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological children he/she or the child has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

10c. How many of them have another type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

11. Have you *(Has your child)* participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she or the child has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 11a. If the participant answers "No" or "Don't know," skip to Question 12.

11a. In which studies have you *(has your child)* participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she, or the child, has participated. The interviewer records up to five study codes that correspond with the study(ies) the affected sibling has participated in.

Questions 12-13 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).

12. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC ASP Exam Form*.

13. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX D
ASP EXAM FORM (PARENT):
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to each biological parent of the proband and affected sibling. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed-up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the mother or father's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the mother or father. The secondary ID is "MO" for the mother and "FA" for the father. The secondary ID is recorded on every page.

1. Interview date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Gender

The participant responds by giving his/her gender.

4. What is your date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 5. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

5. What is your current age?

The participant responds by giving his/her current age at the time of the interview. If the information is abstracted from other sources and transferred onto this form, the interviewer determines the participant's current age. The participant's age is recorded in years.

6a. Are you Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 6b.

6b. Which of the following best describes your race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a

participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she most identifies with and records that choice in the first set of boxes with the word “Primary” beside it.

7. Have you been diagnosed with diabetes?

The participant answers “Yes” if they have been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers “No” or “Don’t know,” the interviewer skips to Question 12. If the participant answers “Don’t know,” continue with the form. If the participant answers “Yes,” continue with Question 8.

8. What type of diabetes do you have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers “Don’t know,” continue with the form.

9. At what age or on what date were you diagnosed with diabetes?

The participant gives the age he/she was when diagnosed with diabetes. If he/she cannot recall the age, an attempt is made to guess, or tell the interviewer the date of diagnosis. If only the year is known, that is acceptable. The participant’s age is recorded in years. If the participant was less than 1 year old, record “00.” If the participant has no recollection of his/her age at diagnosis or year of diagnosis, mark the “Don’t know” box and continue with the form.

10. Did you use insulin within six months of being diagnosed?

The participant answers “Yes” if insulin was used at any point during the first six months after he/she was diagnosed with diabetes. This excludes nasal or inhaled insulin. If the participant answers “Yes,” continue to Question 11. If the participant answers “No,” skip to Question 12.

11. Once you started using insulin, did you ever stop using insulin for a period of six months or more for reasons other than a pancreas transplant?

The participant answers "Yes" if insulin use was started but discontinued for 6 months or longer. More than one interruption is permitted if each is within the allotted time frame. If a participant has had a pancreas transplant and has stopped insulin use for more than 6 months because of the transplant, the participant answers "No." The participant answers "No" if insulin use was never disrupted after starting on insulin, or if any insulin was stopped for periods within 6 months.

12. Do you have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she has any of the diseases listed on the card. If the participant reports having any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If a participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark the "Don't know" box.

Family History.

In this section we wish to obtain information about living and deceased members of your family. We are only interested in your biological relatives.

13. Have any of the following biological relatives – mother, father, sister(s) or brother(s) – ever been diagnosed with diabetes?

The participant responds "Yes" if any member of his/her immediate family (*i.e.,* biological parents and/or full biological siblings) has been diagnosed with diabetes and continues to Question 14. If the participant responds "No" or "Don't know," skip to Question 17.

14. Does/did your biological mother have diabetes?

The participant responds "Yes" if his/her mother has been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers "No" or "Don't know," the interviewer skips to Question 15. If the participant answers "Yes," continue with Question 14a.

14a. What type of diabetes does/did she have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers "Don't know," continue with the form.

15. Does/did your biological father have diabetes?

The participant responds "Yes" if his/her father has been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers "No" or "Don't know," the interviewer skips to Question 16. If the participant answers "Yes," continue with Question 15a.

15a. What type of diabetes does/did he have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers "Don't know," continue with the form.

16. Do you have any full brothers/sisters? Full brothers and sisters are those that have the same biological mother and same biological father.

The participant responds "Yes" if he/she has any biological brothers and sisters and continues to Question 16a. Both living and deceased brothers and sisters are included. Step-siblings, adopted siblings and half siblings are not included. If the participant answers "No" or "Don't know," skip to Question 17.

16a. How many full brothers/sisters do you have?

The participant responds by giving the number of biological brothers and sisters he/she has.

16b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological brothers and sisters he/she has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

16c. How many of them have another type of diabetes?

The participant responds by giving the number of biological brothers and sisters diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

16d. How many of them are not affected or you don't know if they are affected?

The participant responds by giving the number of biological brothers and sisters he/she has without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 16b, 16c, and 16d add up to the answer given in Question 16a.

17. Have you participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 17a. If the participant answers "No" or "Don't know," skip to Question 18.

17a. In which studies have you participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she has participated. The interviewer records up to five study codes that correspond with the study(ies) he/she has participated in.

Questions 18-19 are directed toward clinic staff and are completed as the activity occurs *(i*.e., after interviewing and after editing).

18. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC ASP Exam Form*. .

19. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX E
ASP EXAM FORM (UNAFFECTED SIBING): QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the unaffected sibling or to the unaffected sibling's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). The unaffected sibling is a child not diagnosed with any form of diabetes. Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single

digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the unaffected sibling's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for the individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the unaffected sibling. The secondary ID is "UN1" or "UN2" and it is recorded on every page.

1. Interview Date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Who is completing this form? UNAFFECTED SIBLING IS A CHILD WHO HAS NOT BEEN DIAGNOSED WITH DIABETES. IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.

The interviewer marks "Unaffected Sibling" if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the unaffected sibling. The interviewer may ask the participant his/her relationship to the child, if it is not already known. The interviewer marks "Biological Father" if the man completing the interview believes himself to be the biological father of the unaffected sibling. The interviewer marks "Biological Mother" if the woman completing the interview gave birth to the unaffected sibling. The interviewer marks "Other Guardian" if the person completing this form is neither biological parent of the unaffected sibling. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the unaffected sibling.

4. *(Your child's)* Gender

The participant responds by giving his/her, or the child's, gender.

5. What is your *(child's)* date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 6. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

6. What is your *(child's)* current age?

The participant responds by giving his/her current age, or that of the child, at the time of the interview. If the information is abstracted from other sources and transferred

onto this form, the interviewer determines the unaffected sibling's current age. The unaffected sibling's age is recorded in years.

7a. Are you *(Is your child)* Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself or the child, to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 7b.

7b. Which of the following best describes your *(child's)* race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her, or the child's, race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her, or the child's race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she, or the child, most identifies with and records that choice in the first set of boxes with the word "Primary" beside it.

8. Have you (Has your child) ever been diagnosed with diabetes?

The participant answers "Yes" if he/she, or the child, has been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes, and MODY. If the participant answers "Yes" or "Don't know," stop completing this form; this participant is ineligible. If the participant answers "No," continue to Question 9.

9. Do you (Does your child) have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she, or the child, has any of the diseases listed on the card. If the participant reports that the unaffected sibling has any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If a participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark "Don't know."

Family History.

In this section we wish to obtain information about all of your *(child's)* biological children.

QUESTION 10 REFERS TO THE UNAFFECTED SIBLING'S CHILDREN.

10. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.

The participant responds "Yes" if he/she, or the child, has any biological children and continues to Question 10a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the unaffected sibling is old enough to have children. The interviewer skips to Question 11. The interviewer marks "Question not asked" if the unaffected sibling is not old enough to have children and the interviewer does not ask the question and skips to Question 11. If the participant does not know this information, but the unaffected sibling is old enough to have children, mark the "Don't know" box and skip to Question 11.

10a. How many children do you *(does your child)* have?

The participant responds by giving the number of biological children he/she, or the child, has.

10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with Type 1 diabetes, as defined by the T1DGC.

10c. How many of them have another type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

11. Have you *(Has your child)* participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she, or the child, has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 11a. If the participant answers "No" or "Don't know," skip to Question 12.

11a. In which studies have you *(has your child)* participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she, or the child, has participated. The interviewer records up to five study codes that correspond with the study(ies) the unaffected sibling has participated in.

Questions 12-13 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).

12. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC ASP Exam Form*.

13. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX F
TRIO CONSENT SUMMARY FORM:
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is completed as members of the family consent, assent, sign authorization, and/or refuse to be included in this study. In order for a family to be included, the proband and his/her biological parents must consent to participate. As family members sign the *Informed Consent*, clinic staff assigns individual Participant ID Labels and records the appropriate information.

A child or a guardian can sign the *Informed Consent*. If the child is not old enough to consent for himself/herself, at least one guardian must sign the *Informed Consent*. Consult your local IRB or Ethics Committee for specific requirements. Assent is an agreement with a child that is not old enough to sign a consent form, stating that he/she is willing to participate in the study and understands what the study entails. This can be verbal or written. Certain IRBs or Ethics Committees may require both guardians to sign a consent form and the child to consent or assent. Written authorization is required in the United States **only**, and may be embedded within the consent form. However, any North American clinic and those clinics within Puerto Rico must have the "Consent and written authorization" or "Consent, assent and written authorization" box marked in order for a participant to enroll in the study.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950).

Question by Question Instructions

The interviewer affixes the Family ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

1. Proband (AS1)

This person **must** consent in order for the family to be included. Once he/she consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed and affix the Proband ID Label in the box.

The interviewer marks "Consent" if the proband or his/her guardian(s) signs the *Informed Consent*. The interviewer marks "Refused" if the proband does not want to participate in this study. This form is not completed further if "Refused" is marked, unless there is another affected child in the family. For some clinics, the guardian(s) must sign the *Informed Consent*, and the proband must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the proband is unable to be reached. This form is not completed further if "Not available" is marked.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the proband must assent to participation. Only one date is required.

2. Father (FA)

This person **must** consent in order for the family to be included. Once he consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed and affix the Father ID Label in the box.

The interviewer marks "Consent" if the father signs the *Informed Consent*. The interviewer marks "Refused" if the father does not want to participate in this study. This form is not completed further if "Refused" is marked. If the father is not able to sign the *Informed Consent* himself, the child must sign the *Informed Consent* and the father must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the father is unable to be reached. This form is not completed further if "Not available" is marked.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both the father and a child must sign the *Informed Consent*. Only one date is required.

3. Mother (MO)

This person **must** consent in order for the family to be included. Once he consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed and affix the Mother ID Label in the box.

The interviewer marks "Consent" if the mother signs the *Informed Consent*. The interviewer marks "Refused" if the mother does not want to participate in this study. This form is not completed further if "Refused" is marked. If the mother is not able to sign the *Informed Consent* herself, the child must sign a consent form and the mother

must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating she understands what the study entails. The interviewer marks "Consent and assent" in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks "Consent and written authorization." The interviewer marks "Consent, assent and written authorization" for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained. The interviewer marks "Not available" if the mother is unable to be reached. This form is not completed further if "Not available" is marked.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for "Date informed consent signed" are provided for cases in which both the mother and a child must sign the *Informed Consent*. Only one date is required.

Questions 4-6 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing, after editing, and after no further family members are expected to come into the clinic).

4. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC Trio Consent Summary Form*.

5. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

6. Close-out Date

This portion is recorded when the clinic staff has obtained informed consent from one or more members of the family. This date is updated as new members of the family sign the informed consent. The date should always match the date the last family member consented. Record the close-out date in the appropriate boxes.

APPENDIX G
TRIO EXAM FORM (PROBAND):
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the proband or to the proband's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). The proband is a child diagnosed with type 1 diabetes in the family. Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed-up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the proband's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the proband. The secondary ID is "AS1" and it is recorded on every page.

1. Interview Date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Who is completing this form? IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.

The interviewer marks "Proband" if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the proband. The interviewer may ask the participant

his/her relationship to the child, if it is not already known. The interviewer marks "Biological Father" if the man completing the interview believes himself to be the biological father of the proband. The interviewer marks "Biological Mother" if the woman completing the interview gave birth to the proband. The interviewer marks "Other Guardian" if the person completing this form is neither biological parent of the proband. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the proband.

4. *(Your child's)* Gender

The participant responds by giving his/her, or the child's, gender.

5. What is your *(child's)* date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 6. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

6. What is your *(child's)* current age?

The participant responds by giving his/her current age, or that of the child, at the time of the interview. If the information is abstracted from other sources and transferred onto this form, the interviewer determines the proband's current age. The proband's age is recorded in years.

7a. Are you *(Is your child)* Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself, or the child, to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and

continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 7b.

7b. Which of the following best describes your *(child's)* race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her, or the child's, race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her, or the child's race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she, or the child, most identifies with and records that choice in the first set of boxes with the word "Primary" beside it.

8. Do you *(Does your child)* have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she, or the child, has any of the diseases listed on the card. If the participant reports that the proband has any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If a participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark "Don't know."

9. At the time you were *(your child was)* diagnosed with diabetes, would you consider your *(his/her)* body size as thin, medium or heavy?

The participant recalls the size of his/her, or the child's, body at the time of diagnosis. This is a subjective measure and is up to the participant's perception of thin, medium and heavy. If the participant cannot recollect the proband's body size, mark the "Don't know" box, continue with the form.

Family History.

In this section we wish to obtain information about living and deceased members of your *(child's)* family. We are only interested in your *(child's)* biological relatives.

QUESTION 10 REFERS TO THE PROBAND'S CHILDREN.

10. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.

The participant responds "Yes" if he/she, or the child, has any biological children and continues to Question 10a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the proband is old enough to have children. The interviewer skips to Question 11. The interviewer marks "Question not asked" if the proband is not old enough to have children and the interviewer does not ask the question and skips to Question 11. If the participant does not know this information, but the proband is old enough to have children, mark the "Don't know" box and skip to Question 11.

10a. How many children do you *(does your child)* have?

The participant responds by giving the number of biological children he/she, or the child, has.

10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

10c. How many of them have another type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

11. Do you have any full brothers/sisters? Full brothers and sisters are those that have the same biological mother and same biological father.

The participant responds "Yes" if he/she, or the child, has any full brothers and sisters and continues to Question 11a. Both living and deceased full brothers and sisters are included. Step-siblings, adopted siblings, and half-siblings are not included. If the participant answers "No" or "Don't know," skip to the Question 12.

11a. How many full brothers and sisters do you (does your child) have?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has.

11b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

11c. How many of them have another type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

11d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 11b, 11c, and 11d add up to the answer given in Question 11a.

12. Do you (Does your child) have any half siblings with the common parent being your (child's) mother?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her mother's side; the interviewer continues to Question 12a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 13.

12a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* mother?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side.

12b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

12c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

12d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 12b, 12c, and 12d add up to the answer given in Question 12a.

13. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* father?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her father's side; the interviewer continues to Question 13a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 14.

13a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* father?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side.

13b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

13c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on he/she father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

13d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on he/she father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 13b, 13c, and 13d add up to the answer given in Question 13a.

14. Have you *(Has your child)* participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she, or the child, has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer

continues with Question 14a. If the participant answers “No” or “Don’t know,” skip to Question 15.

14a. In which studies have you *(has your child)* participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she, or the child, has participated. The interviewer records up to five study codes that correspond with the study(ies) the proband has participated in.

Questions 15-16 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).

15. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC Trio Exam Form*.

16. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX H
TRIO EXAM FORM (PARENT):
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to each biological parent of the proband. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed-up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the mother or father's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The interviewer records the secondary ID for the mother or father. The secondary ID is "MO" for the mother and "FA" for the father. The secondary ID is recorded on every page.

1. Interview date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participants has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Gender

The participant responds by giving his/her gender.

4. What is your date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 5. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

5. What is your current age?

The participant responds by giving his/her current age at the time of the interview. If the information is abstracted from other sources and transferred onto this form, the interviewer determines the participant's current age. The participant's age is recorded in years.

6a. Are you Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 6b.

6b. Which of the following best describes your race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD PARTICIPANT'S RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a

participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she most identifies with and records that choice in the first set of boxes with the word “Primary” beside it.

7. Have you been diagnosed with diabetes?

The participant answers “Yes” if they have been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers “No” or “Don’t know,” the interviewer skips to Question 12. If the participant answers “Don’t know,” continue with the form. If the participant answers “Yes,” continue with Question 8.

8. What type of diabetes do you have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers “Don’t know,” continue with the form.

9. At what age or on what date were you diagnosed with diabetes?

The participant gives the age he/she was when diagnosed with diabetes. If he/she cannot recall his/her age, an attempt is made to guess, or tell the interviewer the date of diagnosis. If only the year is known, that is acceptable. The participant’s age is recorded in years. If the participant was less than 1 year old, record “00.” If the participant has no recollection of his/her age at diagnosis or year of diagnosis, mark the “Don’t know” box and continue with the form.

10. Did you use insulin within six months of being diagnosed?

The participant answers “Yes” if insulin was used at any point during the first six months after he/she was diagnosed with diabetes. This excludes nasal or inhaled insulin. If the participant answers “Yes,” continue to Question 11. If the participant answers “No,” skip to Question 12.

11. Once you started using insulin, did you ever stop using insulin for a period of six months or more for reasons other than a pancreas transplant?

The participant answers "Yes" if insulin use was started but discontinued for 6 months or longer. More than one interruption is permitted if each is within the allotted time frame. If a participant has had a pancreas transplant and has stopped insulin use for more than 6 months because of the transplant, the participant answers "No." The participant answers "No" if insulin use was never disrupted after starting on insulin, or if any insulin was stopped for periods within 6 months.

12. Do you have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she has any of the diseases listed on the card. If the participant reports having any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If the participant does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If a participant has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark "Don't know."

Family History.

In this section we wish to obtain information about living and deceased members of your family. We are only interested in your biological relatives.

13. Have any of the following biological relatives – mother, father, sister(s) or brother(s) – ever been diagnosed with diabetes?

The participant responds "Yes" if any member of his/her immediate family (*i.e.,* biological parents and/or full biological siblings) has been diagnosed with diabetes and continues to Question 14. If the participant responds "No" or "Don't know," skip to Question 17.

14. Does/did your biological mother have diabetes?

The participant responds "Yes" if his/her mother has been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers "No" or "Don't know," the interviewer skips to Question 15. If the participant answers "Yes," continue with Question 14a.

14a. What type of diabetes does/did she have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers "Don't know," continue with the form.

15. Does/did your biological father have diabetes?

The participant responds "Yes" if his/her father has been diagnosed with any form of diabetes. This includes, but is not limited to type 1 diabetes, type 2 diabetes and MODY. If the participant answers "No" or "Don't know," the interviewer skips to Question 16. If the participant answers "Yes," continue with Question 15a.

15a. What type of diabetes does/did he have?

The interviewer reads the entire list to the participant and marks all applicable answers. If the participant answers "Don't know," continue with the form.

16. Do you have any full brothers/sisters? Full brothers and sisters are those that have the same biological mother and same biological father.

The participant responds "Yes" if he/she has any biological brothers and sisters and continues to Question 16a. Both living and deceased brothers and sisters are included. Step-siblings, adopted siblings and half siblings are not included. If the participant answers "No" or "Don't know," skip to Question 17.

16a. How many full brothers/sisters do you have?

The participant responds by giving the number of biological brothers and sisters he/she has.

16b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological brothers and sisters he/she has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

16c. How many of them have another type of diabetes?

The participant responds by giving the number of his/her biological brothers and sisters diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

16d. How many of them are not affected or you don't know if they are affected?

The participant responds by giving the number of biological brothers and sisters he/she has without any form of diabetes, or is unsure of his/her diabetes status. The interviewer performs a quick check to be certain the answers to Questions 16b, 16c, and 16d add up to the answer given in Question 16a.

17. Have you participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 17a. If the participant answers "No" or "Don't know," skip to Question 18.

17a. In which studies have you participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she has participated. The interviewer records up to five study codes that correspond with the study(ies) he/she has participated in.

Questions 18-19 are directed toward clinic staff and are completed as the activity occurs *(i*.e., after interviewing and after editing).

18. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC Trio Exam Form*.

19. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX I
CONSENT RECORD (ADDENDUM TO LAYERED CONSENT): QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is completed at the time the case or control participant consent, assent, sign authorization, and/or refuse to be included in this study. In order for an individual to be included, the case or control must consent to participate.

A child or a guardian can sign the *Informed Consent*. If the child is not old enough to consent for himself/herself, at least one guardian must sign the *Informed Consent*. Consult your local IRB or Ethics Committee for specific requirements. Assent is an agreement with a child that is not old enough to sign a consent form, stating that he/she is willing to participate in the study and understands what the study entails. This can be verbal or written. Certain IRBs or Ethics Committees may require both guardians to sign a consent form and the child to consent or assent. Written authorization is required in the United States **only**, and may be embedded within the consent form. However, any North American clinic and those clinics within Puerto Rico must have the "Consent and written authorization" or "Consent, assent and written authorization" box marked in order for a participant to enroll in the study.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950).

Question by Question Instructions

The interviewer affixes the Participant ID Label in the box shown in the upper right hand corner.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center.

The interviewer records the secondary ID for the case or control. The secondary ID is “CAS” for the case and “CON” for the control.

This individual **must** consent in order to be included. Once he/she consents, provides written authorization and/or assents, mark the consent status box, record the date the *Informed Consent* is signed.

The interviewer marks “Consent” if the participant or his/her guardian(s) signs the *Informed Consent*. For some clinics, the guardian(s) must sign the *Informed Consent*, and the participant must either sign the *Informed Consent* or make a verbal agreement (*i.e.,* assent) stating he/she understands what the study entails. The interviewer marks “Consent and assent” in cases such as these. For clinics within the United States, a *Written Authorization* must also be completed, and the interviewer marks “Consent and written authorization.” The interviewer marks “Consent, assent and written authorization” for clinics within the United States where written authorization is required, the *Informed Consent* is signed and assent is obtained.

Record the date the *Informed Consent* is signed in the appropriate boxes. Two date fields for “Date informed consent signed” are provided for a situation in which both guardians must sign the *Informed Consent*, or where a guardian must sign the *Informed Consent* and the participant must assent to participation. Only one date is required.

APPENDIX J
CASE EXAM FORM
(CASE DATA FROM PARTICIPANT OR GUARDIAN)
QUESTION BY QUESTION INSTRUCTIONS

These instructions are meant to assist the interviewer and to provide answers to any questions from a participant or clinic staff member.

This form is administered to the case or to the case's guardian (*i.e.,* the biological mother, the biological father, or other legal guardian). Only one person is interviewed, although more than one can be present. The interviewer reads the questions to the participant and marks or records appropriate answers. For some questions the interviewer reads all the choices listed to the participant and marks affirmative responses.

Information in all capital letters is an instruction to the interviewer and is not read to the participant.

Please complete all parts of the form. Note that certain individual items may be marked "Don't know" and with an asterisk. In these cases, continue completing the form and contact the appropriate individuals within 10 days in order to collect information not known at the time of the initial exam. The participant may need to contact his/her physician or other family members in order to obtain information. Items should be followed-up, but forms should be forwarded to the Regional Network Center when it has become apparent that this information will not be found.

All dates are written as day first, month second, and year third. The day is recorded numerically. If the day is a single-digit number, a "0" is recorded in the first box. The month is written out in its entirety (*e.g.,* January, February). The year is recorded numerically, with all four digits of the year included (*e.g.,* 1950). Any single

digit numerical response is recorded with a leading "0" (*e.g.,* if participant is 5 years old, record "05").

Question by Question Instructions

The interviewer affixes the case's Participant ID Label in the box shown in the upper right hand corner. A label is affixed on every page.

The interviewer records the clinic ID for his/her individual clinic. This number is assigned by the Regional Network Center and it is recorded on every page.

The secondary ID for the case, "CAS", has already been recorded on each page of the Exam Form.

1. Interview Date

This is the date the interview takes place. Record the date of the interview in the appropriate boxes. For some clinics, the information on the form is abstracted from other sources and transferred onto this form. In this case, the interviewer records the date the information is abstracted and the form is completed. **This form should never be completed until the participant has signed the *Informed Consent*.**

2. How was this form completed? MARK ALL THAT APPLY.

The interviewer marks all sources from which information is gathered about the participant. If information is obtained by calling a participant before he/she comes into the clinic, mark "Phone interview." If the participant comes into the clinic and is interviewed in person, the interviewer marks "Face-to-face interview." If information is abstracted from other sources (*e.g.,* other forms, pulling medical records), the interviewer marks "From existing records." The interviewer marks all applicable answers.

3. Who is completing this form? CASE IS THE PERSON/CHILD DIAGNOSED WITH TYPE 1 DIABETES. IF GUARDIAN COMPLETING FORM, READ ITALICIZED TEXT. ONLY ONE GUARDIAN IS INTERVIEWED.

The interviewer marks "Case" if the participant is answering questions about himself/herself. If a guardian is answering the questions, the interviewer determines the relationship the guardian has with the case. The interviewer may ask the guardian his/her relationship to the child, if it is not already known. The interviewer marks "Biological Father" if the man completing the interview believes himself to be the biological father of the case. The interviewer marks "Biological Mother" if the woman completing the interview gave birth to the case. The interviewer marks "Other Guardian" if the guardian completing this form is neither biological parent of the case. Only one guardian answers the questions, however more than one guardian can be present at the interview. The interviewer should be aware of the relationship the guardian has to the child while administering this questionnaire. If the form is administered to the guardian, the italicized text in parentheses is read. Versions of questions may differ based upon the relationship to the case.

4. What is your *(child's)* gender?

The participant responds by giving his/her, or the child's, gender.

5. What is your *(child's)* date of birth?

Record the date of birth in the appropriate boxes. For some clinics, this information is considered an identifier and thus cannot be collected. In this case, the interviewer marks the "Can not collect" box, but must answer Question 6. If clinics are able to collect a portion of the date of birth, the year is recorded in the appropriate boxes.

6. What is your *(child's)* current age?

The participant responds by giving his/her current age, or that of the child, at the time of the interview. If the information is abstracted from other sources and transferred

onto this form, the interviewer determines the case's current age. The case's age is recorded in years.

7a. Are you *(Is your child)* Latino, Hispanic or of Spanish origin?

The participant answers "Yes" if he/she considers himself/herself, or the child, to be either Latino, Hispanic or of Spanish origin. For some clinics, this question is not asked (*e.g.,* Asia-Pacific). In this case, the interviewer marks "Not applicable" and continues with the form. **"Not applicable" is only marked when this question is not read to the participant.** Regardless of the answer to this question, the participant must answer Question 7b.

7b. Which of the following best describes your *(child's)* race (or ethnic origin)? HAND PARTICIPANT CUE CARD AND RECORD RESPONSES.

This question can be read differently depending on the clinic; either the word "race" or "ethnic origin" may be used due to cultural sensitivity. The interviewer hands (or reads) the participant the cue card containing a list of races (or ethnic origins) to choose from. The participant chooses up to three responses that best describe his/her, or the child's, race (or ethnic origin). If the participant does not feel that any race (or ethnic origin) describes his/her, or the child's race (or ethnic origin), the entire list found in Appendix L should be shown to the participant and choices should be made from this list. Record the appropriate code(s) in the boxes. At least one set of boxes must be completed. If a participant chooses more than one category, the interviewer asks which race (or ethnic origin) he/she, or the child, most identifies with and records that choice in the first set of boxes with the word "Primary" beside it.

8. Do you *(Does your child)* have any of the following diseases? HAND PARTICIPANT CUE CARD AND MARK ALL REPORTED RESPONSES.

The interviewer hands (or reads) the participant the cue card containing a list of diseases. The participant informs the interviewer whether he/she, or the child, has any of the diseases listed on the card. If the case reports that he/she or the child has any of the diseases, mark the appropriate box. Leave boxes blank for negative answers. If

the case does not have any of the medical conditions listed, mark the "None of the above" box. If the participant answers "Don't know," the interviewer continues with the form. If the case has one or more of the diseases, but does not know about another disease, mark the box beside the known disease(s). Do not mark "Don't know."

9. At the time you were *(your child was)* diagnosed with diabetes, would you consider your *(his/her)* body size as thin, medium or heavy?

The participant recalls the size of his/her body, or the child's body at the time of diagnosis. This is a subjective measure and is up to the participant's perception of thin, medium and heavy. If the participant cannot recollect the body size, mark the "Don't know" box, continue with the form.

Family History.

In this section we wish to obtain information about living and deceased members of your *(child's)* family. We are only interested in your *(child's)* biological relatives.

QUESTION 10 REFERS TO THE CASE'S CHILDREN.

10. Do you *(Does your child)* have any children? Exclude any adopted children or stepchildren.

The participant responds "Yes" if he/she, or the child has any biological children and continues to Question 10a. Both living and deceased children are included. Stepchildren and adopted children are not included. The participant responds "No" if he/she, or the child, does not have any children, but the case is old enough to have children. The interviewer skips to Question 11. The interviewer marks "Question not asked" if the case is not old enough to have children and the interviewer does not ask the question and skips to Question 11. If the participant does not know this information, but the case is old enough to have children, mark the "Don't know" box and skip to Question 11.

10a. How many children do you *(does your child)* have?

The participant responds by giving the number of biological children he/she, or the child, has.

10b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

10c. How many of them have another type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

10d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological children he/she, or the child, has without any form of diabetes, or is unsure of the children's diabetes status. The interviewer performs a quick check to be certain the answers to Questions 10b, 10c, and 10d add up to the answer given in Question 10a.

QUESTIONS 11a – 11c REFER TO THE CASE'S MATERNAL RELATIVES

11a. Which of the following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1

diabetes, as defined by the T1DGC. If the participant answers "Don't know" to any of the questions, continue with the form.

11b. Which of the following biological relatives have been diagnosed with another type of diabetes?

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

11c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* mother's side?

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her mother's side. These are the biological mother's full siblings. Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 12. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 11c1.

11c1. How many full aunts and uncles on your *(child's)* mother's side do you *(does your child)* have?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side.

11c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

11c3. How many of them have another type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

11c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 11c2, 11c3, and 11c4 add up to the answer given in Question 11c1.

QUESTIONS 12a – 12c REFER TO CASE'S PATERNAL RELATIVES

12a. Which of the following biological relatives have been diagnosed with type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The interviewer can expect a "Yes" or "No" answer to each choice. The participant only answers "Yes" if the family member has been diagnosed with type 1 diabetes, as defined by the T1DGC. If the participant or guardian answers "Don't know" to any of the questions, continue with the form.

12b. Which of the following biological relatives have been diagnosed with another type of diabetes?

The interviewer can expect a "Yes" or "No" answer to each choice. If the participant answers "Don't know" to any of the questions, continue with the form.

12c. Do you *(Does your child)* have any full aunts and uncles on your *(child's)* father's side?

The participant responds "Yes" if he/she, or the child, has any biological full aunts and uncles on his/her father's side. These are the biological father's full siblings. Both living and deceased aunts and uncles are included. Step-aunts, step-uncles, adopted aunts, adopted uncles, aunts-in-law and uncles-in-law are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 13. If the participant answers "Don't know," continue with the form. If the participant answers, "Yes," continue to Question 12c1.

12c1. How many full aunts and uncles on your *(child's)* father's side do you *(does your child)* have?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side.

12c2. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

12c3. How many of them have another type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

12c4. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological aunts and uncles he/she, or the child, has on his/her father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 12c2, 12c3, and 12c4 add up to the answer given in Question 12c1.

13. Do you (*Does your child)* have any full brothers and sisters? Full brothers and sisters are those that have the same biological mother and the same biological father.

The participant responds "Yes" if he/she, or the child, has any full brothers or sisters. Both living and deceased brothers and sisters are included. Step-siblings, adopted siblings and half-siblings are not included. If the participant answers "No" or "Don't know," the interviewer skips to Question 14. If the participant answers "Don't know," continue with the form. If the participant answers "Yes," continue to Question 13a.

13a. How many?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has. Both living and deceased brothers and sisters are included in this count. Step-siblings, adopted siblings and half siblings are not included.

13b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with type 1 diabetes, as defined by the T1DGC.

13c. How many of them have another type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

13d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of biological brothers and sisters he/she, or the child, has without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 13a, 13b, and 13c add up to the answer given in Question 13.

14. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* mother?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her mother's side; the interviewer continues to Question 14a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 15.

14a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* mother?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side.

14b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

14c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

14d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her mother's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 14b, 14c, and 14d add up to the answer given in Question 14a.

15. Do you *(Does your child)* have any half siblings with the common parent being your *(child's)* father?

The participant responds "Yes" if he/she, or the child, has any half brothers and sisters on his/her father's side; the interviewer continues to Question 15a. Both living and deceased half brothers and sisters are included. Step-siblings and adopted siblings are not included. If the participant answers "No" or "Don't know," skip to Question 16.

15a. How many half brothers and sisters do you *(does your child)* have with common parent being your *(child's)* father?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side

15b. How many of them have type 1 diabetes? That is, diagnosis before 35 years old, insulin use within 6 months of diagnosis without stopping for 6 months or more.

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side that have been diagnosed with type 1 diabetes, as defined by the T1DGC.

15c. How many of them have another type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side who have been diagnosed with a type of diabetes other than type 1 diabetes, or type 1 diabetes that does not meet the T1DGC definition.

15d. How many of them are not affected or you don't know if they are affected with any type of diabetes?

The participant responds by giving the number of half brothers and sisters he/she, or the child, has on his/her father's side without any form of diabetes, or the number for whom he/she is unsure of the diabetes status. The interviewer performs a quick check to be certain the answers to Questions 15b, 15c, and 15d add up to the answer given in Question 15a.

16. Have you *(Has your child)* participated in any of the following regional, national or international studies? READ/SHOW PARTICIPANT CUE CARD.

The interviewer hands (or reads) the participant the cue card listing previous and ongoing studies. The participant responds "Yes" if he/she, or the child, has participated in any of the studies on the cue card. If the participant answers "Yes," the interviewer continues with Question 16a. If the participant answers "No" or "Don't know," skip to Question 17.

16a. In which studies have you *(has your child)* participated? RECORD A MAXIMUM OF FIVE STUDY CODES.

The participant responds by giving the study names in which he/she, or the child, has participated. The interviewer records up to five study codes that correspond with the study(ies) in which the case has participated.

Questions 17-18 are directed toward clinic staff and are completed as the activity occurs (*i.e.,* after interviewing and after editing).

17. Interviewer ID

The interviewer records his/her five-digit assigned code in the appropriate boxes after completion of the *T1DGC Case Exam Form*.

18. ID of person editing

This is not completed until a clinic staff member reviews the form to ensure completion and accuracy. The person editing and reviewing the form records his/her five-digit assigned code in the appropriate boxes.

APPENDIX K
CUE CARDS

PLEASE TELL THE INTERVIEWER IF YOU OR ANY MEMBERS OF YOUR IMMEDIATE FAMILY HAVE PARTICIPATED IN ANY OF THE FOLLOWING GENETIC STUDIES.

T1DGC (Type 1 Diabetes Genetics Consortium)

HBDI (Human Biological Data Interchange)

BDA-Warren I (British Diabetes Association-Warren I)

SCAND (Scandinavia genome scan)

T1DGC Eligibility Form

PLEASE TELL THE INTERVIEWER IF YOU (OR YOUR CHILD) HAVE HAD ANY OF THE FOLLOWING GENETIC DISEASES OR DISORDERS DIAGNOSED.

Mitochondrial DNA 3243 mutation

Maturity onset diabetes of youth (MODY)

Type A insulin resistance

Leprechaunism

Rabson-Mendelhall syndrome

Lipoathrophic diabetes

Wolfram's Syndrome

T1/DGC Eligibility Form

READ THE BRIEF DESCRIPTION OF THE STUDY TO THE PARTICIPANT.

You are invited to participate in the Type 1 Diabetes Genetics Consortium. This is an international effort to identify genes that affect the risk of Type 1 (or juvenile) diabetes. Finding genes that contribute to Type 1 diabetes may help us better understand the causes of this disease and help develop strategies in disease prevention and treatment. We are looking for families in which at least two siblings have Type 1 diabetes. In these families, we would like the participation of the people with diabetes, other siblings without diabetes, and their biological parents. If you agree to be part of this study, eligible family members will be asked to come in for one visit to give some blood and complete a questionnaire about your health and your family. We will take about 3 tablespoons of blood from your arm, and process this sample so that DNA can be taken out, stored, and used for research. To allow more researchers to work with your blood, and so only one blood collection will be needed, we are requesting permission to produce and store a living cell line, which means we will keep some of your white blood cells alive for future research. By participating in this study, you will be part of an important research program to help understand the causes of Type 1 diabetes.

T1DGC Eligibility Form

PLEASE CHOOSE UP TO THREE RACES (OR ETHNIC ORIGINS) THAT BEST DESCRIBE YOU (*OR YOUR CHILD*). IF YOU SELECT MORE THAN ONE, PLEASE LET THE INTERVIEWER KNOW WITH WHICH RACE (OR ETHNIC ORIGIN) YOU MOST IDENTIFY WITH.

NETWORK SPECIFIC RACE/ETHNIC ORIGIN CODES FROM APPENDIX L

T1DGC Exam Form/T1DGC Control Eligibility Form

PLEASE READ THE ENTIRE LIST BELOW AND REPORT TO THE INTERVIEWER ANY AND ALL DISEASES THAT YOU (*OR YOUR CHILD*) HAVE HAD DIAGNOSED.

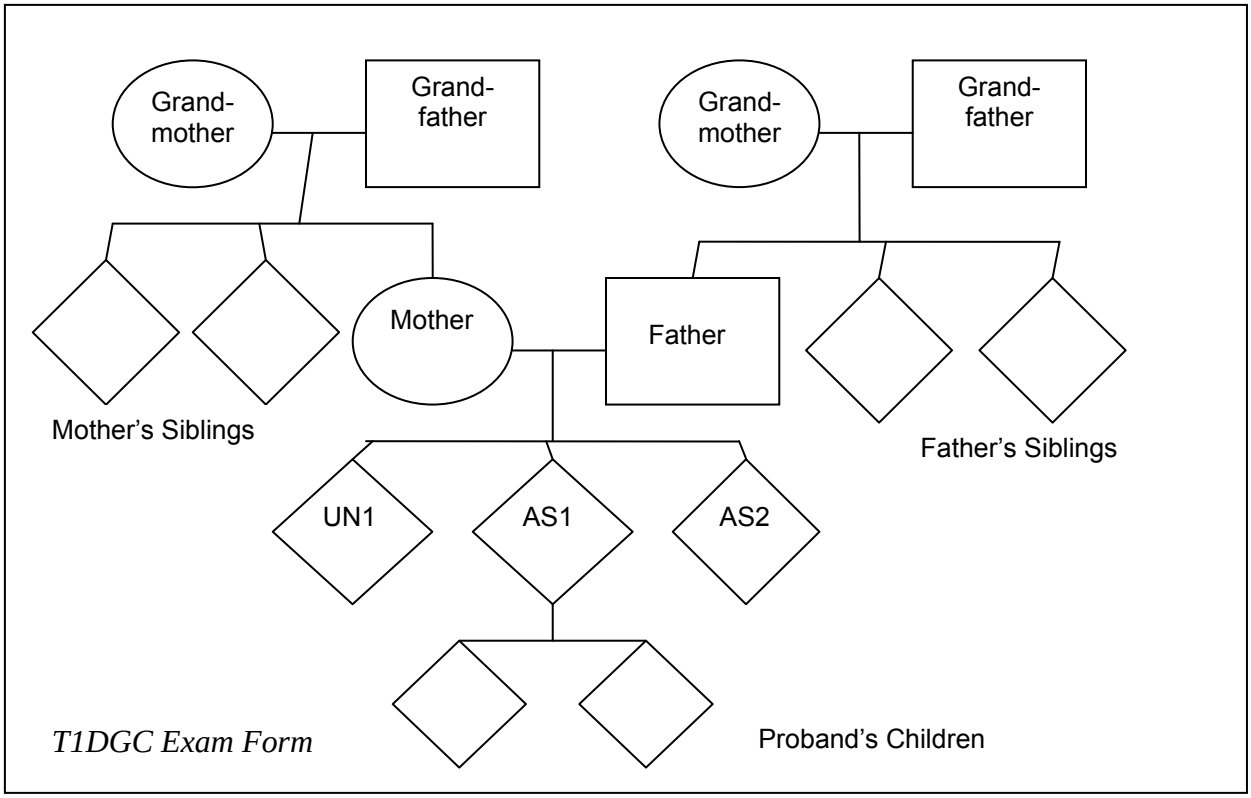
Multiple sclerosis
Celiac disease
Thyroid disease
Myasthenia gravis
Pernicious anemia
Lupus or SLE
Rheumatoid arthritis
Inflammatory Bowel Disease
Vitiligo
Addisons Disease
Psoriasis

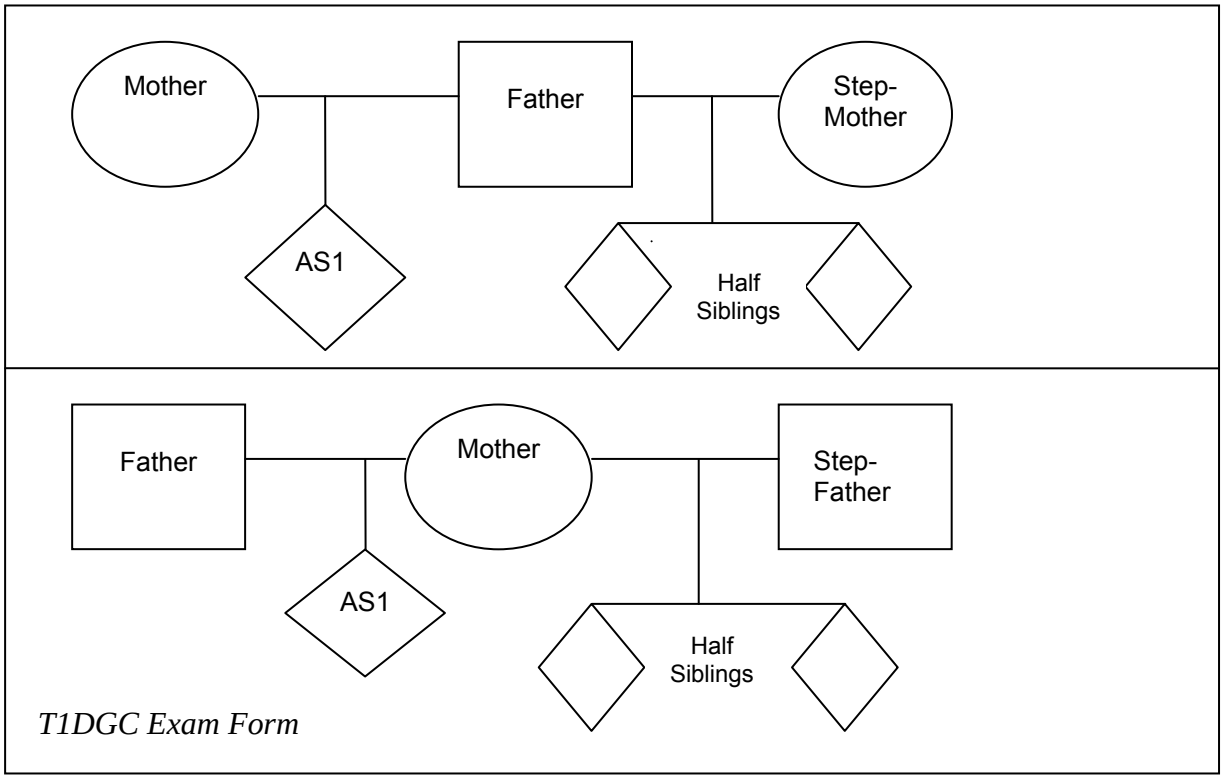
T1DGC Exam Form/T1DGC Control Eligibility Form

PLEASE LET THE INTERVIEWER KNOW IF YOU (OR YOUR CHILD) HAVE PARTICIPATED IN ANY OF THE FOLLOWING REGIONAL, NATIONAL, OR INTERNATIONAL STUDIES. PLEASE IDENTIFY ALL STUDIES IN WHICH YOU (*OR YOUR CHILD*) HAVE PARTICIPATED.

001 DPT-1
002 TrialNet
003 TEDDY
004 SEARCH
005 GoKinD
006 TRIGR
007 EDIC
008 FIND
009 ENDIT
010 PANDA
011 Australian Type 1 Diabetes Repository
012 EURODIAB TIGER
013 BOX (Bart's Oxford)

T1DGC Exam Form/T1DGC Control Eligibility Form


Grand-
mother
Grand-
father
Grand-
mother
Grand-
father
Mother
Father
Mother's Siblings
Father's Siblings
UN1
AS1
AS2
T1DGC Exam Form
Proband's Children


Mother
Father
Step-
Mother
AS1
Half
Siblings
Father
Mother
Step-
Father
AS1
Half
Siblings
T1DGC Exam Form

DEFINITION OF MEXICAN AMERICAN AND AFRICAN AMERICAN FOR TRIO AND CASE-CONTROL COLLECTIONS (**NORTH AMERICAN NETWORK ONLY**)

MEXICAN AMERICAN:

Any individual of **Mexican** descent living in North America (US or Canada). The proband, case or control does not need to be born in North America. While the primary goal of this collection is to ascertain Mexican American individuals, individuals can be recruited and examined if born in Central America: Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, or Panama.

AFRICAN AMERICAN:

Any individual of **non-Caucasian of African** descent living in North America (US or Canada). This includes (but is not limited to) descent from Egypt and Somalia. The proband, case or control does not need to be born in North America. No Caucasians of African descent qualify (*e.g.,* white South African) can be included as trio families or as cases or controls due to the sufficient number of Caucasian participants from previous collections.

T1DGC North American Trio Pre-Eligibility Form, Case and Control Eligibility Forms (North American Network only)

PLEASE CHOOSE THE REGION IN WHICH YOU (*YOUR CHILD)* LIVE OR THE TRIBE TO WHICH YOU (*YOUR CHILD)* BELONG.

ASIA/PACIFIC:

INDIA:

- 101 Odiya
- 102 Hindu
- 103 Muslim
- 104 Indian

EUROPEAN:

CAMEROON:

- 205 Western Highlanders (Semi-Bantu or grassfielders)
- 206 Coastal tropical forest peoples
- 207 Southern tropical forest people
- 208 Kirdis and Fulanis

T1DGC Exam Form/T1DGC Case and Control Eligibility Form (Asia/Pacific and European Network only)

APPENDIX L
CLASSIFICATION OF CULTURAL AND ETHNIC GROUPS

Oceanian

100 Oceanian, no further designation

Australian Peoples

110 Australian Peoples, no further designation

111 Australian

112 Australian Aboriginal

113 Australian South Sea Islander

114 Torres Strait Islander

New Zealand Peoples

120 New Zealand Peoples, no further designation

121 Maori

122 New Zealander

Melanesian and Papuan

130 Melanesian and Papuan, no further designation

131 New Caledonian

132 Ni-Vanuatu

133 Papua New Guinean

134 Solomon Islander

139 Melanesian and Papuan, not elsewhere classified (includes Bisorio, Bougainvillian, and Huli)

Micronesian

140 Micronesian, no further designation

141 I-Kiribati

142 Nauruan

149 Micronesian, not elsewhere classified (includes Marianas Islander, Marshallese, Palauan)

Polynesian

150 Polynesian, no further designation

151 Cook Islander

152 Fijian

153 Niuean

154 Samoan

155 Tongan

159 Polynesian, not elsewhere classified (includes Hawaiian, Pitcairn Islander, and Tahitian)

North-West European

200 North-West European, no further designation

British

210 British, no further designation

211 English

212 Scottish

213 Welsh

219 British, not elsewhere classified (includes Channel Islander, Guernsey Islander, and Manx)

Irish

221 Irish

Western European

230 Western European, no further designation

231 Austrian

232 Breton

233 Dutch

234 Flemish

235 French

236 German

237 Swiss

238 Walloon

239 Western European, not elsewhere classified (includes Alsatian, Frisian, and Luxembourgish)

Northern European

240 Northern European, no further designation

241 Danish

242 Finnish

243 Icelandic

244 Norwegian

245 Swedish

249 Northern European, not elsewhere classified (includes Faeroese, Greenlandic, and Saami)

Southern and Eastern European

300 Southern and Eastern European, no further designation

Southern European

310 Southern European, no further designation

311 Basque

312 Catalan

313 Italian

314 Maltese

315 Portuguese

316 Spanish

319 Southern European, not elsewhere classified (includes Andorran, Galician, and Ladin)

South Eastern European

320 South Eastern European, no further designation
321 Albanian
322 Bosnian
323 Bulgarian
324 Croatian
325 Greek
326 Macedonian
327 Moldovan
328 Montenegrin
341 Romanian
342 Roma/Gypsy
343 Serbian
344 Slovene
329 South Eastern European, not elsewhere classified (includes Aromani, Karakachani, and Vlach)

Eastern European

330 Eastern European, no further designation
331 Belarusan
332 Czech
333 Estonian
334 Hungarian
335 Latvian
336 Lithuanian
337 Polish
338 Russian
351 Slovak
352 Ukrainian
339 Eastern European, not elsewhere classified (includes Adygei, Khanty, and Sorb/Wend)

North African and Middle Eastern

400 North African and Middle Eastern, no further designation

Arab

410 Arab, no further designation
411 Algerian
412 Egyptian
413 Iraqi
414 Jordanian
415 Kuwaiti
416 Lebanese
417 Libyan
418 Moroccan
431 Palestinian
432 Saudi Arabian
433 Syrian
434 Tunisian
419 Arab, not elsewhere classified (includes Baggara, Bedouin, and Yemeni)

Jewish

421 Jewish

Other North African and Middle Eastern

490 Other North African and Middle Eastern, no further designation
491 Assyrian/Chaldean
492 Berber
493 Coptic
494 Iranian
495 Kurdish
496 Sudanese

497 Turkish

499 Other North African and Middle Eastern, not elsewhere classified (includes Azande, Beja, and Nubian)

South-East Asian

500 South-East Asian, no further designation

Mainland South-East Asian

510 Mainland South-East Asian, no further designation

511 Anglo-Burmese

512 Burmese

513 Hmong

514 Khmer

515 Lao

516 Thai

517 Vietnamese

519 Mainland South-East Asian, not elsewhere classified (includes Arakanese, Karen, and Mon)

Maritime South-East Asian

520 Maritime South-East Asian, no further designation

521 Filipino

522 Indonesian

523 Javanese

524 Madurese

525 Malay

526 Sundanese

527 Timorese

529 Maritime South-East Asian, not elsewhere classified (includes Balinese, Irian Jayan, and Sumatran)

North-East Asian

600 North-East Asian, no further designation

Chinese Asian

610 Chinese Asian, no further designation

611 Chinese

612 Taiwanese

619 Chinese Asian, not elsewhere classified (includes Hui, Manchu, and Yi)

Other North-East Asian

690 Other North-East Asian, no further designation

691 Japanese

692 Korean

693 Mongolian

694 Tibetan

699 Other North-East Asian, not elsewhere classified (includes Ainu, Menba, and Xiareba)

Southern and Central Asian

700 Southern and Central Asian, no further designation

Southern Asian

710 Southern Asian, no further designation

711 Anglo-Indian

712 Bengali

713 Burgher

714 Gujarati

715 Gurkha

716 Indian

717 Malayali

718 Marathi

731 Nepalese

732 Pakistani

733 Punjabi

734 Sikh

735 Sinhalese

736 Tamil

719 Southern Asian, not elsewhere classified (includes Bhote, Kashmiri, and Sherpa)

Central Asian

720 Central Asian, no further designation

721 Afghan

722 Armenian

723 Georgian

724 Kazakh

725 Pathan

726 Uzbek

729 Central Asian, not elsewhere classified (includes Azerbaijani, Chechen, and Tatar)

People of the Americas

800 People of the Americas, no further designation

North American

810 North American, no further designation

811 African American

812 American Caucasian

813 Canadian

814 French Canadian

815 Native North American Indian

816 Mexican American

819 North American, not elsewhere classified (includes Bermudan, Inuit, and Metis)

South American

820 South American, no further designation
821 Argentinian
822 Bolivian
823 Brazilian
824 Chilean
825 Colombian
826 Ecuadorian
827 Guyanese
828 Peruvian
851 Uruguayan
852 Venezuelan
829 South American, not elsewhere classified (includes Arawak, Carib, and Surinamese)

Central American

830 Central American, no further designation
831 Mexican
832 Nicaraguan
833 Salvadoran
839 Central American, not elsewhere classified (includes Belizean, Costa Rican, and Mayan)

Caribbean Islander

840 Caribbean, no further designation
841 Cuban
842 Jamaican
843 Trinidadian (Tobagonian)
849 Caribbean Islander, not elsewhere classified (includes Bahamian, Haitian, and Puerto Rican)

Sub-Saharan African

900 Sub-Saharan African, no further designation

Central and West African

910 Central and West African, no further designation
911 Akan
912 Fulani
913 Ghanaian
914 Nigerian
915 Yoruba
919 Central and West African, not elsewhere classified (includes Fang, Kongo, and Liberian)

Southern and East African

920 Southern and East African, no further designation
921 Afrikaner
922 Angolan
923 Eritrean
924 Ethiopian
925 Kenyan
926 Malawian
927 Mauritian
928 Mozambican
931 Namibian
932 Oromo
933 Seychellois
934 Somali
935 South African
936 Tanzanian
937 Ugandan
938 Zambian

941 Zimbabwean

929 Southern and East African, not elsewhere classified (includes Afar, Tutsi, and Zulu)

Other

998 Refused to Answer

999 Don’t Know