

**INSTRUCTIONS:**

At least one family member or close friend should be requested to attend a clinic visit with the subject as early in the staging process as possible. If this is not possible, a telephone interview may be substituted. The study coordinator will interview all family members or friends who accompany the subject to the clinic. THE SUBJECT SHOULD NOT BE PRESENT DURING THIS INTERVIEW WITH HIS/HER FAMILY OR FRIENDS. The interview should be conducted after the family/friend has had an opportunity to view the DPT-1 videotape, read the Research Volunteer's Handbook, and/or discuss the study with the volunteer and the clinic team. It is suggested that the visit during which the complete IVGTT is to be performed might be an appropriate time. [Note: This interview should be conducted by a different parent than the one who completed the Volunteer's Understanding and Expectations Interview (Form VU) if completed for a child less than age 13.]

This interview should be done orally. The interview can be administered during the clinic visit or conducted over the phone, as early in the staging process as possible. This is not intended to be a self-administered interview as the purpose of this interview is to stimulate questions and discussion. Care should be taken NOT TO LEAD THE INTERVIEWEE. Frank and honest answers should be elicited; however, attention should be given to correcting misunderstandings regarding the study. Following completion of the interview, the information should be reviewed with the Principal Investigator, for it could suggest that the subject's compliance may be influenced due to attitudes of family/friends.

SEND COMPLETED COPIES OF THESE INTERVIEW FORMS TO THE DMU IN THE WEEKLY MAILING.

Clinical Center or Affiliate Name: \_\_\_\_\_ Clinical Center ID# \_\_\_\_\_

Name of person completing form (please print): \_\_\_\_\_

**SUBJECT INFORMATION:**

Subject ID #:         Subject Initials:    Date of Interview:   /   /    
F M L M M D D Y Y

**INTERVIEWEE INFORMATION:**

1. Friend/Family member interviewed:

- |  |  |
|--|--|
| <input type="checkbox"/> Subject's father<br><input type="checkbox"/> Subject's mother<br><input type="checkbox"/> Subject's guardian<br><input type="checkbox"/> Subject's spouse | <input type="checkbox"/> Subject's sibling<br><input type="checkbox"/> Subject's child<br><input type="checkbox"/> Subject's other relative, specify relationship _____<br><input type="checkbox"/> Subject's friend |
|--|--|

2. What type of regular contact does this person have with the subject?

- Sees or visits with subject daily  
 Speaks with subject daily, but no other contact  
 Sees or visits with subject weekly  
 Speaks with subject weekly, but no other contact  
 Other less regular contact, describe: \_\_\_\_\_

F	U
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<b>DMU Use Only</b>
Date rcvd: _____

3. Who does the subject live with on a regular basis?

- |  |  |
|--|--|
| <input type="checkbox"/> parents           | <input type="checkbox"/> spouse                |
| <input type="checkbox"/> mother only       | <input type="checkbox"/> spouse and children   |
| <input type="checkbox"/> father only       | <input type="checkbox"/> children              |
| <input type="checkbox"/> other relative    | <input type="checkbox"/> alone                 |
| <input type="checkbox"/> friends/roommates | <input type="checkbox"/> other, specify: _____ |

### INTERVIEW:

1. Can you tell me what you understand the purpose of the DPT-1 to be?

*[The person should state something to the extent that the study will compare the efficacy of insulin in preventing the onset of IDDM.]*

Rate their understanding:  Good  Fair  Poor  Unsure

2. These tests are to determine your risk of developing diabetes.

(a) If (name) is in the “intermediate risk” group, he/she will be eligible for the \_\_\_\_\_ trial.  
*[The person should answer the oral insulin trial.]*

Rate their response:  Correct  Incorrect  Unsure

(b) If (name) is in the “high risk” group, he/she will be eligible for the \_\_\_\_\_ trial.  
*[The person should answer the insulin injection trial.]*

Rate their response:  Correct  Incorrect  Unsure

3. The Insulin Injection Trial is an unmasked, controlled, randomized clinical trial. What are the names (or can you describe) the two treatment groups in the trial?

*[The person should be able to explain that there are two different treatment groups: One that receives the “Experimental” insulin treatment and the other which does not receive any insulin treatment, but is “Closely Monitored.”]*

Rate their understanding:  Good  Fair  Poor  Unsure

4. (a) Can you tell me how insulin will be used in the Experimental Treatment Group of the Insulin Injection trial?

*[The person should state that Experimental Treatment consists of twice daily injections of insulin and insulin given in the hospital for four days every year.]*

Rate their understanding:  Good  Fair  Poor  Unsure

(b) Can you tell me how the medication (insulin crystals or placebo) will be used in the Oral Insulin Trial?  
[The person should state that a capsule containing insulin crystals or placebo will be taken once daily.]

Rate their understanding:  Good  Fair  Poor  Unsure

5. Can you tell me what is meant by randomization?

[The person should state that randomization is the process that will be used to assign the subject to a treatment group. There is a 50% chance of being assigned to either of the two groups.]

Rate their understanding:  Good  Fair  Poor  Unsure

6. (a) Do you have a strong preference for (name) being assigned to one trial over the other? If so, which do you prefer and why?

- No strong preference.
- Yes, strong preference for Insulin Injection Trial.
- Yes, strong preference for Oral Insulin Trial.

Reason for preference: \_\_\_\_\_

(b) Do you have a strong preference for (name) being assigned to one treatment group over the other in the Insulin Injection Trial? If so, which do you prefer, and why?

- No strong preference.
- Yes, strong preference for the Closely Monitored Group.
- Yes, strong preference for Experimental Group.

Reason for preference: \_\_\_\_\_

7. Would you be willing to support the decision of (name) to be randomized into either of the treatment groups and to adhere to the assigned treatment group for the duration of the study?

- No
- Yes
- Unsure

8. If (name) is enrolled in either DPT-1 trial, how often will he/she need to come in to the clinic for routine follow-up appointments?

[The person should state that routine follow-up visits will occur every six months.]

Rate their response:  Overestimate  Accurate Answer  Underestimate

9. If (name) is assigned to the Experimental Group of the Insulin Injection Trial, he/she will need to spend 4-5 days in the hospital right away. After this, how often will he/she need to be hospitalized?

[The person should state that hospitalization will occur once a year]

Rate their response:  Overestimate  Accurate Answer  Underestimate

10. Do you realize that sometimes (name) may have to give priority to this study, causing other family members and friends to change plans? Do you think this will cause problems?

Rate their response:

- They appear to understand the issues involved but do not believe that they will experience problems.
- They appear to understand the issues and agree that problems may arise.
- They do not appear to understand the issues.
- They do not think that they can deal with the problems.

11. Do you understand that (name) may have some expenses for transportation, telephoning the clinic (if long distance), or hiring a baby-sitter? Do you think this will cause problems because these expenses cannot be reimbursed?

Rate their response:

- They understand the issues but do not believe they will experience undue hardship.
- They believe this will cause significant problems.
- They do not appear to understand the issues.

12. Do you understand that (name) may need to miss school or work days in order to keep clinic appointments? Do you think this will cause problems?

Rate their response:

- They understand the issues involved but do not believe that they will experience undue hardship.
- They understand the issues involved and believe that a considerable amount of inconvenience may result.
- They do not appear to understand the issues and that problems may arise.

13. How do you feel about (name) performing blood glucose monitoring at home, which will have to be done five times per day once every 3 months? Would you have problems with him/her doing this?

Would not have a problem  Would have a problem  Unsure

14. Are there any circumstances in (name)'s family life, school life, work situation, etc. that could affect his/her participation in any aspect of this trial?

Yes  No If yes, describe \_\_\_\_\_

15. Have you spoken with friends or family members about (name) enrolling in the DPT-1?

- Yes  No

If yes, who have you spoken with?

- parents  other relative  
 mother only  friends/roommates  
 father only  spouse  
 children  other, specify \_\_\_\_\_

16. Family members often have differences of opinion about the DPT-1. How about your family?

- Yes  No

If yes, describe the conflict:

- Some disagreement but the family is working it out.  
 Serious disagreement between family members that needs to be followed by the DPT-1 Staff; describe:

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