

# **Diabetes Prevention Trial - Type 1**

## **VOLUNTEER'S PRE-RANDOMIZATION STUDY QUIZ**

### **INSTRUCTIONS:**

This form is to be completed prior to obtaining Consent for Randomization. It is suggested that this quiz be given at the visit in which the OGTT is performed. Alternatively, it may be administered over the telephone or by mail. This quiz MAY NOT be given, however, until after the subject has had the opportunity to read and discuss the Volunteer's Handbook with the clinic staff and complete the Expectations and Understanding Interview. For subjects under 13 years of age, parents should complete the quiz.

Subjects should be given Pages 1-3 for completion. All questions should be answered in Section A (Insulin Injection Trial) and Section B (Oral Insulin Trial) since eligibility into either trial is not known until results of the OGTT become available.

The subject should:

1. Be given a pencil with an eraser with which to complete the form.
2. Complete the form himself/herself without help from another person and without looking at the Research Volunteer's Information Handbook.
3. Be allowed as much time as he/she needs to complete the form.

When the individual has completed the quiz, review the questions with him/her to clarify any items to which an incorrect answer was given. DO NOT change any of the responses which the subject gave, however.

If you feel that the person would benefit from viewing the orientation videotape again or by re-reading the Handbook, encourage him/her to do so, and again, inform the individual that he/she should ask for clarification of any point he or she does not understand. The results should be reviewed with the principal investigator to assist in determining the suitability of the volunteer for participation in the DPT-1.

**If the subject answers "NO" to question # 6 in Section A or B, he/she cannot be randomized.**

MAIL THE QUESTIONNAIRE TO THE DMU. RETAIN A COPY FOR YOUR FILES.

# VOLUNTEER'S PRE-RANDOMIZATION STUDY QUIZ

## SUBJECT INFORMATION:

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

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

## INSTRUCTIONS TO THE RESEARCH VOLUNTEER

The Volunteer's Understanding Quiz is based on the Research Volunteer's Information Handbook. The purpose of the questionnaire is to be sure that you understand essential information about this study before you consent to participate. After you complete this quiz, the study team will go over your answers with you and discuss any that are incorrect.

You should place an X or check on the line next to the best answer(s) to each question. You may take as much time as you wish to answer these questions.

## QUIZ

- One reason for doing this study is to see:
  - If people who already have diabetes can be cured by a new treatment.
  - If giving insulin before diabetes starts will keep a person from getting diabetes.
  - If testing blood sugars using a machine is better than testing urine for sugar.
  - I don't know a reason for doing this study.
- If I am enrolled in the study, I will have to come to the DPT-1 Clinical Center twice a year for:
  - Up to two years.
  - Up to three years.
  - Up to six years.
  - I don't know.
- If I agree to participate in this study, I will have to (check all that apply):
  - Choose which group I want to be assigned to.
  - Stay in the treatment group I am assigned to until the study ends.
  - Keep all appointments in the clinic.
  - I don't know.
- If I am enrolled in either trial, I will make visits to a DPT-1 center:
  - Every month.
  - Every three months.
  - Every six months.
  - Every twelve months.
  - I don't know.

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DMU Use Only
Date rcvd:

## Section A - Insulin Injection Trial Pre-Randomization Quiz

- Random assignment means that:

- I have about the same chance of getting in the Experimental Treatment Group as I have of getting in the Closely Monitored Group.
  - I can choose which treatment group I want to be in.
  - The doctor decides which group I will be in.
  - I will be put in the treatment group that is best for me to be in.
  - I don't know what randomization means.
2. If I am in the Closely Monitored Group I will be expected to (check all that apply):
- Do daily blood glucose tests.
  - Give myself shots of insulin every day.
  - Do blood sugar tests at home, five times per day, once every three months.
  - Follow a special diet.
  - I don't know what people in the Closely Monitored Group will do.
3. If I am in the Experimental Treatment Group I will be expected to (check all that apply):
- Take two shots of insulin every day and do blood sugar testing five times a day every three months.
  - Follow a special diet.
  - Adjust insulin doses to fit meals and exercise.
  - Return all used and unused bottles of insulin to the DPT-1 Clinic every six months.
  - Take two insulin shots every day and go to the hospital every year for four days.
  - I don't know what people in the Experimental Group will do.
4. Being in the Closely Monitored Group, compared to being in the Experimental Treatment Group, will:
- Make my risk of getting diabetes greater.
  - Make my risk of having high blood sugars greater.
  - Make my risk of having low blood sugars greater.
  - Do none of the above.
5. If I am in the Experimental Treatment Group, I will be hospitalized for IV insulin infusion (insulin put into my vein):
- Not at all.
  - One or two days every six months.
  - Four days once a year.
  - I don't know.
6. If I participate in the study I would be willing to accept random assignment to either treatment group.
- Yes
  - No
  - I don't know

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### Section B - Oral Insulin Trial Pre-Randomization Quiz

1. Random assignment means that:
- I have about the same chance of getting the capsule with the insulin crystals as I have of getting the capsule that contains no insulin crystals (placebo).
  - I can choose which pill I want to receive.

- The doctor decides which pill I will get.
  - I will be given the pill that is best for me.
  - I don't know what randomization means.
2. A "double masked" or "double blind" clinical trial means (check all that apply):
- I will get to choose the medication I take.
  - I will have the same chance of being given the insulin capsule or the placebo capsule.
  - I will not know which capsule I take and my doctor will not know which capsule I take.
  - Everyone in the trial will take one capsule (either insulin or placebo) everyday.
  - I don't know.
3. Researchers feel that taking Oral Insulin may be helpful in preventing or delaying the onset of Type 1 diabetes because:
- Insulin taken by mouth may help lower the blood sugars and the pancreas won't have to work so hard.
  - Taking insulin by mouth may help to "retrain" the immune system to stop its attack on insulin producing cells (beta cells).
  - I don't know.
4. If I participate in the Oral Insulin Trial I will be expected to (check all that apply):
- Report any suspected side effects related to taking the capsule to my DPT-1 Clinic.
  - Test my blood glucose at home 5 times in one day every three months.
  - Return used bottles of medication to my DPT-1 Clinic at my 6 month visits.
  - Follow a special diet.
  - I don't know.
5. Taking Oral Insulin will have the following side effects (check all that apply):
- There are currently no known side effects.
  - Oral Insulin may cause low blood sugars just like injected insulin.
  - I don't know.
6. If I participate in the trial I would be willing to accept random assignment to either oral insulin or placebo, taking one capsule daily.
- Yes
  - No
  - I don't know