

ORAL GLUCOSE TOLERANCE SCREENING FORM (GTSB Screen 2 of 3)

5. Are you on kidney dialysis? Yes Y
No N

[IF Item 5 IS "YES", EXCLUDE
and SKIP TO EXCLUSION STATEMENT.]

EXCLUSION STATEMENT

Because you (SELECT THE RELEVANT STATEMENT BELOW)

- are taking medication to control diabetes,
- have not been able to fast for 10 hours,
- have had part of your stomach removed,
- are on kidney dialysis,

it may not be useful or safe for you to participate
in this portion of the study.

GO TO ITEM 7

ORAL GLUCOSE TOLERANCE SCREENING FORM (GTSB Screen 3 of 3)

6. Are you willing to participate
in the glucose tolerance test? Yes Y
No N

7. Date of data collection:

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m m / d d / y y

8. Method of data collection: Computer C
Paper P

9. Code number of person completing
this form:

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INSTRUCTIONS FOR THE ORAL GLUCOSE TOLERANCE SCREENING FORM
GTS, VERSION B, 05/08/96
PREPARED 04/09/97

I. GENERAL INSTRUCTIONS

The participant's eligibility and willingness to participate in the oral glucose tolerance test (OGTT) is determined during reception. Include the following in your description of ARIC procedures.

"As we explained earlier, we have added a new test to detect diabetes even in people who have no symptoms. This is the oral glucose tolerance test. You drink 10 oz. of a flavored beverage that contains glucose, a type of sugar that is rapidly absorbed, and then we draw a small amount of blood after 2 hours to see how well your body handles sugar. The results will be included in the final report to you and your physician. This test has been modified in recent years so that few people today ever have any discomfort after drinking the glucola. Before you decide whether you do this, I need to ask you a few questions."

ADMINISTER THE FASTING FORM and then ADMINISTER THE OGTT SCREENING FORM

Review the PIN Sheet to determine whether the participant was being treated for diabetes at Visit 3. These persons are ineligible to participate in the OGTT. The appropriate exclusion statement is read to the participant and the OGTT Screening Form completed accordingly. Indicate on the Itinerary Form that the participant is ineligible for OGTT. Participants not treated for diabetes at Visit 3 are asked if they are currently taking medication to control diabetes or high blood sugar. These medications include insulin or oral hypoglycemics. The medications brought in to the field center are reviewed while the participant changes clothes. The appropriate exclusion statement is read to participants and the OGTT Screening Form is filled out accordingly. Indicate on the Itinerary Form that the participant is ineligible for OGTT.

If the participant will have fasted for LESS THAN 10 HOURS by the time glucose would be given after venipuncture, read the appropriate exclusion statement to the participant, and complete the administrative items. Indicate on the Itinerary Form that the participant is ineligible for OGTT. Note, the actual fasting status for OGTT will be calculated from the fasting time recorded on the Fasting/Tracking form and the time at which the glucose was administered recorded on the Oral Glucose Tolerance Administration form.

If the participant is eligible and agrees to participate, complete the administrative items and continue by saying:

"Thank you. The amount of sugar in the beverage you drink will break your fast and should keep you from feeling hungry. After you have your second blood work drawn, we will serve you a snack. However, please tell us if you feel faint or uncomfortable any time this morning. Do you have any questions?"

If the participant is eligible and does not agree to participate, complete the administrative items and continue by saying:

"That's okay. If you change your mind, let me know."

Continue with the rest of the reception.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1. Was participant treated for diabetes in Visit 3? Refer to the PIN sheet. Do not read the question to the person. If participant was a treated diabetic at Visit 3, select YES and begin and end the administration of this form by reading the EXCLUSION STATEMENT.

Because you are taking medications to control diabetes, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

If the person was not taking medications to control diabetes or high blood sugar during Visit 3 (PIN sheet coded as NO), select NO and continue.

2. Do you regularly take medication to control diabetes (high blood sugar)? Read the question stressing "regularly" and "control diabetes". Include the parenthetical phrase (high blood sugar), if appropriate. If clarification is requested, medications to control diabetes include oral hypoglycemics and insulin. If participant reports regularly using medication to control diabetes, select YES and read the EXCLUSION STATEMENT regarding medications.

Because you are taking medications to control diabetes, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

If the participant's response is NO, select NO and continue with Item 3.

While the participant is changing, the medications brought in are reviewed

and the lack of oral hypoglycemics or insulin is verified. Participants who erroneously report not taking medication to control diabetes are informed by the staff member who meets them after changing that one of their medications is frequently used to control high blood sugar, and therefore, it would not be useful or safe for them to participate in the OGTT. The GTS form is corrected and the Itinerary Sheet marked "NO OGTT".

3. **Has participant fasted at least 10 hours?** Do not read the question out loud. Refer to Item 5 on the Fasting/Tracking Form. If fasting is less than 10 hours when the OGTT screening form is administered, estimate whether the fasting time will be less than 10 hours at the time the glucoala would be administered after venipuncture. If the estimated fasting time will STILL be less than 10 hours immediately following venipuncture, select NO and read the EXCLUSION STATEMENT regarding fasting.

Because you have not been able to fast for 10 hours, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

If the participant will have fasted for at least 10 hours by the time he/she is scheduled for venipuncture, select YES and go to Item 4.

4. **Have you had surgery to remove part of your stomach or small intestine?** Read question. The time frame is a life time history. If asked, "stomach stapling" is considered "surgery to remove part of your stomach" and the participant is not eligible for OGTT. Removal of part of the large intestine does NOT disqualify a person from participation; removal of all of the large intestine, or use of a colostomy, does result in exclusion from the OGTT. Participants who respond "no" or "don't know" to the question are eligible. If YES, read the EXCLUSION STATEMENT.

Because you have had part of your stomach* removed, it may not be useful or safe for you to participate in this portion of the study.

* If the exclusion is due to removal of part of the intestine, substitute "intestine" for the word "stomach".

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

5. **Are you on kidney dialysis?** Read question. The time frame for the question is "current" kidney dialysis. Participants who respond "no" are

eligible. Participants who respond "YES" for any reason are excluded from the glucose tolerance test. If YES, read the EXCLUSION STATEMENT.

Because you are on kidney dialysis, it may not be useful or safe for you to participate in this portion of the study.

Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".

6. Read the question. If the participant asks, it might be helpful to indicate that this test has been used in many epidemiologic studies. The National Heart, Lung, and Blood Institute recently reported that after testing over 10,000 people, there were no serious side effects and less than 0.5% had mild side effects from the OGTT. If NO, thank the participant and indicate that this completes the questions for this section. Complete items 7-9. Mark the Itinerary Sheet "NO OGTT".
7. Enter the date on which the participant completed this interview. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1995 would be entered as:

05 / 03 / 95
 month day year

8. Record "C" if form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form".
9. Enter the interviewer ID.