



## Overview

At the SV3 visit and before randomization, a trained interventionist meets with the participant to explore and help the participant resolve ambivalence or uncertainty about participating in the study. The interview should take about 15 minutes.

The purpose of the interaction is to give the participant the opportunity to reflect on their reasons for participation in the study. When the participant is taken through this process it can help them be more likely to give accurate answers to questions. It is the participant's task and not the interventionist to articulate and resolve any misgivings about participating. It is not the interventionist's role to help the participant solve the challenge or problem, but to summarize and state back to the participant's his/her ambivalence and/or reasons for participating.

At the end of the discussion the participant is able to answer the commitment questions listed on the Diet and Physical Activity Change Questionnaire (Form #40) comfortably and honestly.

## Administration Instructions

### Prior to the Interview

To prepare for the meeting with the participant review the Diet and Physical Activity Checklist (Form #8) completed at the SV1 visit to develop a picture of the participant's ability and interest in making the lifestyle changes. Pay attention to the questions on the Diet and Physical Activity Checklist that are answered with "maybe," in addition to alcohol consumption from the Eligibility Questionnaire, Form #4. Seek out more information for these behaviors. See below for more detail.

### Use Reflective Listening Techniques

Ask the participant the questions allowing them time to answer each question before going on to the next question. Use reflective listening techniques. Listen without judgement, interruption. Use attentive silence and encouragement with words like

- mm-hmm
- tell me more
- for instance
- I see
- Oh?
- Go on
- and
- What else?

Summarize. Reflect back with your own words what you heard the participant say. For example,

*“Let me see if I understand exactly what you said...”*

When asking the questions, make them open ended with words like what, how, etc. instead of words like do or does. This softens the question and helps the participant feel more comfortable.

### To begin the questions

Begin the questions with the statement:

*“We would like to ask you some questions to help us understand better why you are considering participating in the PREMIER study. We recognize that participating in a clinical trial can be a burden and want to make sure you are comfortable with your decision.”*

Follow with a question asking the participant for permission to probe further.

*“Is it OK for me to ask you a few questions about this?”*

If the participant says no, ask them why?

*“You don’t want to talk about your interest in the study. Tell me more or tell me more why this is a problem.”*

### Continuing with the questions:

If the participant says yes, continue. Ask one question at a time. Reflect back the participant’s statements. Reflect with a statement and not a question. This demonstrates empathy and helps the participant feel they are being heard and makes them more comfortable. For example,

Statement: You have concerns about the study.

Question: You are concerned about the study?

*What are your main reasons for participating in the PREMIER study?*

*What about the study makes it important for you?*

*What are the advantages and disadvantages participating in the study?*

*What challenges do you anticipate by participating?*

*How do you see your life will be different both while a participant and after the study is over?*

As the participant gives you feedback, summarize both sides. State back the reasons for participating, along with the reasons for not participating. Refrain from solving the participant's barriers to participating.

*On one side you are feeling that you really want to participate, but at the same time, you are uncomfortable about ... and concerned that it may interfere with your participation.*

#### "Maybe" Questions and Excessive Alcohol

Use the information from the Diet and Physical Activity Checklist (Form #8) and the alcohol question from the Eligibility Questionnaire (Form #4) to help guide the interaction with the participant. Use receptive open-ended questions to seek out more information about questions answered with a "maybe" and for excessive alcohol. Open-ended questions help the participant feel less defensive. Examples are:

*How ready are you to consider eating 9 to 12 servings of fruits and vegetables each day?*

*How might your life be different if you drink less alcohol?*

*I'm wondering if we can spend a few minutes talking about dairy foods.*

#### Ability to attend group sessions

Show the participant the schedules for **all three intervention arms**. Ask them if they have any planned trips or other commitments that would prevent their attending any of the sessions. Have them X out any sessions they could not attend.

**If they would miss three or more** group sessions in phase 1 for any one arm, ask if it is possible that they could reschedule their activities so that they could make the sessions. If not, exclude. If yes, they are eligible to continue.

**If they would miss one or two** group sessions in phase 1, ask if they would be able to reschedule their activities so that they could make the sessions. If Yes, they are eligible to continue. If no, ask if they would be able to schedule a makeup session around the time of each of the missed sessions. If No, exclude. If yes, they are eligible to continue.

**If they would not miss any** sessions, probe to be sure they've looked at the dates carefully. Ask about vacation plans.

Also, review phase 2 just to be sure they don't have any major absences, recognizing that the participant may not know their schedule this far out.

#### Summarize the Interaction

Ask a summary question

*How are you feeling about your participation now?*

Respect and affirm the participant's response with supportive statements. For a negative

response about participating statements can be:

*Even though I would like you to participate in the study, I support and respect your decision to not do so.*

*It sounds like you've pondered over this decision. I understand (respect) your decision.*

*I applaud your decision and really appreciate your honesty.*

For a positive response from the participant the statement can be

*That is great! We would love to have you participate.*

When a participant responds that they feel they can participate, but they have some misgivings or challenges, a response can be

*I am delighted that you want to participate and am confident we can find away around the challenge (state the challenge).*

#### Concluding the interview

After completing the questions ask if there is anything else the participant wants to say.

*Is this all? Do you have any further comments?*

Administer the Diet and Physical Activity Change Questionnaire (Form #40) following the form's instructions, regardless of the participant's response. The participant should now be ready to answer the questions on the form comfortably and honestly.

#### Document the Interaction

After the interview is over, record the participant's comments on this form, the Motivational Session Notes (Form #041), and file in the participant's record. If the participant answered no to the final question, they are ineligible to continue in they study.

### **Coding Instructions**

No coding is required.

### **Review Instructions**

No review is required.

### **Additional Instructions**

This form is not entered. The outcome from form #40 is recorded on the SV3 Visit Form.