INSTRUCTIONS FOR INFORMED CONSENT FORM (ICR)

I. General Instructions

This form is completed by project staff after the initial study informed consent is signed. In order to randomize a participant, the ICR form must be completed, ICR1 must equal A, and the form must be marked COMPLETE and LOCKED in the form grid.

II. Detailed instructions for each item

Enter form information for Participant ID selected from the study ID list:

0a. Enter the date the form was completed.

0b. Enter staff ID of the person who administered the form

1. Record the consent response from the participant after the consent process.

- Select A if participant consents: Skip to question 2
- Select N if participant declines to consent

1a. Record the participant's reason for declining consent

2. Record the participant's response about interest in participation in future studies

- Select A if participant agrees
- Select N if participant does not agree