



ID: _____

Date: ____ / ____ / ____

Participant Closeout Form

Complete this form for all participants who decline to participate or who are found to be ineligible **prior to randomization**. This form is to be used **between visits**. Use the visit forms for closeouts during a visit.

Reason for closeout (select one):

- Local lab – renal insufficiency 11
- Local lab – blood sugar 12
- Eligibility review questionnaire ineligible 14
- Time limit exceeded 19
- Investigator discretion for safety 18
- Not willing to stop exclusionary medications 20
- Transportation problems 21
- Started BP medication 22
- Started other exclusionary medication 23
- Physician’s orders..... 24
- Illness..... 25
- Death 26
- Moved..... 27
- Schedule/time conflict..... 28
- Refused..... 88
- Other (contact the coordinating center for an appropriate code)..... ____

Description: _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

This form is used by clinic staff to close out a participant who drops out or is excluded **between visits** and **prior to randomization**.

Coding Instructions

Before completing the form, check to be sure that the participant can not be closed out using a visit form. Also check to be sure the participant is not randomized. If the participant is already randomized, use a Premature Termination Form (#37) to close out the participant.

Reason: When selecting the reason for the closeout, be sure to review all of the choices before making a selection. If the situation does not fit any of the choices, note the reason at the bottom of the form or on an attached sheet and fax the form to the Data Clerk at the Coordinating Center for a coding decision.

See the attached list of Closeout Reason Codes for a detailed explanation of when to use each code. If there is a reason that is even close to the situation you are trying to code, use that reason instead of requesting a new code.

Do not code as "Other" without first consulting the Coordinating Center.

Description: Briefly describe the reason for the closeout. Include as much detail as possible.

Review Instructions

Make sure the ID, date, and reason for closeout have been completed.

Only one reason should be checked.

Review the notes and make sure the reason has been correctly coded.

Additional Instructions

Do not enter this form until all other forms for the participant has been entered. Once the participant is closed out, you will not be able to enter any new forms. Also be sure any edits to the participant's data have been completed. Once the participant is closed out, many of the restricted edits will no longer be allowed.

Explanations of Closeout Reason Codes

<u>Category</u>	<u>When to use this category</u>
Local lab – renal insuf.	Participant becomes ineligible due to renal insufficiency on the local lab results and needs to be closed out before the next visit.
Local lab – blood sugar	Participant becomes ineligible due to blood sugar on the local lab results and needs to be closed out before the next visit.
Eligibility review Q	Eligibility Review Questionnaire is completed after the Pre-randomization Checklist has already been entered, and participant is ineligible. (This would happen only if the participant's randomization visit date changes after the Pre-Randomization Checklist has been entered, and the new date requires that the Eligibility Review Questionnaire be completed.)
Time limit exceeded	More than 4 months has elapsed between PSV and SV1, or more than 6 months has elapsed between SV1 and the projected randomization date, or participant could not be randomized within the randomization window.
Investigator discretion	Any time the PI decides a participant should be excluded (when their data otherwise makes them eligible). This can be used to close out participants with positive Rose Questionnaires where the project clinician does not give permission for them to continue in the trial.
Exclusionary medications	A participant agrees to stop taking one of the exclusionary medications, the Medication Questionnaire or Eligibility Questionnaire is coded as eligible, and then the participant later refuses to stop taking the medication.
Transportation problems	Participant is unable to make their next visit due to transportation problems. This code should only be used if transportation issues come up between visits. If this comes up at a visit, code it as a refusal on the visit form.
Started BP medication	A participant starts taking BP medication and it is not caught on the Medication Questionnaire, Eligibility Questionnaire, or Eligibility Review Questionnaire.
Started other medication	A participant starts taking an exclusionary medication other than BP medication, and it is not caught on the Medication Questionnaire, Eligibility Questionnaire, or Eligibility Review Questionnaire.
Physician's orders	The participant's personal physician decides that the participant should not take part in the trial. This can be used to close out participants with positive Rose Questionnaires who do not get physician approval (alternative to the Pre-Randomization Checklist).
Illness	Participant illness (code family illness as schedule/time conflict).
Death	Participant death (code death in family as a schedule/time conflict)

(continued on next page)

Explanations of Closeout Reason Codes

<u>Category</u>	<u>When to use this category</u>
Schedule/time conflict	Participant is unable to make their screening visits due to a scheduling problem or time conflict. This includes work schedule conflicts, inability to get day care, and vacations. Also can be used if participant will be unable to attend all of the intervention sessions due to a scheduling problem or time conflict.
Refusal	Participant refused to complete a clinic visit or complete a required study measure, or repeatedly misses scheduled appointments (passive refusal). Use only if none of the above reasons apply.