



ID: _____

Date: ____ / ____ / ____

Premature Termination Form

Complete this form for all **randomized** participants who terminate study participation **after randomization**.

Reason for termination (select one):

- Started on blood pressure medication..... 31
- Physician's orders 32
- Illness 33
- Injury..... 34
- Pregnancy..... 35
- Death..... 36
- Moved out of area 37
- Schedule/time conflict..... 38
- Transportation problems 39
- Refused to continue..... 40
- Reason: _____
- Other (contact the coordinating center for an appropriate code)..... ____

Cause of death:

Yes No

Was the cause of death due to a CV Event? (see coding instructions)..... 1 2

Description:

		Reviewed by (staff ID): _____ Entered by (staff ID): _____
Principal Investigator Signature	Date	

Overview

This form is used by clinic staff to close out a participant who drops out or is excluded **after randomization**. If participant is still coming in for minimal study measures, do not complete this form.

Coding Instructions

Before completing the form, check to be sure the participant is has been randomized. If the participant is not yet randomized, use a Participant Closeout Form (#28) to close out the participant.

- Date:** Enter the date of the participant's **last** contact with the study.
- Reason:** When selecting the reason for the termination, 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 Termination 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.
- Cause of Death:** Complete this question only if the participant has died. Indicate the cause of death as being CV-related or non-CV related. CV-related deaths include: Myocardial Infarct (heart attack), Stroke, Heart Failure, or Arrhythmia. If you are unsure whether a death is CV-related or not, call the coordinating center.
- Description:** Briefly describe the reason for the termination. Include as much detail as possible.
- PI Signature:** PI must sign and date the form for the termination to take effect.

Review Instructions

Make sure the ID, date, and reason for termination 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 terminated, 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 terminated, many of the restricted edits will no longer be allowed.

Explanations of Termination Reason Codes

<u>Category</u>	<u>When to use this category</u>
Started on BP meds	If participant reports going on BP medications. This could come up on a Medication Use Questionnaire, or may be mentioned by the participant during another contact.
Physician's orders	If the participant's physician or the study clinician request that the participant stop participating in the study. If the participant is also put on BP medication, use that code instead.
Illness	Participant illness (code family illness as schedule/time conflict).
Injury	Participant injury. Do not code as termination reason unless participant stops all study activities due to the injury. Do not terminate if participant merely stops doing the physical activity portion of the intervention.
Pregnancy	Participant pregnancy.
Death	Participant death (code death in family as a schedule/time conflict)
Moved out of area	Participant has left the area permanently. Do not code if participant will be coming back later during the follow up period, or if the participant will be returning for follow up measures.
Schedule/time conflict	Participant is unable to make their clinic and intervention visits due to a scheduling problem or time conflict. This includes work schedule conflicts, inability to get day care, and vacations.
Transportation problems	Participant is unable to get to their clinic and intervention visits due to transportation problems. If transportation arrangements can be made to get the participant to at least their clinic visits, do not terminate.
Refusal	Participant refused to complete any further clinic or intervention visits. Use only if none of the above reasons apply.