Informant Interview Form Instructions
INF Version B: 3/18/2003
QxQ Date: 8/31/2007

I. GENERAL INSTRUCTIONS

The purpose of the Informant Interview form (INF) is to obtain information about the participant from someone responding on behalf of the participant. The informant must be someone very close to the participant, such as a relative, caretaker, or friend, who is in frequent or daily direct contact with the participant.

This form should be completed when the participant has died outside of the hospital, or when data cannot be collected from the participant during a scheduled telephone or clinic visit. This could be due to the participant's extreme illness, incompetence, difficulty in communicating, refusal, or because the participant has moved and cannot be located. Any time this form is completed, the first section of the Follow-up Form (FUP) should also be completed to indicate why the INF is necessary.

Prior to completing the INF, interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

A. Vitamins

1. Record the frequency, if known, with which participant took the study vitamin over the past six months. Select the best choice given what the informant tells you. May want to read the selections to the informant.
2. Record whether a pill count can be performed. If not go to item 6.
3. Record whether participant took the study vitamin on day of interview, or on day of death, if deceased.
4. Record the total number of bottles dispensed to participant since the last pill count. Refer to the participant's Vitamin Distribution Log (VDL).
5. Record the total number of pills remaining in the bottles. If the interview is being conducted over the telephone you will need to have the informant count the pills to provide this count.

6. Record whether the participant is currently taking (or was taking at time of death) vitamin supplements other than the study vitamin. Such supplements include multivitamins, B-group vitamins, and individual vitamins containing folic acid ("folate"), vitamin B6, or vitamin B12.

7. Record whether the supplements specifically contain folic acid, vitamin B6, or B12.

B. Vitamin Side Effects

8. Record whether participant experienced side effects (symptom experienced after taking the study medication that you did not want or expect).since the last follow-up contact date that may be associated with the study vitamins.

9. Record whether specific side effects were experienced by the participant, based on the informant's response. Do not probe for the symptoms listed; just record whether or not they are mentioned by the informant. If significant side effects mentioned are not on the list, enter them under "Other significant side effects.

C. Hospitalization and Procedure History

10. Record whether the participant was hospitalized since the date of last contact. If "Yes", complete a Hospitalization (HOS) form.

11. Record approximate date[s] of hospital admission.

12. Record whether the participant underwent outpatient angioplasty (surgical procedure in which a balloon-tipped catheter (thin tube) is inserted into a diseased, narrowed blood vessel; inflation of balloon stretches vessel opening, improving blood flow through it.) of the lower extremity arteries, renal arteries, or coronary arteries since the date of last contact. If "Yes", complete an HOS form.

13. Record approximate date[s] of outpatient angioplasty.

14. Record whether the participant underwent outpatient carotid artery endarterectomy (an operation to clean out an artery and restore normal blood flow through the artery) or carotid artery angioplasty since the date of last contact. If "Yes", complete an HOS form.

15. Record approximate date[s] of outpatient carotid artery endarterectomy or carotid artery angioplasty.

16. Record whether the participant re-initiated dialysis since the date of last contact.

17. Record approximate date the participant re-initiated dialysis.

D. Death

18. Record whether the participant is deceased. If "Yes", complete an Outcomes Documentation (OUT) form.

19. Record the date of death. This is not necessarily the date "pronounced dead". If someone is "found dead", date of death may be estimated if the time since last seen alive was short. However, if long, date of death may be unknown.

20. Record presumed cause of death.

21. Record location of death. If the informant says "in the hospital", clarify by asking if the participant died in the emergency room, and record the appropriate response. If the participant died "In hospital", complete an HOS form.

22. Record the assigned "Event Packet ID". For an out-of-hospital death, an "Event Packet ID" must be assigned and used on this form and on the corresponding OUT form.

23. Record whether the participant's death was witnessed. "Witnessed" is defined as someone being within sight or sound of the participant at the time of death.

24. Record the length of time between the last time the participant was seen alive and the time of death. Enter the shortest interval known to be true.

25. Record whether the participant was found in bed.

26. Record whether the participant was receiving hospice care. Hospice care is defined as a facility or program designed to provide a caring environment for meeting the physical and emotional needs of the terminally ill. It involves an interdisciplinary health care team offering support based on their particular areas of expertise. They provide comprehensive palliative care aimed at relieving symptoms and giving social, emotional, and spiritual support.

27. Record whether emergency resuscitation, such as closed chest massage or CPR was attempted. The informant may not be familiar with these procedures. If so, tell the informant they are procedures used to restore breathing or revive persons who are experiencing heart attacks and have no pulse or breath. Inform them that they usually involve "mouth-to-mouth" or other ventilation along with compression of the chest to circulate the blood.

28. Record whether death was clinically expected, considering the participant's condition in the days and hours prior to death.

E. Administrative Information

29. Record who the informant was in relation to the participant.

30. Record, the reliability of information provided by the informant.

31. Record date of data collection.

32. Record your official certified initials that have been given to the DCC.

Outcomes Documentation Form Instructions
INF Version A: 1/7/2003
QxQ Date: 2/3/2003

I. GENERAL INSTRUCTIONS

The purpose of the INF form is to obtain information about the participant from someone responding on behalf of the participant. The informant must be someone very close to the participant, such as a relative, caretaker, or friend, who is in frequent or daily direct contact with the participant.

This form should be filled out when the participant has died outside of the hospital, or when data cannot be collected from the participant during a scheduled telephone or clinic visit. This could be due to the participant's extreme illness, incompetence, difficulty in communicating, refusal, or because the participant has moved and cannot be located. Any time this form is filled out, the first section of the FUP should also be completed to indicate why the INF is being completed.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

A. Vitamins

1. Record frequency, if known, with which participant took the study vitamin over the past six months.
2. Record whether a pill count can be performed.
3. Record whether participant took the study vitamin on day of interview, or on day of death, if deceased.
4. Record the total number of bottles dispensed to participant since the last pill count. Refer to the participant's VDL forms.
5. Record the total number of pills remaining in the bottles.
6. Record whether the participant is currently taking (or was taking at time of death, if deceased) vitamin supplements other than the study vitamin. Such supplements include multivitamins, B-group vitamins, and individual vitamins containing folic acid ("folate"), vitamin B6, or vitamin B12.
7. Record whether the supplements specifically contain folic acid, B6, or B12.

B. Vitamin Side Effects

8. Record whether participant experienced side effects since the last follow-up contact date that may be associated with the study vitamins.

9. Record whether specific side effects were experienced by the participant, based on the informant's response. Do not probe for the symptoms listed; just record whether or not they are mentioned by the informant. If significant side effects mentioned are not on the list, enter them under "Other significant side effect".

C. Hospitalization and Procedure History

10. Record whether the participant was hospitalized since the date of last contact. If "Yes", also complete a Hospitalization (HOS) form.

11. Record approximate date[s] of hospital admission.

12. Record whether the participant underwent outpatient angioplasty of the lower extremity arteries, renal arteries, or coronary arteries since the date of last contact. If "Yes", also complete an HOS form.

13. Record approximate date[s] of outpatient angioplasty.

14. Record whether the participant underwent outpatient carotid artery endarterectomy or carotid artery angioplasty since the date of last contact. If "Yes", also complete an HOS form.

15. Record approximate date[s] of outpatient carotid artery endarterectomy or carotid artery angioplasty.

16. Record whether the participant re-initiated dialysis since the date of last contact.

17. Record approximate date the participant re-initiated dialysis.

D. Death

18. Record whether the participant is deceased. If "Yes", also complete an Outcomes Documentation (OUT) form.

19. Record date of death. This is not necessarily the date "pronounced dead". If someone is "found dead", date of death may be estimated if the time since last seen alive was short. However, if long, date of death may be unknown.

20. Record presumed cause of death.

21. Record location of death. If the informant says “in the hospital”, clarify by asking if the participant died in the emergency room, and record the appropriate response. If the participant died “In hospital”, also complete an HOS form.

22. Record whether the participant’s death was witnessed. “Witnessed” is defined as someone being within sight or sound of the participant at the time of death.

23. Record the assigned “Event Packet ID”. For an out-of-hospital death, an “Event Packet ID” must be assigned and used on this form and the corresponding OUT form.

24. Record the length of time between the last time the participant was seen alive and the time of death. Enter the shortest interval known to be true.

25. Record whether the participant was found in bed.

26. Record whether the participant was receiving hospice care.

27. Record whether emergency resuscitation, such as closed chest massage or CPR was attempted. The informant may not be familiar with these procedures. If so, tell the informant they are procedures used to restore breathing or revive persons who are experiencing heart attacks and have no pulse or breath. They usually involve “mouth-to-mouth” or other ventilation along with compression of the chest to circulate the blood.

28. Record whether death was clinically expected, considering the participant’s condition in the days and hours prior to death.

E. Administrative Information

29. Record informant source.

30. Record, in the interviewer’s opinion, the reliability of information provided by the informant.

31. Record date of data collection.

32. Record interviewer’s initials.