Follow-Up Contact Form Instructions
FUP Version C, 11/01/2007
QxQ Date: 11/01/2007

I. GENERAL INSTRUCTIONS

During the follow-up period, clinical and brief/phone follow-ups for participants will alternate every six months until the study exit contact or death. Participants who develop dialysis dependent end stage renal disease are followed through their first primary outcome, after which they are followed only for mortality.

The Follow-up Contact Form (FUP) is designed to capture all hospitalizations, particularly those related to potential arteriosclerotic CVD outcomes, and/or major renal graft dysfunction; document interim intake of both study related and unrelated vitamin supplements; determine study vitamin compliance; and determine any possible adverse reactions to the study vitamin. During clinic contacts, the FUP requires the following: record blood pressure twice and obtain height and weight; review smoking history; document specific medical diagnoses, including hypertension, arteriosclerotic cardiovascular disease (CVD) diagnoses, and diabetes; document interim intake of both study-related and unrelated vitamin supplements; review interim intake of specific cereals, or liquid/powdered food supplements with high folic acid contents; and review interim physical activity patterns.

For more information on follow-up contacts, read chapter 7: Follow-Up, in the FAVORIT Manual of Operations (MOP).

Interviewers must be familiar with and understand MOP chapter 14: Administrative 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. Contact Information

1. Record the type of contact:

   Record “A” if the contact is a regularly scheduled clinic visit, then go to item 5.

   Record “B” if the contact is a regularly scheduled brief/phone contact, then go to item 9.

   Record “C” if a phone contact is replacing a clinic visit, then go to Item 9.

   Record “D” if clinic visit is replacing a brief/phone contact, then go to Item 5.

   Record “E” if participant missed the contact, regardless if it was a clinic or brief/phone visit, then go to the next item.

2. Record the main reason the contact was missed:

   Record "A" if participant refused to participate in either the clinic or the telephone visit, then go to item 4. Please note this item only pertains to the current visit.

   Record "B" if participant is incapacitated (i.e., participant is unable to come to the clinic and/or to talk on the telephone), then go to item 4.

   Record "C" if participant withdrew consent, then go to the next item.

   Record "D" if you are unable to locate participant, then go to item 39. This should be documented on the Record of Contact Form (REC). Upon completion of this form complete the Informant Interview Form (INF).

   Record "E" if for some reason the participant contact was overlooked (i.e., participant was not scheduled for a follow-up visit), then go to item 39.

   Record "F" if participant died, then go to item 39. Upon completion of this form complete the Outcomes Documentation Form (OUT). Complete an Informant Interview Form if participant died out of the hospital. If the participant was hospitalized between the last contact and death, a Hospitalization form (HOS) must be completed.

3. Withdrawal of consent (upon completion of this form complete an Informed Consent Modification or Withdrawal Form (ICM)). If a participant does not want to continue taking the study vitamins they do not need to withdraw from the study. They can remain in the study for follow-up visits. See Chapter 7 in the Manual of Procedures for more details.

   a. Record the date participant withdrew consent using the US order (month/day/year). Record numbers using leading zeroes where necessary to fill all boxes.

   b. Record "Yes" if participant gave a reason for withdrawing consent. If participant did give a reason, record the reason for withdrawal in a notelog, then go to item 39.

4. Record "Yes" if participant is currently on the study medication. Record "No" if they are no longer on the study medication and record a "U" if this information is unobtainable. Go to item 39.

B. Clinic Examination

This section is recorded only at the clinic visits.

5. Blood pressure will be taken twice during this visit, and should be taken from the right arm (preferably), while participant is seated. Continuing through the questions following the first blood pressure will allow adequate time between the first and second readings, but at least 5 minutes must elapse. If for some reason, blood pressure cannot be measured using either arm, enter equal signs in the relevant fields; leg pressures cannot be substituted.

a. Record systolic blood pressure using leading zeros where necessary to fill all boxes.

b. Record diastolic blood pressure using leading zeros where necessary to fill all boxes.

c. Indicate on which arm blood pressure was taken by circling "R" for right or "L" for left.

6. Obtain the height with shoes removed. Record the height in inches; if using a scale with centimeters, divide centimeters by 2.54 to obtain inches, filling in the fields using leading zeroes where necessary. Round fractional inches to the nearest whole inch.

   The following guidelines have been approved by the FAVORIT Executive Committee for the measurement of height of amputees or wheelchair-bound participants:

   For a bilateral amputee, height should be missing data. Participants with unilateral amputations or confined to a wheelchair should be supported and their height measured. If this is not possible, height becomes missing data.

7. Obtain weight in street clothes with shoes removed. Record the weight in pounds; if using a scale with kilograms, divide kilograms by 0.45, filling in the fields using leading zeroes where necessary. Round fractional pounds to the nearest whole pound.

   The following guidelines have been approved by the FAVORIT Executive Committee for the measurement of weight of amputees or wheelchair-bound participants:

   Weight should be obtained by using an available scale in the clinic or hospital. Self-reported weight should not be used. Weight should be body weight without prostheses. If weight must be taken with prostheses, obtain weight and then subtract the weight of the prostheses.

8. The DMS will automatically calculate the body mass index (BMI). If the BMI is greater than or equal to 40, the Study Coordinator must notify participant's primary care physician and inform him/her of this information.

C. Follow-Up Interview

This section is recorded for both clinic and telephone visits.

9. Look up the date of the last brief/phone or clinic contact with participant, this information can either be found on the Schedule of Contacts Report, which is generated by the data management system or on participant's chart. Record "Yes" if participant reports having been hospitalized overnight at any time since the date of the last contact, otherwise record "No". If participant was hospitalized, then after completing this form complete **one** Hospitalization Form for **each** hospitalization that occurred since the last contact.

10. Record “Yes” if participant has undergone an angioplasty of the lower extremity arteries, renal arteries, or coronary arteries, as an outpatient, otherwise record “No”. If participant reports having had one of the listed procedures, then after completing this form complete **one** Hospitalization Form for **each** outpatient angioplasty that was performed since the last contact.

11. Bone Fractures

    Items 11a through 11f3 capture any bone fractures that occurred since the last participant contact. There is space to include information for up to three bone fractures that might have occurred since the last contact. If more than three fractures occurred, then record the following information in a notelog (location of fracture, date of fracture, how the fracture occurred and where the fracture was treated) for the additional fractures.

    a. Record “Yes” if participant had a bone fracture since the last contact. Record “No” if the participant did not have any bone fractures since the last contact and go to item 12.
    b. Record how many fractures the participant had since the last contact. There is space to enter information on up to 3 bone fractures, if more than 3 occurred since the last contact please record the following information in a notelog: type of fracture, date of fracture, how fracture occurred and if the participant was treated in the hospital for the additional fractures.
    c1. For the first fracture, record the type of fracture using the location of fracture key given on the form. If the location is not listed, please enter “Other” and describe in a notelog.
    d1. Record the date of the first fracture.
    e1. Record how the first fracture occurred. If the reason is not listed, enter “Other” and describe in a notelog.
    f1. Record where the first fracture was treated. If it was treated in the hospital, complete a HOS form. If the location treated is not listed, enter ”Other” and describe in a notelog.

    If the participant reports only one fracture, skip to item 12; else complete items c2-f2.

    c2. For the second fracture, record the type of fracture using the location of fracture key given on the form. If the location is not listed, please enter “Other” and describe in a notelog.
    d2. Record the date of the second fracture.
    e2. Record how the second fracture occurred. If the reason is not listed, enter “Other” and describe in a notelog.
    f2. Record where the second fracture was treated. If it was treated in the hospital, complete a HOS form. If the location treated is not listed, enter ”Other” and describe in a notelog.

If the participant reports only two fractures, skip to item 12; else complete items c3-f3.

c3. For the third fracture, record the type of fracture using the location of fracture key given on the form. If the location is not listed, please enter “Other” and describe in a notelog.
d3. Record the date of the third fracture.
e3. Record how the third fracture occurred. If the reason is not listed, enter “Other” and describe in a notelog.
f3. Record where the third fracture was treated. If it was treated in the hospital, complete a HOS form. If the location treated is not listed, enter ”Other” and describe in a notelog.

If more than three fractures, record the information in the notelog.

12. Renal Graft Function:

a. Record “Yes” if participant reports being told by his/her physician that his/her renal graft function has deteriorated, otherwise record “No”, then go to Item 13.

b. Record “Yes” if participant was hospitalized related to his/her deteriorated renal graft function, otherwise record “No”. If a "Yes" was recorded and the hospitalization(s) is a separate incident from the hospitalizations reported in Items 9 and 10, then after completing this form complete **one** Hospitalization Form for **each** hospitalization.

Initiation of dialysis:

c. Record “Yes” if participant is currently on dialyses, then after completing this form complete and fax a copy of the Initiation of Dialysis Fax Notification Form to the DCC, otherwise record “No”, then go to Item 13. If you reported this dialysis initiation on previous FUPs, <u>do not</u> fax another Initiation of Dialysis Notification Form (DIA) if in the opinion of the investigator the participant will remain on dialysis for 3 months or longer (DIA item 2=’Y’). However, if you reported ‘N’ or ‘U’ to item 2 on the initiation of dialysis fax notification form then please complete a second DIA.

d. Record the date the current dialysis was initiated using standard US order, Month/Day/Year, and leading zeros where necessary.

D. Side Effects Monitoring

This section should be recorded for both clinic and brief/phone contacts.

13. Record “Yes” if participant experienced any side effects that may be associated with the study vitamins, otherwise record "No" and go to Item 15.

14. Ask participant to describe side effects that may be associated with the study vitamin. **Do not** probe for specific symptoms. Record "Yes" or "No" based on participant's response:
    a. Record whether participant reported itching related to the study vitamin.
    b. Record whether participant reported gastrointestinal disturbances related to the study vitamin.
    c. Record whether participant reported having headache related to the study vitamin.
    d. Record whether participant reported fatigue related to the study vitamin.
    e. Record whether participant reported a change in appetite or weight related to the study vitamin.
    f. Record whether participant reported any other significant side effect related to the study vitamin. If a participant's reported side effects cannot be classified into the categories available in a-e, then indicate "Yes", and record the other side effect. If "No", go to Item 15.

E. Study Medication Interview

This section is to be recorded at both the clinic and the telephone visits.

15. Record frequency with which participant has been taking the study vitamin over the past six months.

    Record "A" if participant takes the vitamin every day, then go to item 18.

    Record "B" if participant takes the vitamin almost every day, then go to item 18.

    Record "C" if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record "D" if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record "E" if participant takes the vitamin approximately 50% to 74% of the time, then go to item 17.

    Record "F" if participant takes the vitamin approximately 25% to 49% of the time, then go to item 17.

    Record "G" if participant does not take the vitamin, then go to the next item.

16. If participant does not take the study vitamin attempt to convince participant to resume taking the study vitamin. Record "S" if participant is successfully converted to resume the study vitamin and "U" if an unsuccessful attempt to convert participant is made. Please note participants not taking the study vitamin can and should remain in the study.

17. Record the primary reason participant gives for not taking the study vitamin every day or almost every day. Do not probe for specific reasons, but let participant answer freely.

Record “A” if participant forgets to take the vitamin.

Record “B” if participant misplaced or lost the vitamins

Record “C” if participant is not taking the vitamin due to side effects.

Record “D” and the reason if there are other reasons the participant is not taking the study vitamin. “D” can also be used when more than one reason is provided by the participant.

18. Record “Yes” if participant took the study vitamin the day of the contact, otherwise record “No”.

19. Record “Yes” if participant takes any vitamin supplements, other than the study vitamin, that contain folic acid, vitamin B6 or vitamin B12, otherwise record "No", go to Item 21.

20. Record which vitamins the supplements contain:
    a. Record “Yes” if the supplements contain folic acid, "folate", otherwise record “No”.
    b. Record “Yes” if the supplements contain Vitamin B6, otherwise record “No”.
    c. Record “Yes” if the supplements contain Vitamin B12, otherwise record “No”.

21. Record whether the current contact is a telephone contact. If "Yes", then go to Item 39.

F. Risk Factor and Interview Information

22. Record whether participant is currently (i.e., over the past month) undergoing treatment for hypertension with one or more specific anti-hypertensive medications. Even if participant is not taking the treatment record “Yes” if it is documented in their chart.

Smoking History: The smoking history questions focus on current or former cigarette smoking (cigar smoking or chewing tobacco is excluded), duration, intensity, and length of time since quitting. “Currently” refers to at least one cigarette per day on average over the past month.

23. Record participant's smoking status:
    a. Indicate smoking status by circling “A” if participant never smoked and go to item 25; circle “B” if participant is a current smoker (i.e. smokes at least one cigarette a day) and continue to the next item; or circle “C” if participant has ever smoked but is not currently smoking (i.e., former smoker) and go to item 24.
    b. Items 23 b and c are to be completed if participant is a current smoker. Record the total number of years participant has smoked, filling in the fields using leading zeroes where necessary.
    c. Record the average number of cigarettes currently (over the past month) smoked per day, filling in the fields using leading zeroes where necessary and go to item 25.

24. Items 27a-d are to be completed **only** by former smokers:

    a. Record the number of full years it has been since participant quit smoking. Calculate since the most recent quit date.

    b. Record the number of months, in addition to the years in Item 24a, it has been since participant quit smoking, within 0 to 11 months.

       For example, if participant stopped smoked 27 months ago (2 years and 3 months), 02 would be recorded in Item 24a and 03 would be recorded in Item 24b.

    c. Record the average number of cigarettes smoked per day when participant smoked.

    d. Record the number of years participant smoked.

Dietary Interview: The dietary questions document regular intake of heavily fortified cereals with large amounts of folic acid per serving.

25. Record “Yes” if participant has eaten a one cup (8 ounce) serving of cold breakfast cereals at least 3 times a week for the past three months. If not record "No", then go to Item 27.

26. Record the heavily fortified cold breakfast cereals that the participant eats at least three times a week over the past three months. It is important that the cereal be identified by **both** brand name and type. If after going through the list of cereals, the participant indicates that he/she eats at least three cups per weeks of a combination of these specific cereals, record “Yes” for each one.

    a. Record whether participant eats 100% Bran cereal (by Nabisco).

    b. Record whether participant eats Multi Grain Cheerios Plus (by General Mills).

    c. Record whether participant eats Total Raisin Bran (by General Mills).

    d. Record whether participant eats Total Corn Flakes (by General Mills).

    e. Record whether participant eats Total Whole Grain (by General Mills).

    f. Record whether participant eats Smart Start (by Kellogg's).

    g. Record whether participant eats Product 19 (by Kellogg's).

    h. Record whether participant eats Kretschmer Honey Crunch Wheat Germ (by Quaker).

Drink Supplements: This section documents regular intake of heavily fortified liquid/powdered dietary supplements with large amounts of folic acid per serving.

27. Record “Yes” if participant has drunk a one cup (8 ounce) serving of any liquid or powdered dietary supplement at least three times per week over the past three months. If not record "No", then go to Item 29.

28. Record which liquid or powdered dietary supplements participant drank at least three times a week over the past three months:

a. Record whether participant drank Ensure Plus HN.

b. Record whether participant drank Replena.

c. Record whether participant drank Sandoz Nutrition Citrotein.

d. Record whether participant drank Pulmocare.

e. Record whether participant drank Magnacal Renal.

f. Record whether participant drank any other liquid or powdered dietary supplement. If not record "No", then go to Item 29.

g. Record the name of the other dietary supplement participant reported drinking.

G. Physical Activity

The physical activity items, 29-36, ask about participant's activities during the past month. All activities are graded according to intensity and/or duration. The activities may be part of work, household tasks or leisure. Seven response cards are provided by the DCC to be shown to participant while you are reading the responses. This allows him/her to more easily remember the options for each item. The DCC will calculate a physical activity summary score based on the raw data.

29. Record frequency with which participant participated in vigorous activities, for at least 10 minutes or more, over the past month. The activities should have caused large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #1 to participant, then read the responses, ask participant to choose one response, A through E, and record their answer. If s/he chooses "A", Not at all", go to item 31.

30. Record average duration for which participant engaged in vigorous activities. Show Card #2 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

31. Record frequency with which participant walked 10 or more minutes without stopping, and was **not** strenuous enough to cause large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #3 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer. If s/he chooses "A, Not at all", go to item 33, otherwise continue to the next item.

32. Record average duration for which participant walked non-strenuously. Show Card #4 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

33. Record duration per day during which participant is moving about on his/her feet. Show Card #5 to participant then read the responses, ask participant to choose one of responses, A through F, and record their answer

34. Record the duration per day during which participant is standing or moving on her/his feet. Show Card #6 to participant then read the responses, ask participant to choose one of the responses, A through F, and record their answer.

35. Record duration per day during which participant spends sitting. Show Card #7 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer.

36. Record number of flights of stairs participant climbs **up** on a typical day during the past month. Ten steps equal one flight of stairs. Do not count steps down.

H. Second Blood Pressure

37. Second seated blood pressure measurement. It is preferred to use the same arm for the second seated BP measurement as was used for the first:
    a. Record the systolic BP using leading zeros where necessary to fill all boxes.
    b. Record the diastolic BP using leading zeros where necessary to fill all boxes.
    c. Indicate on which arm the BP was taken by circling "R" for right or "L" for left.

38. Average Blood Pressure calculations:

    a-b. The average systolic and diastolic BP is calculated automatically by the DMS. If the average systolic value is between 180 mmHg and 199 mmHg (or higher) participant's primary care physician should be notified. If the average systolic value is greater than or equal to 200 mmHg participant must be seen immediately by a physician. If the average diastolic value is between 100 mmHg and 109 mmHg (or higher) participant's primary care physician should be notified. If the average diastolic value is greater than or equal to 110 mmHg participant must be seen immediately by a physician.

39. Record date of data collection using the US order, Month/Day/Year, and leading zeros where necessary.

40. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

41. Enter examiner's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

- If any hospitalization or outpatient angioplasties were reported on this form, complete one or more HOS forms.

- If any bone fractures were reported on this form and treated in the hospital, complete one or more HOS forms.

- If participant is deceased, complete an Outcomes Documentation Form and an Informant Information Form.

- If participant withdrawals from the study, complete the Informed Consent Modification and Withdrawal Form.

- If participant missed the contact and is incapacitated, or location is unknown, complete an INF.

- If this is a clinic visit, update the Participant Update Form (PUF) and complete the Medication Survey Forms and the Phlebotomy Forms.

- Schedule/Remind participant of the next study contact.

Follow-Up Contact Form Instructions
FUP Version B, 02/21/2005
QxQ Date: 1/21/2007

I. GENERAL INSTRUCTIONS

During the follow-up period, clinical and brief/phone follow-ups for participants will alternate every six months until the study exit contact or death. Participants who develop dialysis dependent end stage renal disease are followed through their first primary outcome, after which they are followed only for mortality.

The Follow-up Contact Form (FUP) is designed to capture all hospitalizations, particularly those related to potential arteriosclerotic CVD outcomes, and/or major renal graft dysfunction; document interim intake of both study related and unrelated vitamin supplements; determine study vitamin compliance; and determine any possible adverse reactions to the study vitamin. During clinic contacts, the FUP requires the following: record blood pressure twice and obtain height and weight; review smoking history; document specific medical diagnoses, including hypertension, arteriosclerotic cardiovascular disease (CVD) diagnoses, and diabetes; document interim intake of both study-related and unrelated vitamin supplements; review interim intake of specific cereals, or liquid/powdered food supplements with high folic acid contents; and review interim physical activity patterns.

For more information on follow-up contacts, read chapter 7: Follow-Up, in the FAVORIT Manual of Operations (MOP).

Interviewers must be familiar with and understand MOP chapter 14: Administrative 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. Contact Information

1. Record the type of contact:

   Record “A” if the contact is a regularly scheduled clinic visit, then go to item 5.

   Record “B” if the contact is a regularly scheduled brief/phone contact, then go to item 9.

   Record “C” if a phone contact is replacing a clinic visit, then go to Item 9.

   Record “D” if clinic visit is replacing a brief/phone contact, then go to Item 5.

   Record “E” if participant missed the contact, regardless if it was a clinic or brief/phone visit, then go to the next item.

2. Record the main reason the contact was missed:

   Record "A" if participant refused to participate in either the clinic or the telephone visit, then go to item 4. Please note this item only pertains to the current visit.

   Record "B" if participant is incapacitated (i.e., participant is unable to come to the clinic and/or to talk on the telephone), then go to item 4.

   Record "C" if participant withdrew consent, then go to the next item.

   Record "D" if you are unable to locate participant, then go to item 39. This should be documented on the Record of Contact Form (REC). Upon completion of this form complete the Informant Interview Form (INF).

   Record "E" if for some reason the participant contact was overlooked (i.e., participant was not scheduled for a follow-up visit), then go to item 39.

   Record "F" if participant died, then go to item 39. Upon completion of this form complete both the Outcomes Documentation Form (OUT) and the Informant Interview Form. If the participant was hospitalized between the last contact and death, an Hospitalization form (HOS) must be completed.

3. Withdrawal of consent (upon completion of this form complete an Informed Consent Modification or Withdrawal Form (ICM)). If a participant does not want to continue taking the study vitamins they do not need to withdraw from the study. They can remain in the study for follow-up visits. See Chapter 7 in the Manual of Procedures for more details.

   a. Record the date participant withdrew consent using the US order (month/day/year). Record numbers using leading zeroes where necessary to fill all boxes.

   b. Record "Yes" if participant gave a reason for withdrawing consent. If participant did give a reason, record the reason for withdrawal in a notelog, then go to item 39.

4. Record "Yes" if participant is currently on the study medication. Record "No" if they are no longer on the study medication and record a "U" if this information is unobtainable. Go to item 39.

B. Clinic Examination

This section is recorded only at the clinic visits.

5. Blood pressure will be taken twice during this visit, and should be taken from the right arm (preferably), while participant is seated. Continuing through the questions following the first blood pressure will allow adequate time between the first and second readings, but at least 5 minutes must elapse. If for some reason, blood pressure cannot be measured using either arm, enter equal signs in the relevant fields; leg pressures cannot be substituted.

a. Record systolic blood pressure using leading zeros where necessary to fill all boxes.

b. Record diastolic blood pressure using leading zeros where necessary to fill all boxes.

c. Indicate on which arm blood pressure was taken by circling "R" for right or "L" for left.

6. Obtain the height with shoes removed. Record the height in inches; if using a scale with centimeters, divide centimeters by 2.54 to obtain inches, filling in the fields using leading zeroes where necessary. Round fractional inches to the nearest whole inch.

   The following guidelines have been approved by the FAVORIT Executive Committee for the measurement of height of amputees or wheelchair-bound participants:

   For a bilateral amputee, height should be missing data. Participants with unilateral amputations or confined to a wheelchair should be supported and their height measured. If this is not possible, height becomes missing data.

7. Obtain weight in street clothes with shoes removed. Record the weight in pounds; if using a scale with kilograms, divide kilograms by 0.45, filling in the fields using leading zeroes where necessary. Round fractional pounds to the nearest whole pound.

   The following guidelines have been approved by the FAVORIT Executive Committee for the measurement of weight of amputees or wheelchair-bound participants:

   Weight should be obtained by using an available scale in the clinic or hospital. Self-reported weight should not be used. Weight should be body weight without prostheses. If weight must be taken with prostheses, obtain weight and then subtract the weight of the prostheses.

8. The DMS will automatically calculate the body mass index (BMI). If the BMI is greater than or equal to 40, the Study Coordinator must notify participant's primary care physician and inform him/her of this information.

C. Follow-Up Interview

This section is recorded for both clinic and telephone visits.

9. Look up the date of the last brief/phone or clinic contact with participant, this information can either be found on the Schedule of Contacts Report, which is generated by the data management system or on participant's chart. Record "Yes" if participant reports having been hospitalized overnight at any time since the date of the last contact, otherwise record "No". If participant was hospitalized, then after completing this form complete **one** Hospitalization Form for **each** hospitalization that occurred since the last contact.

10. Record "Yes" if participant has undergone an angioplasty of the lower extremity arteries, renal arteries, or coronary arteries, as an outpatient, otherwise record "No". If participant reports having had one of the listed procedures, then after completing this form complete

one Hospitalization Form for **each** outpatient angioplasty that was performed since the last contact.

11. Renal Graft Function:
    a. Record “Yes” if participant reports being told by his/her physician that his/her renal graft function has deteriorated, otherwise record “No”, then go to Item 13.
    b. Record “Yes” if participant was hospitalized related to his/her deteriorated renal graft function, otherwise record “No”. If a "Yes" was recorded and the hospitalization(s) is a separate incident from the hospitalizations reported in Items 9 and 10, then after completing this form complete **one** Hospitalization Form for **each** hospitalization.

12. Initiation of dialysis:
    a. Record “Yes” if participant is currently on dialyses, then after completing this form complete and fax a copy of the Initiation of Dialysis Fax Notification Form to the DCC, otherwise record “No”, then go to Item 13. If you reported this dialysis initiation on previous FUPs, do not fax another Initiation of Dialysis Notification Form (DIA) if in the opinion of the investigator the participant will remain on dialysis for 3 months or longer (DIA item 2=’Y’). However, if you reported ‘N’ or ‘U’ to item 2 on the initiation of dialysis fax notification form then please complete a second DIA.
    b. Record the date the current dialysis was initiated using standard US order, Month/Day/Year, and leading zeros where necessary.

D. Side Effects Monitoring

This section should be recorded for both clinic and brief/phone contacts.

13. Record “Yes” if participant experienced any side effects that may be associated with the study vitamins, otherwise record "No" and go to Item 15.

14. Ask participant to describe side effects that may be associated with the study vitamin. **Do not** probe for specific symptoms. Record "Yes" or "No" based on participant's response:
    a. Record whether participant reported itching related to the study vitamin.
    b. Record whether participant reported gastrointestinal disturbances related to the study vitamin.
    c. Record whether participant reported having headache related to the study vitamin.
    d. Record whether participant reported fatigue related to the study vitamin.
    e. Record whether participant reported a change in appetite or weight related to the study vitamin.
    f. Record whether participant reported any other significant side effect related to the study vitamin. If a participant’s reported side effects cannot be classified into the

categories available in a-e, then indicate "Yes", and record the other side effect. If "No", go to Item 15.

E. Study Medication Interview

This section is to be recorded at both the clinic and the telephone visits.

15. Record frequency with which participant has been taking the study vitamin over the past six months.

    Record “A” if participant takes the vitamin every day, then go to item 18.

    Record “B” if participant takes the vitamin almost every day, then go to item 18.

    Record “C” if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record “D” if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record “E” if participant takes the vitamin approximately 50% to 74% of the time, then go to item 17.

    Record “F” if participant takes the vitamin approximately 25% to 49% of the time, then go to item 17.

    Record “G” if participant does not take the vitamin, then go to the next item.

16. If participant does not take the study vitamin attempt to convince participant to resume taking the study vitamin. Record “S” if participant is successfully converted to resume the study vitamin and “U” if an unsuccessful attempt to convert participant is made. Please note participants not taking the study vitamin can and should remain in the study.

17. Record the primary reason participant gives for not taking the study vitamin every day or almost every day. Do not probe for specific reasons, but let participant answer freely.

    Record “A” if participant forgets to take the vitamin.

    Record “B” if participant misplaced or lost the vitamins

    Record “C” if participant is not taking the vitamin due to side effects.

    Record “D” and the reason if there are other reasons the participant is not taking the study vitamin. “D” can also be used when more than one reason is provided by the participant.

18. Record “Yes” if participant took the study vitamin the day of the contact, otherwise record “No”.

19. Record “Yes” if participant takes any vitamin supplements, other than the study vitamin, that contain folic acid, vitamin B6 or vitamin B12, otherwise record "No", go to Item 21.

20. Record which vitamins the supplements contain:

a. Record “Yes” if the supplements contain folic acid, "folate", otherwise record “No”.

b. Record “Yes” if the supplements contain Vitamin B6, otherwise record “No”.

c. Record “Yes” if the supplements contain Vitamin B12, otherwise record “No”.

21. Record whether the current contact is a telephone contact. If "Yes", then go to Item 39.

F. Risk Factor and Interview Information

22. Record whether participant is currently (i.e., over the past month) undergoing treatment for hypertension with one or more specific anti-hypertensive medications. Even if participant is not taking the treatment record “Yes” if it is documented in their chart.

Smoking History: The smoking history questions focus on current or former cigarette smoking (cigar smoking or chewing tobacco is excluded), duration, intensity, and length of time since quitting. “Currently” refers to at least one cigarette per day on average over the past month.

23. Record participant's smoking status:

a. Indicate smoking status by circling “A” if participant never smoked and go to item 25; circle “B” if participant is a current smoker (i.e. smokes at least one cigarette a day) and continue to the next item; or circle “C” if participant has ever smoked but is not currently smoking (i.e., former smoker) and go to item 24.

b. Items 23 b and c are to be completed if participant is a current smoker. Record the total number of years participant has smoked, filling in the fields using leading zeroes where necessary.

c. Record the average number of cigarettes currently (over the past month) smoked per day, filling in the fields using leading zeroes where necessary and go to item 25.

24. Items 27a-d are to be completed **only** by former smokers:

a. Record the number of full years it has been since participant quit smoking. Calculate since the most recent quit date.

b. Record the number of months, in addition to the years in Item 24a, it has been since participant quit smoking, within 0 to 11 months.

For example, if participant stopped smoked 27 months ago (2 years and 3 months), 02 would be recorded in Item 24a and 03 would be recorded in Item 24b.

c. Record the average number of cigarettes smoked per day when participant smoked.

d. Record the number of years participant smoked.

Dietary Interview: The dietary questions document regular intake of heavily fortified cereals with large amounts of folic acid per serving.

25. Record “Yes” if participant has eaten a one cup (8 ounce) serving of cold breakfast cereals at least 3 times a week for the past three months. If not record "No", then go to Item 27.

26. Record the heavily fortified cold breakfast cereals that the participant eats at least three times a week over the past three months. It is important that the cereal be identified by **both** brand name and type. If after going through the list of cereals, the participant indicates that he/she eats at least three cups per weeks of a combination of these specific cereals, record “Yes” for each one.

    a. Record whether participant eats 100% Bran cereal (by Nabisco).

    b. Record whether participant eats Multi Grain Cheerios Plus (by General Mills).

    c. Record whether participant eats Total Raisin Bran (by General Mills).

    d. Record whether participant eats Total Corn Flakes (by General Mills).

    e. Record whether participant eats Total Whole Grain (by General Mills).

    f. Record whether participant eats Smart Start (by Kellogg's).

    g. Record whether participant eats Product 19 (by Kellogg's).

    h. Record whether participant eats Kretschmer Honey Crunch Wheat Germ (by Quaker).

Drink Supplements: This section documents regular intake of heavily fortified liquid/powdered dietary supplements with large amounts of folic acid per serving.

27. Record “Yes” if participant has drunk a one cup (8 ounce) serving of any liquid or powdered dietary supplement at least three times per week over the past three months. If not record "No", then go to Item 29.

28. Record which liquid or powdered dietary supplements participant drank at least three times a week over the past three months:

    a. Record whether participant drank Ensure Plus HN.

    b. Record whether participant drank Replena.

    c. Record whether participant drank Sandoz Nutrition Citrotein.

    d. Record whether participant drank Pulmocare.

    e. Record whether participant drank Magnacal Renal.

    f. Record whether participant drank any other liquid or powdered dietary supplement. If not record "No", then go to Item 29.

    g. Record the name of the other dietary supplement participant reported drinking.

G. Physical Activity

The physical activity items, 29-36, ask about participant's activities during the past month. All activities are graded according to intensity and/or duration. The activities may be part of work, household tasks or leisure. Seven response cards are provided by the DCC to be shown to participant while you are reading the responses. This allows him/her to more easily remember the options for each item. The DCC will calculate a physical activity summary score based on the raw data.

29. Record frequency with which participant participated in vigorous activities, for at least 10 minutes or more, over the past month. The activities should have caused large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #1 to participant, then read the responses, ask participant to choose one response, A through E, and record their answer. If s/he chooses "A", Not at all", go to item 31.

30. Record average duration for which participant engaged in vigorous activities. Show Card #2 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

31. Record frequency with which participant walked 10 or more minutes without stopping, and was **not** strenuous enough to cause large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #3 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer. If s/he chooses "A, Not at all", go to item 33, otherwise continue to the next item.

32. Record average duration for which participant walked non-strenuously. Show Card #4 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

33. Record duration per day during which participant is moving about on his/her feet. Show Card #5 to participant then read the responses, ask participant to choose one of responses, A through F, and record their answer

34. Record the duration per day during which participant is standing or moving on her/his feet. Show Card #6 to participant then read the responses, ask participant to choose one of the responses, A through F, and record their answer.

35. Record duration per day during which participant spends sitting. Show Card #7 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer.

36. Record number of flights of stairs participant climbs **up** on a typical day during the past month. Ten steps equal one flight of stairs. Do not count steps down.

H. Second Blood Pressure

37. Second seated blood pressure measurement. It is preferred to use the same arm for the second seated BP measurement as was used for the first:
    a. Record the systolic BP using leading zeros where necessary to fill all boxes.
    b. Record the diastolic BP using leading zeros where necessary to fill all boxes.
    c. Indicate on which arm the BP was taken by circling "R" for right or "L" for left.

38. Average Blood Pressure calculations:

    a-b. The average systolic and diastolic BP is calculated automatically by the DMS. If the average systolic value is between 180 mmHg and 199 mmHg (or higher) participant's primary care physician should be notified. If the average systolic value is greater than or equal to 200 mmHg participant must be seen immediately by a physician. If the average diastolic value is between 100 mmHg and 109 mmHg (or higher) participant's primary care physician should be notified. If the average diastolic value is greater than or equal to 110 mmHg participant must be seen immediately by a physician.

39. Record date of data collection using the US order, Month/Day/Year, and leading zeros where necessary.

40. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

41. Enter examiner's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

- If any hospitalization or outpatient angioplasties were reported on this form, complete one or more HOS forms.

- If participant is deceased, complete an Outcomes Documentation Form and an Informant Information Form.

- If participant withdrawals from the study, complete the Informed Consent Modification and Withdrawal Form.

- If participant missed the contact and is incapacitated, or location is unknown, complete an INF.

- If this is a clinic visit, update the Participant Update Form (PUF) and complete the Medication Survey Forms and the Phlebotomy Forms.

- Schedule/Remind participant of the next study contact.

Follow-Up Contact Form Instructions
FUP Version A, 03/25/2002
QxQ Date: 06/10/2002

I. GENERAL INSTRUCTIONS

During the five-year follow-up period, clinical and telephone follow-ups for participants will alternate every six months for a maximum of 60 months or until the occurrence of death. Participants who develop dialysis dependent end stage renal disease are followed through their first primary outcome, after which they are followed only for mortality.

The Follow-up Contact Form (FUP) is designed to capture all hospitalizations, particularly those related to potential arteriosclerotic CVD outcomes, and/or major renal graft dysfunction; document interim intake of both study related and unrelated vitamin supplements; determine study vitamin compliance; and determine any possible adverse reactions to the study vitamin. During clinic contacts, the FUP requires the following: record blood pressure twice and obtain height and weight; review smoking history; document specific medical diagnoses, including hypertension, arteriosclerotic cardiovascular disease (CVD) diagnoses, and diabetes; document interim intake of both study-related and unrelated vitamin supplements; review interim intake of specific cereals, or liquid/powdered food supplements with high folic acid contents; and review interim physical activity patterns.

For more information on follow-up contacts, read chapter 7: Follow-Up, in the FAVORIT Manual of Operations (MOP).

Interviewers must be familiar with and understand MOP chapter 14: Administrative 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

Please note the box containing information regarding contact occasions and month is for your use only. It is a quick reference to determine which month coincides with the contact occasion. This information will not be entered into the Data Management System (DMS).

A. Contact Information

1. Record the type of contact:

   Record "A" if the contact is a regularly scheduled clinic visit, then go to item 5.

   Record "B" if the contact is a regularly scheduled phone contact, then go to item 9.

   Record "C" if a phone contact is replacing a clinic visit, then go to Item 9.

   Record "D" if clinic visit is replacing a phone contact, then go to Item 5.

   Record "E" if participant missed the contact, regardless if it was a clinic or telephone visit, then go to the next item.

2. Record the main reason the contact was missed:

   Record "A" if participant refused to participate in either the clinic or the telephone visit, then go to item 4. Please note this item only pertains to the current visit.

   Record "B" if participant is incapacitated (i.e., participant is unable to come to the clinic and/or to talk on the telephone), then go to item 4.

   Record "C" if participant withdrew consent, then go to the next item.

   Record "D" if you are unable to locate participant, then go to item 41. This should be documented on the Record of Contact Form (REC). Upon completion of this form complete the Informant Interview Form (INF).

   Record "E" if for some reason the participant contact was overlooked (i.e., participant was not scheduled for a follow-up visit), then go to item 41.

   Record "F" if participant died, then go to item 41. Upon completion of this form complete both the Outcomes Documentation Form (OUT) and the Informant Interview Form (INF). If the participant was hospitalized between the last contact and death, an HOS form must be completed.

3. Withdrawal of consent (Record on FUP **and** on ICM forms):

   a. Record the date participant withdrew consent using the US order (month/day/year). Record numbers using leading zeroes where necessary to fill all boxes.

   b. Record "Yes" if participant gave a reason for withdrawing consent. If participant did give a reason, record the reason for withdrawal.

4. Record "Yes" if participant is currently on the study medication. Record "No" if they are no longer on the study medication and record a "U" if this information is unobtainable.

B. Clinic Examination

This section is recorded only at the clinic visits.

5. Blood pressure will be taken twice during this visit, and should be taken from the right arm (preferably), while participant is seated. Continuing through the questions following the first blood pressure will allow adequate time between the first and second readings, but at least 5 minutes must elapse. If for some reason, blood pressure cannot be measured using either arm, enter equal signs in the relevant fields; leg pressures cannot be substituted.
    a. Record systolic blood pressure using leading zeros where necessary to fill all boxes.
    b. Record diastolic blood pressure using leading zeros where necessary to fill all boxes.
    c. Indicate on which arm blood pressure was taken by circling "R" for right or "L" for left.

6. Obtain the height with shoes removed. Record the height in inches; if using a scale with centimeters, divide centimeters by 2.54 to obtain inches, filling in the fields using leading zeroes where necessary. Round fractional inches to the nearest whole inch.

7. Obtain weight in street clothes with shoes removed. Record the weight in pounds; if using a scale with kilograms, divide kilograms by 0.45, filling in the fields using leading zeroes where necessary. Round fractional pounds to the nearest whole pound.

8. Calculate participant's Body Mass Index (BMI) by the following formula:

    BMI = [Weight in pounds w Height in inches w Height in inches] x 703

    The DMS will automatically calculate the body mass index (BMI). If the BMI is greater than or equal to 40, the Study Coordinator must notify participant's primary care physician and inform him/her of this information.

C. Follow-Up Interview

This section is recorded for both clinic and telephone visits.

9. Look up the date of the last phone or clinic contact with participant, this information can either be found on the Schedule of Contacts Report, which is generated by the data management system or on participant's chart. Record "Yes" if participant reports having been hospitalized overnight at any time since the date of the last contact, otherwise record "No". If participant was hospitalized, then after completing this form complete **one** Hospitalization form (HOS) for **each** hospitalization that occurred since the last contact.

10. Record "Yes" if participant has undergone an angioplasty of the lower extremity arteries, renal arteries, or coronary arteries, as an outpatient, otherwise record "No". If participant

reports having had one of the listed procedures, then after completing this form complete **one** Hospitalization Form (HOS) for **each** outpatient angioplasty that was performed since the last contact.

11. Renal Graft Function:
    a. Record “Yes” if participant reports being told by his/her physician that his/her renal graft function has deteriorated, otherwise record “No”, then go to Item 13.
    b. Record “Yes” if participant was hospitalized related to his/her deteriorated renal graft function, otherwise record “No”. If a "Yes" was recorded and the hospitalization(s) is a separate incident from the hospitalizations reported in Items 9 and 10, then after completing this form complete **one** Hospitalization Form (HOS) for **each** hospitalization.

12. Re-initiation of dialysis:
    a. Record “Yes” if participant re-initiated dialyses, otherwise record “No”, then go to Item 13.
    b. Record the date dialysis was re-initiated using standard US order, Month/Day/Year, and leading zeros where necessary.

D. Side Effects Monitoring

This section should be recorded for both clinic and telephone visits.

13. Record “Yes” if participant experienced any side effects that may be associated with the study vitamins, otherwise record "No" and go to Item 15.

14. Ask participant to describe side effects that may be associated with the study vitamin. **Do not** probe for specific symptoms. Record "Yes" or "No" based on participant's response:
    a. Record whether participant reported itching related to the study vitamin.
    b. Record whether participant reported gastrointestinal disturbances related to the study vitamin.
    c. Record whether participant reported having headache related to the study vitamin.
    d. Record whether participant reported fatigue related to the study vitamin.
    e. Record whether participant reported a change in appetite or weight related to the study vitamin.
    f. Record whether participant reported any other significant side effect related to the study vitamin. If a participant’s reported side effects cannot be classified into the categories available in a-e, then indicate "Yes", and record the other side effect. If "No", go to Item 15.

E. Study Medication Interview

This section is to be recorded at both the clinic and the telephone visits.

15. Record frequency with which participant has been taking the study vitamin over the past six months.

    Record "A" if participant takes the vitamin every day, then go to item 18.

    Record "B" if participant takes the vitamin almost every day, then go to item 18.

    Record "C" if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record "D" if participant takes the vitamin approximately 75% to 90% of the time, then go to item 17.

    Record "E" if participant takes the vitamin approximately 50% to 74% of the time, then go to item 17.

    Record "F" if participant takes the vitamin approximately 25% to 49% of the time, then go to item 17.

    Record "G" if participant does not take the vitamin, then go to the next item.

16. If participant does not take the study vitamin attempt to convince participant to resume taking the study vitamin. Record "S" if participant is successfully converted to resume the study vitamin and "U" if an unsuccessful attempt to convert participant is made.

17. Record the primary reason participant gives for not taking the study vitamin every day or almost every day. Do not probe for specific reasons, but let participant answer freely.

    Record "A" if participant forgets to take the vitamin.

    Record "B" if participant misplaced or lost the vitamins

    Record "C" if participant is not taking the vitamin due to side effects.

    Record "D" and the reason if there are other reasons the participant is not taking the study vitamin. "D" can also be used when more than one reason is provided by the participant.

18. Record "Yes" if participant took the study vitamin the day of the contact, otherwise record "No".

19. Record the total number of study vitamin bottles dispensed to participant since the last pill count, using leading zeros where necessary. This information can be found on participant's Vitamin Distribution Log.

20. Record the total number of bottles of study vitamins participant brought to the clinic using leading zeros where necessary.

21. Obtain and record the pill count. This should include both opened and unopened bottles. At each clinic visit, participant will bring the vitamin bottles dispensed at the previous visit, and the Study Coordinator will record the number of bottles participant brought to the clinic as well as record the total number of bottles that were dispensed to participant (this information can be found on the Vitamin Distribution Log). The Study Coordinator will record the number of remaining pills, including pills in any unopened bottles.

    At telephone contacts, the Study Coordinator will ask participant to count the tablets remaining in any open vitamin bottles dispensed at the previous visit. The Study Coordinator will also ask participant for the number of unopened vitamin bottles the participant has. Then the Study Coordinator will record the total number of pills, which includes both the number of tablets in opened bottles, and the tablets in unopened bottles.

    Pill counts at the 6-month telephone contacts **are necessary**. Remind participants at the reminder call/postcard that they will be asked to count their remaining pills during the 6-month telephone contact.

22. Record “Yes” if participant takes any vitamin supplements, other than the study vitamin, that contain folic acid, vitamin B6 or vitamin B12, otherwise record "No", go to Item 24.

23. Record which vitamins the supplements contain:
    a. Record “Yes” if the supplements contain folic acid, "folate", otherwise record “No”.
    b. Record “Yes” if the supplements contain Vitamin B6", otherwise record “No”.
    c. Record “Yes” if the supplements contain Vitamin B12", otherwise record “No”.

24. Record whether the current contact is a telephone contact. If "Yes", then go to Item 41.

F. Risk Factor and Interview Information

25. Record whether participant is currently (i.e., over the past month) undergoing treatment for hypertension with one or more specific anti-hypertensive medications. Even if participant is not taking the treatment record “Yes” if it is documented in their chart.

Smoking History: The smoking history questions focus on current or former cigarette smoking (cigar or chewing tobacco is excluded), duration, intensity, and length of time since quitting. “Currently” refers to at least one cigarette per day on average over the past month.

26. Record participant's smoking status:
    a. Indicate smoking status by circling “A” if participant never smoked and go to item 28; circle “B” if participant is a current smoker (i.e. smokes at least one cigarette a day) and continue to the next item; or circle “C” if participant has ever smoked but is not currently smoking (i.e., former smoker) and go to item 27.

b. Items 26 b and c are to be completed if participant is a current smoker. Record the total number of years participant has smoked, filling in the fields using leading zeroes where necessary.

c. Record the average number of cigarettes currently (over the past month) smoked per day, filling in the fields using leading zeroes where necessary and go to item 28.

27. Items 27a-d are to be completed **only** by former smokers:

a. Record the number of full years it has been since participant quit smoking. Calculate since the most recent quit date.

b. Record the number of months, in addition to the years in Item 27a, it has been since participant quit smoking, within 0 to 11 months.

For example, if participant stopped smoked 27 months ago (2 years and 3 months), 02 would be recorded in Item 27a and 03 would be recorded in Item 27b.

c. Record the average number of cigarettes smoked per day when participant smoked.

d. Record the number of years participant smoked.

Dietary Interview: The dietary questions document regular intake of heavily fortified cereals, and/or liquid/powdered dietary supplements with large amounts of folic acid per serving.

28. Record “Yes” if participant has eaten a one cup (8 ounce) serving of cold breakfast cereals at least 3 times a week for the past three months. If not record "No", then go to Item 30.

29. Record the heavily fortified cold breakfast cereals that the participant eats at least three times a week over the past three months. It is important that the cereal be identified by **both** brand name and type.

a. Record whether participant eats 100% Bran cereal (by Nabisco).

b. Record whether participant eats Multi Grain Cheerios Plus (by General Mills).

c. Record whether participant eats Total Raisin Bran (by General Mills).

d. Record whether participant eats Total Corn Flakes (by General Mills).

e. Record whether participant eats Total Whole Grain (by General Mills).

f. Record whether participant eats Smart Start (by Kellogg's).

g. Record whether participant eats Product 19 (by Kellogg's).

h. Record whether participant eats Kretschmer Honey Crunch Wheat Germ (by Quaker).

If after going through the list of cereals, the participant indicates that he/she eats at least three cups per weeks of a combination of **these specific cereals**, record “Yes” for each one.

30. Record “Yes” if participant has drunk a one cup (8 ounce) serving of any liquid or powdered dietary supplement at least three times per week over the past three months. If not record "No", then go to Item 32.

31. Record which liquid or powdered dietary supplements participant drank at least three times a week over the past three months:
    a. Record whether participant drank Ensure Plus HN.
    b. Record whether participant drank Replena.
    c. Record whether participant drank Sandoz Nutrition Citrotein.
    d. Record whether participant drank Pulmocare.
    e. Record whether participant drank Magnacal Renal.
    f. Record whether participant drank any other liquid or powdered dietary supplement. If not record "No", then go to Item 32.
    g. Record the name of the other dietary supplement participant reported drinking.

G. Physical Activity

The physical activity items, 32-38, ask about participant's activities during the past month. All activities are graded according to intensity and/or duration. The activities may be part of work, household tasks or leisure. Six response cards are provided by the DCC to be shown to participant while you are reading the responses. This allows him/her to more easily remember the options for each item. The DCC will calculate a physical activity summary score based on the raw data.

32. Record frequency with which participant participated in vigorous activities, for at least 10 minutes or more, over the past month. The activities should have caused large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #1 to participant, then read the responses, ask participant to choose one response, A through E, and record their answer. If s/he chooses "A", Not at all", go to item 34.

33. Record average duration for which participant engaged in vigorous activities. Show Card #2 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

34. Record frequency with which participant walked 10 or more minutes without stopping, and was **not** strenuous enough to cause large increases in breathing and heart rate, or leg fatigue, or caused participant to perspire. Show Card #3 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer. If s/he chooses "A, Not at all", go to item 36, otherwise continue to the next item.

35. Record average duration for which participant walked non-strenuously. Show Card #4 to participant, then read the responses, ask participant to choose on of the responses, A through C, and record their answer.

36. Record duration per day during which participant is moving about on his/her feet. Show Card #5 to participant then read the responses, ask participant to choose one of responses, A through F, and record their answer

37. Record duration per day during which participant spends sitting. Show Card #6 to participant, then read the responses, ask participant to choose one of the responses, A through E, and record their answer.

38. Record number of flights of stairs participant climbs **up** on a typical day during the past month. Ten steps equal one flight of stairs. Do not count steps down.

H. Second Blood Pressure

39. Second seated blood pressure measurement. It is preferred to use the same arm for the second seated BP measurement as was used for the first:
    a. Record the systolic BP using leading zeros where necessary to fill all boxes.
    b. Record the diastolic BP using leading zeros where necessary to fill all boxes.
    c. Indicate on which arm the BP was taken by circling "R" for right or "L" for left.

40. Average Blood Pressure calculations:

    a-b. The average systolic and diastolic BP is calculated automatically by the DMS. If the average systolic value is between 180 mmHg and 199 mmHg (or higher) participant's primary care physician should be notified. If the average systolic value is greater than or equal to 200 mmHg participant must be seen immediately by a physician. If the average diastolic value is between 100 mmHg and 109 mmHg (or higher) participant's primary care physician should be notified. If the average diastolic value is greater than or equal to 110 mmHg participant must be seen immediately by a physician.

41. Record date of data collection using the US order, Month/Day/Year, and leading zeros where necessary.

42. Enter examiner's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

If any hospitalization or outpatient angioplasties were reported on this form, complete one or more HOS forms.

If participant is deceased, complete an Outcomes Documentation Form (OUT) and an Informant Information Form (INF).

If participant missed the contact and is incapacitated, or location is unknown, complete an INF.

If this is a clinic visit, update the PUF and complete the Medication Survey Forms and the Phlebotomy Forms.

Schedule/Remind participant of the next study contact.