FAVORIT

Folic Acid for Vascular Outcome
Reduction in Transplantation

HOSPITALIZATION FORM

FORM CODE: HOS   VERSION: B   04/13/07

ID NUMBER: ☐☐☐☐☐☐   CONTACT OCCASION: ☐☐   SEQUENCE NUMBER: ☐☐

PATIENT LAST NAME: ☐☐☐☐☐☐☐☐☐☐☐☐   FIRST/MIDDLE INITIALS: ☐☐

Section A. Administrative Information   HOS1

1a. Was the hospitalization at a FAVORIT affiliated or non-FAVORIT affiliated hospital, or was this an outpatient Angioplasty?

   F   FAVORIT affiliated — Go to item 8

   N   Non-FAVORIT affiliated — Go to item 8

   O   Outpatient Angioplasty (coronary, lower extremities, renal arteries) — Go to item 2

   H   Hospitalization not found — REQUIRED: Enter into note log steps taken to locate hospitalization

1b. For the hospitalization that was <u>not</u> found, record the "contact occasion" for the corresponding FOLLOW-UP CONTACT FORM where the participant indicated that he/she was hospitalized.   HOSB1B

   FUP CONTACT OCCASION: ☐☐ — Go to item 34

Section B. Coronary Disease Events - Outpatient   HOS2

2. Have you obtained access to review the outpatient chart, is access pending, or have you exhausted all possibilities to get the associated outpatient chart?

   O   Obtained access to chart

   P   Pending access to chart — Update this form when access is obtained; **Go to item 34**

   N   No possibility of ever accessing chart — Go to item 34

   It is essential that the study obtain an accurate report of events that occurred during this outpatient procedure. In order to do this, the medical records are crucial. Please make every effort to obtain the medical records.

ID_____   CO_____   Seq No_____

Please indicate whether or not each of the following occurred during this
outpatient visit:

HOS3A

3a. Coronary artery angioplasty as an outpatient

    Y   Yes

    N   No —— Go to item 4a

HOS3B

 b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
                Month   Day   Year

4a. Angioplasty of the lower extremity arteries as an outpatient

HOS4A

    Y   Yes

    N   No —— Go to item 5a

HOS4B

 b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
                Month   Day   Year

5a. Angioplasty of the renal arteries as an outpatient

HOS5A

    Y   Yes

    N   No —— Go to item 6a

HOS5B

 b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
                Month   Day   Year

6a. Carotid artery endarterectomy as an outpatient

HOSB6A

    Y   Yes

    N   No —— Go to item 7a

HOSB6B

 b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
                Month   Day   Year

7a. Carotid artery angioplasty as an outpatient

HOSB7A

    Y   Yes

    N   No —— Go to item 34

HOSB7B

 b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐ —— Go to item 34
                Month   Day   Year

Section C. Hospital Administrative Information

8. Have you obtained access to review the hospital chart, is access
    pending, or have you exhausted all possibilities to get the associated
    hospital chart?

    HOS6

    O   Obtained access to chart

    P   Pending access to chart ── Update this form when access
                                        is obtained;
                                        Go to item 34

    N   No possibility of ever accessing chart ── Go to item 34

    It is essential that the study obtain an accurate report of events
    that occurred during this hospitalization. In order to do this, the
    medical records are crucial. Please make every effort to obtain
    the hospital records.

9. Date of hospital admission: ☐☐ / ☐☐ / ☐☐☐☐   HOS7
                                  Month   Day   Year

10. Date of discharge (nonfatal cases) or death: ☐☐ / ☐☐ / ☐☐☐☐   HOS8
                                                  Month   Day   Year

Section D. Discharge Information

11. What was the disposition of the patient on discharge?

    HOS9

    D   Deceased ── Complete Outcomes Documentation Form upon completion of
                        this form

    T   Transferred to another hospital ── Complete a separate Hospitalization Form upon
                                                completion of this form;
                                                Go to item 14

    M   Transferred to another medical care facility (e.g., Rehab, nursing home, ── Go to item 14
           long-term care)

    H   Discharged to home ── Go to item 14

12. Are any causes of death given on the discharge summary?   HOS10

    Y   Yes

    N   No ── Go to item 14

13. Causes of death on the discharge summary: HOS11A

    a. _____

    b. _____   HOS11B

    c. _____   HOS11C

    d. _____   HOS11D

    e. _____   HOS11E

    f. _____   HOS11F

14. List the hospital discharge diagnosis **codes** exactly as they appear on the front sheet of the discharge summary (if none appear then leave this item blank):

    a. ☐☐☐☐☐☐☐   HOS12A   h. ☐☐☐☐☐☐☐   HOS12H

    b. ☐☐☐☐☐☐☐   HOS12B   i. ☐☐☐☐☐☐☐   HOS12I

    c. ☐☐☐☐☐☐☐   HOS12C   j. ☐☐☐☐☐☐☐   HOS12J

    d. ☐☐☐☐☐☐☐   HOS12D   k. ☐☐☐☐☐☐☐   HOS12K

    e. ☐☐☐☐☐☐☐   HOS12E   l. ☐☐☐☐☐☐☐   HOS12L

    f. ☐☐☐☐☐☐☐   HOS12F   m. ☐☐☐☐☐☐☐   HOS12M

    g. ☐☐☐☐☐☐☐   HOS12G   n. ☐☐☐☐☐☐☐   HOS12N

For items 13 - 16 use Diag_niddkv1; many of the ICD codes were recoded using a nosologist.

14. List the hospital discharge diagnosis **codes** exactly as they appear on the front sheet of the discharge summary (if none appear then leave this item blank):

o. ☐☐☐☐☐☐☐ HOSB14O

p. ☐☐☐☐☐☐☐ HOSB14P

q. ☐☐☐☐☐☐☐ HOSB14Q

r. ☐☐☐☐☐☐☐ HOSB14R

s. ☐☐☐☐☐☐☐ HOSB14S

t. ☐☐☐☐☐☐☐ HOSB14T

u. ☐☐☐☐☐☐☐ HOSB14U

v. ☐☐☐☐☐☐☐ HOSB14V

w. ☐☐☐☐☐☐☐ HOSB14W

x. ☐☐☐☐☐☐☐ HOSB14X

y. ☐☐☐☐☐☐☐ HOSB14Y

z. ☐☐☐☐☐☐☐ HOSB14Z

15. Coding System: HOS13

A   ICD-9

B   ICD-10

C   No codes entered in Item 14

16. Discharge diagnoses (**Text descriptors**, NOT ICD CODES). Do not split a single diagnosis across two or more response items:

a. _____ HOS14A

b. _____ HOS14B

c. _____ HOS14C

d. _____ HOS14D

e. _____ HOS14E

f. _____ HOS14F

g. _____ HOS14G

For items 13 - 16 use Diag_niddkv1; many of the ICD codes were recoded using a nosologist.

16. Discharge diagnoses (Text descriptors, NOT ICD CODES). Do not split a single diagnosis across two or more response items:

h. _____   HOS14H

i. _____   HOS14I

j. _____   HOS14J

k. _____   HOS14K

l. _____   HOS14L

m. _____   HOS14M

n. _____   HOS14N

16. Discharge Diagnoses (cont):

o. _____   HOSB16O

p. _____   HOSB16P

q. _____   HOSB16Q

r. _____   HOSB16R

s. _____   HOSB16S

t. _____   HOSB16T

u. _____   HOSB16U

v. _____   HOSB16V

w. _____   HOSB16W

16. Discharge Diagnoses(cont):

x. _____   HOSB16X

y. _____   HOSB16Y

z. _____   HOSB16Z

For items 13 - 16 use Diag_niddkv1; many of the ICD codes were recoded using a nosologist.

Note: Refer to QxQ's for additional terms that would be included for the conditions in sections E-F.

Section E.   Events Requiring Outcomes Documentation: Please complete an Outcomes Documentation Form if any of the events in this section have occurred.

17.   Myocardial Infarction

HOS15A

a. Did a Myocardial Infarction (MI) occur during this hospitalization?

Y   Yes

N   No —— Go to item 18a

b. How many MI events occurred during this hospitalization? ☐ —— Complete Outcomes Documentation Form for each event upon completion of this form   HOS15B

Record the dates of the reported Myocardial Infarction event(s). The Event Numbers to the left of each date will be used to uniquely identify each MI occurrence. Use chronological sequencing if possible. However, do NOT change this assignment once it is made.

17c. **MI Event 1**   ☐☐ / ☐☐ / ☐☐☐☐   HOS15C
          Month   Day   Year

d. **MI Event 2**   ☐☐ / ☐☐ / ☐☐☐☐   HOS15D
          Month   Day   Year

e. **MI Event 3**   ☐☐ / ☐☐ / ☐☐☐☐   HOS15E
          Month   Day   Year

---

18.   Unstable Angina

HOS16A

a. Did Unstable Angina (USA) (i.e., patient experienced pain due to myocardial ischemia but it was determined that the patient did not have a myocardial infarction) occur during this hospitalization?

Y   Yes

N   No —— Go to item 19a

b. How many USA events occurred during this hospitalization? ☐ —— Complete Outcomes Documentation Form for each event upon completion of this form   HOS16B

Record the dates of the reported Unstable Angina event(s). The Event
Numbers to the left of each date will be used to uniquely identify each USA
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

18c. **USA Event 1** | | / | | / | | | HOS16C
Month   Day   Year

d. **USA Event 2** | | / | | / | | | HOS16D
Month   Day   Year

e. **USA Event 3** | | / | | / | | | HOS16E
Month   Day   Year

19. Stroke

a. Did a Stroke (neurological deficit lasting 24 hours or more) occur HOS17A
during this hospitalization?

Y   Yes

N   No —— | Go to item 20a |

b. How many Strokes occurred during this hospitalization? ☐ —— | Complete Outcomes Documentation Form for each event upon completion of this form | HOS17B

Record the dates of the reported Stroke event(s). The Event Numbers to
the left of each date will be used to uniquely identify each Stroke
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

19c. **Stroke Event 1** | | / | | / | | | HOS17C
Month   Day   Year

d. **Stroke Event 2** | | / | | / | | | HOS17D
Month   Day   Year

e. **Stroke Event 3** | | / | | / | | | HOS17E
Month   Day   Year

20. Resuscitated Sudden Death

   a. Was participant resuscitated after cardiac arrest?   HOS18A

      Y   Yes

      N   No —— Go to item 21a

   b. How many RSD events occurred during this hospitalization? [ ] —— Complete Outcomes Documentation Form for each event upon completion of this form

   HOS18B

Record the dates of the reported RSD event(s). The Event Numbers to the left of each date will be used to uniquely identify each RSD occurrence. Use chronological sequencing if possible. However, do NOT change this assignment once it is made.

20c. **RSD Event 1** [| | / | | | / | | |]   HOS18C
                       Month   Day   Year

  d. **RSD Event 2** [| | / | | | / | | |]   HOS18D
                       Month   Day   Year

  e. **RSD Event 3** [| | / | | | / | | |]   HOS18E
                       Month   Day   Year

Section F. Coronary Disease Events - Hospitalization

Please indicate whether or not each of the following occurred during this admission:

21a. (Inpatient) Coronary Artery angioplasty, or other percutaneous
     coronary revascularization procedures (i.e., laser, rotational/directional/   HOS19A
     extraction atherectomy, stent implants) **(Excluding Coronary Artery Bypass
     Surgery (CABG))**

      Y   Yes

      N   No —— Go to item 22a

  b. Date of procedure: [| | / | | | / | | |]   HOS19B
                          Month   Day   Year

  c. Time of procedure: [| | : | |]   d.   A   AM   HOS19D
                          Hour   Minute
   HOS19C
                                                      P   PM

ID_____   CO_____   Seq No_____

21e. Is an MI event being reported in association with this procedure?   HOS19E

    Y   Yes ⎯ Complete Outcomes Documentation
                      Form for this MI

    N   No

  f. Was the procedure performed urgently (i.e., not an elective surgery)?   HOS19F

    Y   Yes ⎯ Complete applicable sections of the Outcomes
                      Documentation Form, including the Urgent
                      Revascularization section. For additional
                      instructions, refer to QxQ's.

    N   No

    U   Unknown

22a. Did Coronary Artery Bypass Graft Surgery (CABG) occur during this hospitalization?   HOS20A

    Y   Yes

    N   No ⎯ Go to Item 23

  b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS20B
                   Month   Day   Year

  c. Time of procedure: [ ][ ] : [ ][ ]   d. A   AM   HOS20D
     HOS20C   Hour Minute

                              P   PM

  e. Is an MI being reported in association with this procedure?   HOS20E

    Y   Yes ⎯ Complete the Outcomes
                      Documentation Form for this MI

    N   No

22f. Was the Coronary Artery Bypass Graft performed urgently
    (i.e., not an elective surgery)?   HOS20F

    Y   Yes ⎯ Complete applicable sections of the Outcomes
                      Documentation Form, including the Urgent
                      Revascularization section. For additional
                      instructions, refer to QxQ's.
    N   No

    U   Unknown

23. Did Congestive Heart Failure occur during this hospitalization?   HOS21

    Y   Yes

    N   No

24. Did cardiac arrhythmia occur during this hospitalization?   HOS22

    Y   Yes

    N   No

Section G. Peripheral Vascular Disease

Please indicate whether or not each of the following occurred during this admission:

	Yes	No

HOS23A

25a. Carotid artery endarterectomy or carotid artery angioplasty   Y   N ⟶ Go to item 26a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS23B

HOS24A

26a. Thoraco-abdominal aortic aneurysm repair   Y   N ⟶ Go to item 27a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS24B

Please indicate whether or not each of the following occurred during this admission:

	Yes	No

HOS25A

27a. Lower extremity arterial bypass graft surgery   Y   N ⟶ Go to item 28a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS25B

HOS26A

28a. Renal arterial bypass graft surgery   Y   N ⟶ Go to item 29a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS26B

Please indicate whether or not each of the following occurred during this admission:

	Yes	No

HOS27A

29a. Angioplasty for lower extremity arterial disease   Y   N ⟶ Go to item 30a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS27B

HOS28A

30a. Lower extremity amputation above the ankle   Y   N ⟶ Go to item 31a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
                        Month   Day   Year

HOS28B

30c. Reason for amputation:

    A   Arterial disease (including severe rest pain or gangrene)   HOS28C

    B   Other

        If "other", specify: _____   HOS29A

31a. Angioplasty for renal arterial disease   Y   N —| Go to item 32a

  b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS29B
                 Month   Day   Year

Section H. Other Conditions of Interest

32.   Please indicate whether or not each of the following occurred during this
      admission:

                                           Yes   No

  a. Renal graft dysfunction/rejection   Y   N   HOS30A

  b. Abnormal renal biopsy   Y   N   HOS30B

  c. Infection/sepsis   Y   N   HOS30C

  d. Gastrointestinal complications   Y   N   HOS30D

  e. Diabetic complications   Y   N   HOS30E

32.   Please indicate whether or not each of the following occurred during this
      admission:
                                      Yes   No   HOS30F

  f. Organ transplant   Y   N —| Go to item 33a

  g. Specify type of transplant _____   HOS30G

  h. Date of transplant: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS30H
                  Month   Day   Year

Section I. Administrative Information

33a. Does an Outcome Documentation (OUT) Form need to be completed? HOS31A

    Y   Yes, related to this HOS

    T   Yes, related to a transfer HOS

    B   Yes, related to both
             transfer HOS and 1st HOS

    N   No ── Go to item 34

> NOTE: Use the same "Event Packet ID" (EPID) for both the HOS prior to the transfer and the transfer HOS. Be sure to record the EPID on both HOS forms if the participant is transferred to another hospital, if either trigger an OUT. (The response to item 31a might need to be updated.) (See QxQ's for additional instructions.)

33b. An "Event Packet ID" (EPID) must be assigned/used whenever a Hospitalization Form (or forms, when participant is transferred from one hospital to another) triggers an Outcomes Documentation (OUT) Form. The same Event Packet ID must be used on the resulting OUT form(s).

    Refer to EPID Log and record appropriate FAVORIT Event Packet ID:

    [ ][ ][ ][ ][ ][ ][ ] Blind_EPID

34. Method of data collection: HOSB34

    P   Paper

    C   Computer

35. Date of Data Collection:

    [ ][ ] / [ ][ ] / [ ][ ][ ][ ] HOS32

    Month   Day   Year

36. Data Collector's Initials: [ ][ ][ ] Blind_staff_ID

FAVORIT

Folic Acid for Vascular Outcome
Reduction in Transplantation

HOSPITALIZATION FORM

FORM CODE: HOS   VERSION: A   12/03/02

ID NUMBER: ☐☐☐☐☐☐☐   CONTACT OCCASION: ☐☐   SEQUENCE NUMBER: ☐☐

PATIENT LAST NAME: ☐☐☐☐☐☐☐☐☐☐☐☐   FIRST/MIDDLE INITIALS: ☐☐

Seq #:	0,1,2…	0,1,2…	**0,1,2…**	0,1,2…	**0,1,2…**	0,1,2…	**0,1,2…**	0,1,2…	**0,1,2…**	0,1,2…	**0,1,2…**
Contact #:	**1**	2	**3**	4	**5**	6	**7**	8	**9**	10	**11**
Study Month:	**0**	6	**12**	18	**24**	30	**36**	42	**48**	54	**60**

HOSPITALIZATION FORM (HOSA Screen 1 of 32)

Section A. Administrative Information

1. Was the hospitalization at a FAVORIT affiliated or non-FAVORIT affiliated hospital, or was this an outpatient Peripheral Angioplasty?

   HOS1

   F   FAVORIT affiliated ── Go to item 6

   N   Non-FAVORIT affiliated ── Go to item 6

   O   Outpatient Peripheral Angioplasty (coronary, lower extremities, renal arteries)

HOSPITALIZATION FORM (HOSA Screen 2 of 32)

Section B. Coronary Disease Events - Outpatient

2. Have you obtained access to review the outpatient chart, is access pending, or have you exhausted all possibilities to get the associated outpatient chart?

   HOS2

   O   Obtained access to chart

   P   Pending access to chart ── Update this form when access is obtained; **Go to item 32**

   N   No possibility of ever accessing chart ── Go to item 32

   It is essential that the study obtain an accurate report of events that occurred during this outpatient procedure. In order to do this, the medical records are crucial. Please make every effort to obtain the medical records.

ID_____   CO_____   Seq No_____

Please indicate whether or not each of the following occurred during this outpatient visit:

HOS3A

3a. Coronary artery angioplasty as an outpatient

    Y   Yes

    N   No —— | Go to item 4a |

HOS3B

  b. Date of procedure: | | | | / | | | / | | | | |
               Month   Day   Year

4a. Angioplasty of the lower extremity arteries as an outpatient

    Y   Yes

HOS4A

    N   No —— | Go to item 5a |

  b. Date of procedure: | | | | / | | | / | | | | |
               Month   Day   Year

HOS4B

5a. Angioplasty of the renal arteries as an outpatient

    Y   Yes

HOS5A

    N   No —— | Go to item 32 |

  b. Date of procedure: | | | | / | | | / | | | | | —— | Go to item 32 |
               Month   Day   Year

HOS5B

Section C. Hospital Administrative Information

HOS6

6. Have you obtained access to review the hospital chart, is access pending, or have you exhausted all possibilities to get the associated hospital chart?

    O   Obtained access to chart

    P   Pending access to chart —— | Update this form when access is obtained; **Go to item 32** |

    N   No possibility of ever accessing chart —— | Go to item 32 |

| It is essential that the study obtain an accurate report of events that occurred during this hospitalization. In order to do this, the medical records are crucial. Please make every effort to obtain the hospital records. |

7. Date of hospital admission: ⬚⬚ / ⬚⬚ / ⬚⬚⬚⬚   **HOS7**
                                      Month   Day   Year

8. Date of discharge (nonfatal cases) or death: ⬚⬚ / ⬚⬚ / ⬚⬚⬚⬚   **HOS8**
                                                 Month   Day   Year

Section D. Discharge Information

9. What was the disposition of the patient on discharge?   **HOS9**

   D   Deceased — | Complete Outcomes Documentation Form upon completion of this form |

   T   Transferred to another hospital — | Complete a separate Hospitalization Form upon completion of this form; **Go to item 12** |

   M   Transferred to another medical care facility (e.g., Rehab, nursing home, — | Go to item 12 | long-term care)

   H   Discharged to home — | Go to item 12 |

10. Are any causes of death given on the discharge summary?   **HOS10**

    Y   Yes

    N   No — | Go to item 12 |

11. Causes of death on the discharge summary:

    a. _____   **HOS11A**

    b. _____   **HOS11B**

    c. _____   **HOS11C**

    d. _____   **HOS11D**

    e. _____   **HOS11E**

    f. _____   **HOS11F**

12. List the hospital discharge diagnosis **codes** exactly as they appear on the front sheet of the discharge summary (if none appear then leave this item blank):

a. ☐☐☐☐☐☐☐ HOS12A   h. ☐☐☐☐☐☐☐ HOS12H

b. ☐☐☐☐☐☐☐ HOS12B   i. ☐☐☐☐☐☐☐ HOS12I

c. ☐☐☐☐☐☐☐ HOS12C   j. ☐☐☐☐☐☐☐ HOS12J

d. ☐☐☐☐☐☐☐ HOS12D   k. ☐☐☐☐☐☐☐ HOS12K

e. ☐☐☐☐☐☐☐ HOS12E   l. ☐☐☐☐☐☐☐ HOS12L

f. ☐☐☐☐☐☐☐ HOS12F   m. ☐☐☐☐☐☐☐ HOS12M

g. ☐☐☐☐☐☐☐ HOS12G   n. ☐☐☐☐☐☐☐ HOS12N

13. Coding System:

    HOS13

    A   ICD-9

    B   ICD-10

    C   No codes entered in Item 12

For items 13 - 16 use Diag_niddkv1; many of the ICD codes were recoded using a nosologist.

14. Discharge diagnoses (**Text descriptors**, NOT ICD CODES). Do <u>not</u> split a single diagnosis across two or more response items:

a. _____ HOS14A

b. _____ HOS14B

c. _____ HOS14C

d. _____ HOS14D

e. _____ HOS14E

f. _____ HOS14F

g. _____ HOS14G

14. Discharge diagnoses (Text descriptors, NOT ICD CODES). Do <u>not</u> split a
    single diagnosis across two or more response items:

    h. _____   `HOS14H`

    i. _____   `HOS14I`

    j. _____   `HOS14J`

    k. _____   `HOS14K`

    l. _____   `HOS14L`

    m. _____   `HOS14M`

    n. _____   `HOS14N`

Note: Refer to QxQ's for additional terms that would be included for the
      conditions in sections E-F.

**Section E.   Events Requiring Outcomes Documentation: Please complete an
           Outcomes Documentation Form if any of the events in this section
           have occurred.**

15. Myocardial Infarction

   a. Did a Myocardial Infarction (MI) occur during this hospitalization?   `HOS15A`

     Y   Yes

     N   No — | Go to item 16a |

   b. How many MI events occurred during this hospitalization? [ ] — | Complete Outcomes Documentation Form for each event upon completion of this form   `HOS15B` |

ID_____   CO_____   Seq No_____

Record the dates of the reported Myocardial Infarction event(s). The Event
Numbers to the left of each date will be used to uniquely identify each MI
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

15c. **MI Event 1** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS15C
                     Month   Day   Year

  d. **MI Event 2** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS15D
                     Month   Day   Year

  e. **MI Event 3** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS15E
                     Month   Day   Year

16.   Unstable Angina

  a. Did Unstable Angina (USA) (i.e., patient experienced pain due to   HOS16A
     myocardial ischemia but it was determined that the patient did not
     have a myocardial infarction) occur during this hospitalization?

     Y   Yes

     N   No —— [Go to item 17a]

  b. How many USA events occurred during this hospitalization? [ ] —— Complete Outcomes Documentation
                                                                       Form for each event upon
                                                                       completion of this form

                                                                                       HOS16B

Record the dates of the reported Unstable Angina event(s). The Event
Numbers to the left of each date will be used to uniquely identify each USA
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

16c. **USA Event 1** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS16C
                      Month   Day   Year

  d. **USA Event 2** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS16D
                      Month   Day   Year

  e. **USA Event 3** [ ][ ]/[ ][ ]/[ ][ ][ ][ ]   HOS16E
                      Month   Day   Year

ID_____   CO_____   Seq No_____

17. Stroke

   a. Did a Stroke (neurological deficit lasting 24 hours or more) occur   HOS17A
       during this hospitalization?

       Y   Yes

       N   No ── Go to item 18a

   b. How many Strokes occurred during this hospitalization? [ ] ── Complete Outcomes Documentation
                                                                    Form for each event upon
                                                                    completion of this form   HOS17B

Record the dates of the reported Stroke event(s). The Event Numbers to
the left of each date will be used to uniquely identify each Stroke
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

17c. **Stroke Event 1**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS17C
                          Month   Day   Year

   d. **Stroke Event 2**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS17D
                          Month   Day   Year

   e. **Stroke Event 3**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS17E
                          Month   Day   Year

18.   Resuscitated Sudden Death

  a. Did Resuscitated Sudden Death (RSD) (patient is successfully resuscitated
      after cardiac arrest) occur during this hospitalization?   HOS18A

      Y   Yes

      N   No ── Go to item 19a

  b. How many RSD events occurred during this hospitalization? [ ] ── Complete Outcomes Documentation
                                                                        Form for each event upon
                                                                        completion of this form

                                                                 HOS18B

Record the dates of the reported RSD event(s). The Event Numbers to
the left of each date will be used to uniquely identify each RSD
occurrence. Use chronological sequencing if possible. However, do NOT
change this assignment once it is made.

18c. **RSD Event 1**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS18C
                       Month   Day   Year

  d. **RSD Event 2**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS18D
                       Month   Day   Year

  e. **RSD Event 3**   [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS18E
                       Month   Day   Year

Section F. Coronary Disease Events - Hospitalization

Please indicate whether or not each of the following occurred during this
admission:

19a. (Inpatient) Coronary Artery angioplasty, or other percutaneous
      coronary revascularization procedures (i.e., laser, rotational/directional/   HOS19A
      extraction atherectomy, stent implants) **(Excluding Coronary Artery Bypass
      Surgery (CABG))**

      Y   Yes

      N   No ── Go to item 20a

  b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS19B
                           Month   Day   Year

  c. Time of procedure: [ ][ ] : [ ][ ]   d.   A   AM   HOS19D

         HOS19C   Hour   Minute

                                                        P   PM

19e. Is an MI event being reported in association with this procedure?   HOS19E

    Y   Yes ── Complete Outcomes Documentation
                 Form for this MI

    N   No

  f. Was the procedure performed urgently (i.e., not an elective surgery)?   HOS19F

    Y   Yes ── Complete applicable sections of the Outcomes
                 Documentation Form, including the Urgent
                 Revascularization section. For additional
                 instructions, refer to QxQ's.

    N   No

    U   Unknown

20a. Did Coronary Artery Bypass Graft Surgery (CABG) occur during this hospitalization?   HOS20A

    Y   Yes

    N   No ── Go to Item 21

  b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐   HOS20B
                    Month   Day   Year

  c. Time of procedure: ☐☐ : ☐☐   d.   A   AM   HOS20D
   HOS20C
                 Hour   Minute
                                   P   PM

  e. Is an MI being reported in association with this procedure?   HOS20E

    Y   Yes ── Complete the Outcomes
                 Documentation Form for this MI

    N   No

20f. Was the Coronary Artery Bypass Graft performed urgently
     (i.e., not an elective surgery)?   HOS20F

     Y   Yes ── Complete applicable sections of the Outcomes
                     Documentation Form, including the Urgent
                     Revascularization section. For additional
     N   No   instructions, refer to QxQ's.

     U   Unknown

21. Did Congestive Heart Failure occur during this hospitalization?   HOS21

     Y   Yes

     N   No

22. Did cardiac arrhythmia occur during this hospitalization?   HOS22

     Y   Yes

     N   No

Section G. Peripheral Vascular Disease

Please indicate whether or not each of the following occurred during this
admission:
                                                   <u>Yes</u>   <u>No</u>   HOS23A

23a. Carotid artery endarterectomy or carotid artery
     angioplasty   Y   N ── Go to item 24a

  b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
     HOS23B   Month   Day   Year

                                                               HOS24A

24a. Thoraco-abdominal aortic aneurysm repair   Y   N ── Go to item 25a

  b. Date of procedure: ☐☐ / ☐☐ / ☐☐☐☐
     HOS24B   Month   Day   Year

Please indicate whether or not each of the following occurred during this admission:

<u>Yes</u>   <u>No</u>   HOS25A

25a. Lower extremity arterial bypass graft surgery   Y   N — Go to item 26a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
HOS25B
              Month   Day   Year

HOS26A

26a. Renal arterial bypass graft surgery   Y   N — Go to item 27a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
HOS26B
              Month   Day   Year

Please indicate whether or not each of the following occurred during this admission:

<u>Yes</u>   <u>No</u>   HOS27A

27a. Angioplasty for lower extremity arterial disease   Y   N — Go to item 28a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
HOS27B
              Month   Day   Year

HOS28A

28a. Lower extremity amputation above the ankle   Y   N — Go to item 29a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
HOS28B
              Month   Day   Year

28c. Reason for amputation: HOS28C

    A   Arterial disease (including severe rest pain or gangrene)

    B   Other

       If "other", specify: _____   HOS29A

29a. Angioplasty for renal arterial disease   Y   N — Go to item 30a

b. Date of procedure: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]   HOS29B
              Month   Day   Year

Section H. Other Conditions of Interest

30. Please indicate whether or not each of the following occurred during this
     admission:

	Yes	No

a. Renal graft dysfunction/rejection   Y   N   HOS30A

b. Abnormal renal biopsy   Y   N   HOS30B

c. Infection/sepsis   Y   N   HOS30C

d. Gastrointestinal complications   Y   N   HOS30D

e. Diabetic complications   Y   N   HOS30E

30. Please indicate whether or not each of the following occurred during this
     admission: HOS30F

	Yes	No

f. Organ transplant   Y   N ── Go to item 31a

g. Specify type of transplant _____   HOS30G

h. Date of transplant: [ ] [ ] / [ ] [ ] / [ ] [ ] [ ]   HOS30H
                         Month   Day   Year

Section I. Administrative Information

31a. Does an Outcome Documentation (OUT) Form need to be completed?   HOS31A

    Y   Yes, related to this HOS

    T   Yes, related to a transfer HOS

    B   Yes, related to both
             transfer HOS and 1st HOS

    N   No ——| Go to item 32 |

> NOTE: Use the same "Event Packet ID" (EPID) for both the HOS prior to the transfer and the transfer HOS. Be sure to record the EPID on both HOS forms if the participant is transferred to another hospital, if either trigger an OUT. (The response to item 31a might need to be updated.) (See QxQ's for additional instructions.)

31b. An "Event Packet ID" (EPID) must be assigned/used whenever a Hospitalization Form (or forms, when participant is transferred from one hospital to another) triggers an Outcomes Documentation (OUT) Form. The same Event Packet ID must be used on the resulting OUT form(s).

    Refer to EPID Log and record appropriate FAVORIT Event Packet ID:

    | | | | | | | | Blind_EPID

32.   Date of Data Collection:

    | | | / | | | / | | | | HOS32

    Month   Day   Year

33.   Data Collector's Initials: | | | | Blind_staff_ID