INTRODUCTION TO FORM 42 – DONOR SPECIMEN PROCESSING INFORMATION FORM

A separate Form 42 was to be filled out for each red blood cell or platelet unit transfused. The variables linking Form 42 with Form 43 are PUB_ID and UNIT_ID.

DONOR SPECIMEN PROCESSING INFORMATION FORM – FORM 42 QxQ

This form is being used to track the collection of unit (donor and/or issue) information and specimens for every Red Cell and Platelet unit issued to a VATS participant. This form may be completed at different points or by more than one person depending, for example, on whether blood products are obtained from outside suppliers. Specimens from both the donor bag (1.0 ml. segment) and the study issue bag (1 ml. aliquot) are to be collected and frozen. Locations within freezer boxes, to facilitate specimen identification for Central Lab tests, will also be tracked by this form. VATS staff responsible for completing this form will need to read, and be familiar with, the Central Laboratory portion of the VATS Manual of Operations regarding processing, storage and shipment of these specimens.

SECTION A -- GENERAL INFORMATION

This section, as well as sections C, D and E, are to be completed by the VATS Transfusion Service

A1.   Affix the VATS study ID label or record the VATS study ID number of the participant who was issued the unit number reflected on this form, (i.e. the unit number that will be recorded at question B2.).

A2.   Record the date or, if information is being added over more than one day's time, one of the dates you are completing/filling out this form.

SECTION B -- BLOOD SUPPLIER/SEGMENT INFORMATION

This section is to be completed by the blood supplier. Specific unit and donor information is requested.

B1.   The technician completing this section of the form is to record his/her initials in the space provided. In some cases, this may be a VATS' site technician who is transcribing information previously requested and received from an outside supplier.

B2. THROUGH B4.

Record the donor unit ID number, the date it was collected and the donor's gender.

B5.   This question refers to any unit that has been leukoreduced between collection (from the donor) and issued to a VATS participant. Sites may need to obtain dates units were leukoreduced from their outside suppliers.

B6.   Indicate whether a segment from the Red Cell donor bag (i.e., prior to leukoreduction and/or transfer to a study issue bag) has been obtained. NOTE: Donor segments are not being collected from Platelets, therefore the "No" box should be checked for platelet units.

SECTION C--TRANSFUSION SERVICE INFORMATION

This section needs to be completed if the answer to question B6. is "Yes." If a donor segment was not obtained, skip to Section D.

Refer to the Central Laboratory instructions regarding preparation and freezing of donor segments if needed. After recording the specimen ID number assigned to the segment for this unit, the volume and freezer box location of the tube, the technician should record his/her initials at C3.

SECTION D -- TRANSFUSION SERVICE INFORMATION

VATS transfusion service staff need to record specific unit information and obtain a 1 ml. specimen from each Red Cell issue bag prior to dispensing it to the participant, stored as two 0.5 ml. aliquots. A 1 ml. sample will be obtained from each apheresis unit or pool for platelet transfusions and stored as two 0.5 ml aliquots.

D1.   Record the date the unit was issued by the transfusion service for transfusion.

D2.   Check the component type issued. Study components consist of either packed red cells or platelets. If another component (i.e., a non-study component) was issued, check box "3." and specify the product type. Please note: Any irradiated products (even if they are packed red cells/platelets) are considered "non-study" components, and are to be recorded as such.

D3.   It is important that the transfusion service weigh and record the unit weight (in grams) at the time of issue. The weight of the unit will be needed in some cases to calculate results of central lab studies.

SECTION E -- UNIT ALIQUOTS

E1. THROUGH E3.

If needed, refer to the Central Laboratory portion of the VATS Manual of Operations regarding aliquoting and storage of unit aliquots from product issue bags. The technician processing these specimens is to record his/her initials after completing the information requested. Please note: These aliquots are required on all units issued as part of the VATS. If for some reason, they are not obtained, E1-E4 should be left blank, and "not obtained" recorded.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 42 -- DONOR/SPECIMEN PROCESSING INFORMATION FORM

SECTION A -- GENERAL INFORMATION

SECTIONS A, C, D & E TO BE COMPLETED BY TRANSFUSION SERVICE. **SECTION B TO BE COMPLETED BY BLOOD SUPPLIER.**		

A1. Subject ID: ___ ___ - ___ ___ ___ - ___

A2. Form version: _0_ _1_ / _1_ _5_ / _9_ _6_

A3. Today's date: ___ ___ / ___ ___ / ___ ___

SECTION B -- BLOOD SUPPLIER/SEGMENT INFORMATION

B1. Initials of technician: ___. ___. ___.

B2. Blood Unit ID: _____

B3. Date unit collected: ___ ___ / ___ ___ / ___ ___

B4. Sex of donor: [   ] 1. Male

[   ] 2. Female

B5. Leukoreduced? [   ] 1. Yes ➔ | a. Date Leukoreduced: ___ ___ / ___ ___ / ___ ___ |

[   ] 2. No

B6. Donor unit segment(s) obtained? [   ] 1. Yes

[   ] 2. No ➔ **Skip to Section D**

SECTION C -- TRANSFUSION SERVICE SEGMENT INFORMATION

	a. Spec. ID #	b. Volume Saved	c. Box #	LOCATION d. Row	e. Column
C1. (1.0 ml) Segment (B0)	___ ___ - ___ ___ ___ -BO	___ . ___ ml	_____	_____	_____

C2. Date frozen: ___ ___ / ___ ___ / ___ ___

C3. Initials of technician: ___. ___. ___.

SECTION D -- TRANSFUSION SERVICE INFORMATION

D1. Date unit issued: ___ ___ / ___ ___ / ___ ___

D2. Component Type:

Study Components [   ] 1. Packed RBCs

[   ] 2. Platelets

Non-Study Components [   ] 3. Specify_____

D3. Product weight at issue: _____ gms.

D4 Initials of technician: ___. ___. ___.

SECTION E -- UNIT ALIQUOTS

	a. Spec. ID #	b. Volume Saved	c. Box #	LOCATION d. Row	e. Column
E1. (0.5 ml) Aliquot (T1)	___ ___ - ___ ___ ___ -T1	___ . ___ ml	_____	_____	_____
E2. (0.5 ml) Aliquot (T2)	___ ___ - ___ ___ ___ -T2	___ . ___ ml	_____	_____	_____

E3. Date frozen: ___ ___ / ___ ___ / ___ ___

E4. Initials of technician: ___. ___. ___.

END OF FORM

DONOR SPECIMEN PROCESSING INFORMATION FORM – FM42DATA CODEBOOK

```
PUB_ID ------------------------------------------------------- SUBJECT ID
              type:  numeric (float)

             range:  [1,531]                      units:  1
     unique values:  521               coded missing:  0 / 4099

              mean:  269.532
         std. dev:  148.989

       percentiles:         10%       25%       50%       75%       90%
                            58        148       276       395       468


FORM_V --------------------------------------------------- A2.FORM VERSION DATE
              type:  numeric (float)
             label:  FORM_V

             range:  [12979,13163]                units:  1
     unique values:  2                 coded missing:  0 / 4099

        tabulation:  Freq.    Numeric  Label
                      937       12979   07/15/95
                     3162       13163   01/15/96


UNIT_ID ------------------------------------------------------ B2.UNIT ID
              type:  string (str12), but longest is str11

     unique values:  4099              coded missing:  0 / 4099

          examples:  "2023379"
                     "4B2069"
                     "7X4511"
                     "K36493"


COLLECTD --------------------------------------------- B3.DATE BLOOD COLLECTED
              type:  numeric (float)

             range:  [-33,1113]                   units:  1
     unique values:  596               coded missing:  8 / 4099

              mean:  146.337
         std. dev:  233.659

       percentiles:         10%       25%       50%       75%       90%
                            -10        -5        42       191       494
```

COLLECTD:
  1. This variable has been coded as the number of days since Randomization
     (Negative values indicate dates before Randomization, positive values
     indicate dates subsequent to Randomization).

```
DONORSEX -------------------------------------------------- B4.SEX OF DONOR
                type:  numeric (float)
               label:  DONORSEX

               range:  [1,3]                          units:  1
       unique values:  3                      coded missing:  93 / 4099

          tabulation:  Freq.   Numeric  Label
                       2147         1   1:Male
                       1823         2   2:Female
                         36         3   3:See note

DONORSEX:
   1.  Clincial sites were generally to use only single-donor blood units.
       Sometimes, however, pooled platelet units were used, which contain
       blood from more than one donor. In that case, DONORSEX was coded as 3,
       and SWOMEN and SMEN were assigned values that indicate the number of
       female and male donors whose blood was included in the unit.


SWOMEN --------------------------------------- POOLED UNITS - NUMBER OF WOMEN
                type:  numeric (float)

               range:  [0,5]                          units:  1
       unique values:  6                      coded missing:  4066 / 4099

          tabulation:  Freq.  Value
                           1      0
                           3      1
                           7      2
                          13      3
                           8      4
                           1      5


SMEN ------------------------------------------- POOLED UNITS - NUMBER OF MEN
                type:  numeric (float)

               range:  [1,6]                          units:  1
       unique values:  6                      coded missing:  4066 / 4099

          tabulation:  Freq.  Value
                           1      1
                           6      2
                          11      3
                          12      4
                           1      5
                           2      6


LEUKORED ------------------------------------------------- B5.LEUKOREDUCED?
                type:  numeric (float)
               label:  LEUKORED

               range:  [1,2]                          units:  1
       unique values:  2                      coded missing:  0 / 4099

          tabulation:  Freq.   Numeric  Label
                       2197         1   1:Yes
                       1902         2   2:No
```

```
LEUKO_DT ------------------------------------------------- B5a.DATE LEUKOREDUCED
                type:  numeric (float)

              range:  [-36,1058]                      units:  1
      unique values:  496                     coded missing:  1907 / 4099

               mean:   167.998
           std. dev:   254.11

        percentiles:        10%        25%        50%        75%        90%
                            -9         -3         52      249.5        543
```

LEUKO_DT:
  1. This variable has been coded as the number of days since Randomization
     (Negative values indicate dates before Randomization, positive values
     indicate dates subsequent to Randomization).

```
FROZ_DT -------------------------------------------------- C2.DATE SEGMENT FROZEN
                type:  numeric (float)

              range:  [0,1120]                        units:  1
      unique values:  516                     coded missing:  502 / 4099

               mean:   154.121
           std. dev:   228.478

        percentiles:        10%        25%        50%        75%        90%
                             1          2         53        205        488
```

FROZ_DT:
  1. This variable has been coded as the number of days since Randomization
     (Negative values indicate dates before Randomization, positive values
     indicate dates subsequent to Randomization).

```
ISSUE_DT ------------------------------------------------- D1.DATE UNIT ISSUED
                type:  numeric (float)

              range:  [-1,1120]                       units:  1
      unique values:  560                     coded missing:  10 / 4099

               mean:   155.305
           std. dev:   233.762

        percentiles:        10%        25%        50%        75%        90%
                             0          1         51        202        504
```

ISSUE_DT:
  1. This variable has been coded as the number of days since Randomization
     (Negative values indicate dates before Randomization, positive values
     indicate dates subsequent to Randomization).

```
COMPTYPE ------------------------------------------------- D2.COMPONENT TYPE
                type:  numeric (float)
               label:  COMPTYPE

              range:  [1,3]                            units:  1
      unique values:  3                       coded missing:  7 / 4099

         tabulation:  Freq.    Numeric  Label
                      3780           1  1:Packed RBC's
                       270           2  2:Platelets
                        42           3  3:Non-study components
```

```
COMPSPEC ------------------------------------- D2.NONSTUDY COMPONENT SPECIFY
              type:  string (str25)

      unique values:  10                    coded missing:  4057 / 4099

         tabulation:  Freq.  Value
                          2  "LPC'S"
                          1  "PACKED RBC'S/CMV NEGATIVE"
                          1  "PACKED RBC/CMV-/IRRADIATD"
                          1  "PACKED RBS/CMV-/IRRADIATD"
                          1  "PACKED RED CELLS/CMV NEG."
                         12  "PLATELETS"
                          1  "PLATLETS"
                         17  "RBC"
                          1  "RBC-1"
                          5  "WHOLE BLOOD"

            warning:  variable has embedded blanks


PROD_WT ------------------------------------- D3.PRODUCT WEIGHT AT ISSUE (GM)
              type:  numeric (float)

              range:  [104,523]                  units:  1
      unique values:  279              coded missing:  164 / 4099

               mean:  305.966
           std. dev:  55.4213

        percentiles:      10%       25%       50%       75%       90%
                          230       265       310       348       375


FROZEN_D --------------------------------------- E3.DATE ALIQUOTS FROZEN
              type:  numeric (float)

              range:  [0,1120]                   units:  1
      unique values:  534              coded missing:  237 / 4099

               mean:  158.974
           std. dev:  236.767

        percentiles:      10%       25%       50%       75%       90%
                            1         2        53       206       529
```

FROZEN_D:
  1. This variable has been coded as the number of days since Randomization
      (Negative values indicate dates before Randomization, positive values
      indicate dates subsequent to Randomization).