INTRODUCTION TO FORM 45 – UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS

Information on any unblinding or withdrawal from study components was recorded on this form. A patient could be unblinded as to their study arm and/or withdraw from study components without being deactivated from the study.

UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS – FORM 45 QxQ

Use this form if the patient is withdrawn from study components and/or if the treatment arm is intentionally or unintentionally unblinded for any reason. Note that it is possible to withdraw from study components without unblinding and it is possible to unblind without withdrawing from study components.

SECTION A -- GENERAL INFORMATION

A1.   Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.

A2.   Enter the visit number.

A3.   Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box

A5.   Record the date that this form is completed.

A6.   Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

For the 01/15/96 version the visit number was deleted from the form and the questions were renumbered as follows:

A1.   Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.

A2.   Record the date that this form is completed.

A3.   Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box

A5.   Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

SECTION B -- WITHDRAWAL FROM STUDY COMPONENTS

B1.   If circumstances warrant that a patient receive leukoreduced blood in the future, check yes. Note that if this does happen, it may still be possible to keep the original treatment arm blinded. For example, a patient may be told that from now on they will receive leukoreduced units, but which arm they received previously will be kept blinded. This would be considered being withdrawn from blinded study components.

If the patient was previously withdrawn from study components, (e.g. recorded on a Form 45 already submitted) and now reporting unblinding of the treatment randomization arm, check "No" and go to B4.

B2.   Give the date that the decision was made to withdraw the patient from blinded study components.

B3.   Check one box only, i.e., give the primary reason for withdrawal from blinded study components.

B4.   If the patient was unblinded to the original treatment group assignment, answer yes and complete C1-C7. If the patient is being withdrawn from blinded study components, without unblinding the treatment arm, check "No" and proceed to question C4.

SECTION C -- UNBLINDING

C1.   Give the date that the treatment arm was unblinded.

C2.   Check one box only, i.e., give the primary reason for unblinding.

C3.   Give more details about subsequent actions taken regarding patient care.

C4.   If the patient is not going to continue on the VATS study, complete Form 47 (Deactivation Form). Note that removal from blinded study components and unblinding do not ordinarily result in deactivation. See protocol, Section 7.2.

C5. THROUGH C7.

Three signatures are required if the patient is removed from blinded study components and/or unblinded.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 45 -- WITHDRAWAL FROM BLINDED STUDY COMPONENTS/ UNBLINDING OF RANDOMIZATION

SECTION A -- GENERAL INFORMATION

A1.   Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)   ___ ___ - ___ ___ ___ - ___

A2.   Visit number: ___ ___

A3.   Subject initials: ___. ___. ___.

A4.   Form version: _0_ _7_ / _1_ _5_ / _9_ _5_

A5.   Today's date: ___ ___ / ___ ___ / ___ ___

A6.   Initials of person completing form: ___. ___. ___.

SECTION B -- WITHDRAWAL FROM STUDY COMPONENTS

B1.   Is subject being withdrawn from blinded   [   ] 1. Yes
      study components at this time?   [   ] 2. No ➔ **SKIP TO B4**

B2.   Date withdrawn from   ___ ___ / ___ ___ / ___ ___
      blinded study components:

B3.   Primary reason withdrawn: [   ] 1. Patient request

                                                  [   ] 2. Primary physician's
                                                              request

                                                  [   ] 3. Transfusion reaction(s)
                                                              warranting
                                                         leukoreduced
                                                              units

                                                  [   ] 4. 0ther medical indication ✔

                                                  Specify: _____

                                                  _____

                                                  _____

B4.   Was randomization treatment arm   [   ] 1. Yes
      unblinded?   [   ] 2. No   ➔ **SKIP TO C4**

SECTION C -- UNBLINDING

C1. Date randomization
treatment arm unblinded: ___ ___ / ___ ___ / ___ ___

C2. Reason randomization   [   ]   1. Medically indicated   ➔   a. Specify reaction/event:
treatment arm unblinded: due to adverse   _____
reaction/event   _____
_____

[   ]   2. Primary Physician's request

[   ]   3. Patient request

[   ]   4. Other reason   ➔   a. Specify _____
_____
_____
_____

C3. Action Taken:

_____
_____
_____
_____
_____

C4. Is patient continuing on the   [   ]   1. Yes
VATS study?   [   ]   2. No   ➔   **COMPLETE FORM 47
DEACTIVATION
FORM**

_____   ___ ___ / ___ ___ / ___ ___
C5. Transfusion Service Physician's signature   a. Date signed

_____   ___ ___ / ___ ___ / ___ ___
C6. Transfusion Coordinator's signature   a. Date signed

_____   ___ ___ / ___ ___ / ___ ___
C7. Clinical Coordinator's signature   a. Date signed

END OF FORM

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VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 45 -- WITHDRAWAL FROM BLINDED STUDY COMPONENTS/ UNBLINDING OF RANDOMIZATION

</div>

SECTION A -- GENERAL INFORMATION

A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)   __ __ - __ __ __ - __

A2. Today's Date: __ __ / __ __ / __ __

A3. Subject initials: __. __. __.

A4. Form version: _0_ _1_ / _1_ _5_ / _9_ _6_

A5. Initials of person completing form: __. __. __.

SECTION B -- WITHDRAWAL FROM STUDY COMPONENTS

B1. Is subject being withdrawn from blinded study components at this time?
  [   ] 1. Yes
  [   ] 2. No ➔ **SKIP TO B4**

B2. Date withdrawn from blinded study components: __ __ / __ __ / __ __

B3. Primary reason withdrawn:
  [   ] 1. Patient request
  [   ] 2. Primary physician's request
  [   ] 3. Transfusion reaction(s) warranting leukoreduced units
  [   ] 4. 0ther medical indication ↓

  Specify: _____

  _____

  _____

B4. Was randomization treatment arm unblinded?
  [   ] 1. Yes
  [   ] 2. No ➔ **SKIP TO C4**

SECTION C -- UNBLINDING

C1. Date randomization
treatment arm unblinded: ___ ___ / ___ ___ / ___ ___

C2. Reason randomization   [____]   1. Medically indicated   ➔   a. Specify reaction/event:
treatment arm unblinded: due to adverse   _____
                                   reaction/event   _____
                                                                    _____

                          [____]   2. Primary Physician's request

                          [____]   3. Patient request

                          [____]   4. Other reason   ➔   a. Specify _____
                                                                    _____
                                                                    _____
                                                                    _____

C3. Action Taken:

_____
_____
_____
_____
_____

C4. Is patient continuing on the   [____]   1. Yes
VATS study?   [____]   2. No   ➔   **COMPLETE FORM 47 DEACTIVATION FORM**

_____   ___ ___ / ___ ___ / ___ ___
C5. Transfusion Service Physician's signature   a. Date signed

_____   ___ ___ / ___ ___ / ___ ___
C6. Transfusion Coordinator's signature   a. Date signed

_____   ___ ___ / ___ ___ / ___ ___
C7. Clinical Coordinator's signature   a. Date signed

END OF FORM

UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS – FM45DATA CODEBOOK

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

              range:  [9,521]                        units:  1
      unique values:  11                     coded missing:  0 / 11

         tabulation:  Freq.   Value
                        1          9
                        1         15
                        1         38
                        1         59
                        1        245
                        1        288
                        1        335
                        1        483
                        1        487
                        1        492
                        1        521


FORM_V --------------------------------------------------------- A4.FORM VERSION
               type:  numeric (float)
              label:  FORM_V

              range:  [12979,13163]                  units:  1
      unique values:  2                      coded missing:  0 / 11

         tabulation:  Freq.    Numeric  Label
                        3        12979  07/15/95
                        8        13163  01/15/96


WITHDRAW --------------------------------- B1.SUBJECT WITHDRAWN BLINDED COMP
               type:  numeric (float)
              label:  WITHDRAW

              range:  [1,2]                           units:  1
      unique values:  2                      coded missing:  0 / 11

         tabulation:  Freq.   Numeric  Label
                        7         1  1:Yes
                        4         2  2:No


WDRAW_DT ------------------------------- B2.DATE WITHDRAWN FROM BLINDED COMP
               type:  numeric (float)

              range:  [0,798]                         units:  1
      unique values:  7                      coded missing:  4 / 11

         tabulation:  Freq.   Value
                        1          0
                        1          2
                        1          6
                        1        158
                        1        180
                        1        355
                        1        798
```

```
WDRAW_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).


W_REASON -------------------------------------------------- B3.WITHDRAW REASON
              type:  numeric (float)
             label:  W_REASON

             range:  [3,4]                            units:  1
     unique values:  2                        coded missing:  4 / 11

        tabulation:  Freq.   Numeric  Label
                        2          3  3:Transfusion reaction(s)
                                      warranting leukoreduced units
                        5          4  4:Other medicalindication


WREASPEC ------------------------------------------- B3.WITHDRAW REASON SPECIFY
              type:  string (str30)

     unique values:  5                        coded missing:  6 / 11

        tabulation:  Freq.   Value
                        1  "BASELINE CMV WAS NEGATIVE"
                        1  "CMV NEGATIVE"
                        1  "CMV NEGATIVE PATIENT"
                        1  "NOT CMV +"
                        1  "ONCO. ONLY WANT FILTERED BLOOD"

           warning:  variable has embedded blanks


TXUNBLND ----------------------------------------- B4.TREATMENT ARM UNBLINDED
              type:  numeric (float)
             label:  TXUNBLND

             range:  [1,2]                            units:  1
     unique values:  2                        coded missing:  0 / 11

        tabulation:  Freq.   Numeric  Label
                        4          1  1:Yes
                        7          2  2:No


UNBL_DT ------------------------------------- C1.DATE TREATMENT ARM UNBLINDED
              type:  numeric (float)

             range:  [1,205]                          units:  1
     unique values:  4                        coded missing:  7 / 11

        tabulation:  Freq.   Value
                        1          1
                        1         32
                        1        176
                        1        205
```

```
UNBL_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).


UNB_REAS -------------------------------- C2.REASON TREATMENT ARM UMBLINDED
              type:  numeric (float)
             label:  UNB_REAS

             range:  [4,4]                          units:  1
     unique values:  1                       coded missing:  7 / 11

         tabulation:  Freq.   Numeric  Label
                          4         4  4:Other reason


REAS_SPC -------------------------------------- C2a.REASON UNBLINDED SPECIFY
              type:  string (str30)

     unique values:  4                       coded missing:  7 / 11

         tabulation:  Freq.   Value
                          1   "BLD BNK STAFF REVEALED TX ARM"
                          1   "OFF-SITE, COULDNT SAY LR/NLR"
                          1   "RBC'S NOT PUT IN BLINDED BAG"
                          1   "SUPERV. REVEALED ARM TO COORDI"

           warning:  variable has embedded blanks


ACT_TAKN ---------------------------------------------------- C3.ACTION TAKEN
              type:  string (str16)

     unique values:  2                       coded missing:  7 / 11

         tabulation:  Freq.   Value
                          3   "Staff re-trained"
                          1   "none"

           warning:  variable has embedded blanks


PT_CONT ------------------------------------------- C4.PT CONTINUNG IN STUDY
              type:  numeric (float)
             label:  PT_CONT

             range:  [1,2]                          units:  1
     unique values:  2                       coded missing:  0 / 11

         tabulation:  Freq.   Numeric  Label
                         10         1  1:Yes
                          1         2  2:No
```

```
TXMDSIGN --------------------------------- C5.TRANSFUSION SERVICE MD SIGNED
                  type:  numeric (float)
                 label:  TXMDSIGN

                 range:  [1,1]                        units:  1
         unique values:  1                    coded missing:  0 / 11

           tabulation:  Freq.   Numeric  Label
                         11           1  1:Yes


MDSIGN_D ------------------------------- C5a.DATE TRANSFUSION SERVICE MD SIGN
                  type:  numeric (float)

                 range:  [9,1167]                     units:  1
         unique values:  11                   coded missing:  0 / 11

           tabulation:  Freq.   Value
                          1           9
                          1          10
                          1          11
                          1          37
                          1          47
                          1         160
                          1         176
                          1         187
                          1         205
                          1         356
                          1        1167

MDSIGN_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).


TXCOSIGN --------------------------------- C6.TRANSFUSION COORDINATOR SIGNED
                  type:  numeric (float)
                 label:  TXCOSIGN

                 range:  [1,1]                        units:  1
         unique values:  1                    coded missing:  0 / 11

           tabulation:  Freq.   Numeric  Label
                         11           1  1:Yes
```

```
COSIGN_D ----------------------------------- C6a.DATE TX COORDINATOR SIGNED
                 type:  numeric (float)

                range:  [1,1167]                         units:  1
        unique values:  11                       coded missing:  0 / 11

           tabulation:  Freq.   Value
                            1        1
                            1        8
                            1        9
                            1       10
                            1       37
                            1      160
                            1      176
                            1      187
                            1      205
                            1      356
                            1     1167
```

COSIGN_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).

```
CLCOSIGN ----------------------------------- C7.CLINICAL COORDINATOR SIGNED
                 type:  numeric (float)
                label:  CLCOSIGN

                range:  [1,1]                            units:  1
        unique values:  1                        coded missing:  0 / 11

           tabulation:  Freq.   Numeric  Label
                           11         1  1:Yes
```

```
CLSIGN_D ------------------------------- C7a.DATE CLINICAL COORDINATOR SIGNED
                 type:  numeric (float)

                range:  [1,1162]                         units:  1
        unique values:  10                       coded missing:  0 / 11

           tabulation:  Freq.   Value
                            1        1
                            1        6
                            2        8
                            1       34
                            1      158
                            1      176
                            1      187
                            1      205
                            1      356
                            1     1162
```

CLSIGN_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).