INTRODUCTION TO FORM 9 – BASELINE LOCAL LAB RESULTS

It is important to note that there were three form versions, reflecting changing decisions during the course of the study about which laboratory values to record on the form.

BASELINE LOCAL LAB RESULTS -- FORM 9 QxQ

Selected results of the complete blood count (CBC), platelet count, and WBC differential, performed at your local laboratory, are to be transcribed onto this form. If these tests were performed within 72 hours prior to enrollment, results may be abstracted as the baseline tests. Otherwise, specimens must be drawn and sent at enrollment and *prior to* the first transfusion, with results transcribed onto this form once received from the lab. Follow your local institution's requirements for requisitions, the type of blood tube or tubes and volumes required for these tests.

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. At the baseline visit, this question will always be completed in advance by the Medical Coordinating Center. Since this form is **only** used at the baseline visit, this number will always be "00".

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.

SECTION B -- CBC, Platelets and WBC Differential

B1. Record the date the specimen was drawn for this test, i.e., the date of the blood draw. If the results are being abstracted from tests performed within 72 hours of enrollment, and all that is available is the date the CBC/diff were performed, record that date in the space provided.

B2. Record the total white blood cell count reported in $10^3/\mu L$ or its equivalent (see page 2).

B3. Record the total red cell count reported in $10^6/\mu L$ or its equivalent (see page 2).

B4. Record the hemoglobin count reported in g/dL or its equivalent (see page 2).

B5. Record the reported platelet count in $10^3/\mu L$ or its equivalent (see page 2).

B6 through B11

Questions B6 through B11 are not in the 1/15/96 version.

In the 7/15/95 version Questions B6 through B8 refer to a 3 to 5– part differential as follows:

B6. through B8.

Record the percentage and/or absolute counts from a 3 or 5 part automated differential for Lymphocytes, Monocytes and cells synonymously reported as either Neutrophils, Segments (or Segs) or Bands. If, for some reason, a manual rather than automated differential was performed, **please note "manual count" or "manual" on this form**.

In the 8/01/96 version of Form 09 questions B6 –B11 refers to the WBC Differential as follows:

For Questions B6 through B11 (WBC differential), it is preferred that the absolute count rather than the percentage be recorded. If the absolute count is not available for any of the categories listed, then record the percentage. If neither the absolute count nor the percentage is available for any of the categories listed, then record "no result" in the right-hand margin next to the corresponding category.

B6. Record the absolute count in $10^3/\mu L$, or percentage, of Neutrophils/Granulocytes.

B7. Record the absolute count in $10^3/\mu L$, or percentage, of Bands.

B8. Record the absolute count in $10^3/\mu L$, or percentage, of Lymphocytes.

B9. Record the absolute count in $10^3/\mu L$, or percentage, of Monocytes.

B10. Record the absolute count in $10^3/\mu L$, or percentage, of Eosinophils.

B11. Record the absolute count in $10^3/\mu L$, or percentage, of Basophils.

SECTION C -- LYMPHOCYTE PHENOTYPING

Section C appears only in the 7/15/95 and 1/15/96 versions of Form 9

C1. Record the date blood was drawn for this test. If the results are being abstracted from tests performed within 72 hours of enrollment, and all that is available is the date the flow cytometry/phenotyping was performed, record that date in the space provided and **note on the form** that this is a test date versus a specimen date.

C2.a. Record the percent CD4 reported by your lab, or the CD3+/CD4+ quadrant result, if transcribing from a flow cytometry print-out.

C2.b. Record the absolute CD4 count calculated and reported by your local lab. If the count is not reported by your lab, calculate it according to the following formula:

CD4 % (C2.a.) x absolute Lymphocyte count (B6. b.) = absolute CD4 count (C2. b.)
If the absolute Lymphocyte count was not reported by your lab, this can be calculated by using the following formula:

Absolute WBC count (B2.) x Lymphocyte % (B6.b.) = Absolute Lymphocyte count per μL or its equivalent (see below).

C3.a. Record the percent CD8 reported by your lab, or the CD3+/CD8+ quadrant result, if transcribing from a flow cytometry print-out.

C3.b. Record the absolute CD8 count calculated and reported by your local lab. If the count is not reported by your lab, calculate it according to the formula(s) listed above in C2.b., substituting the CD8 percentage wherever CD4 appears in the formula(s).

EQUIVALENTS

/μL	= /cumm or /mm^3
10^3	= K
10^6/μL	= 10^6/mm^3
g/dL	= Gm/DL

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

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

A2. Visit number: _0_ _0_

A3. Subject initials: ___. ___. ___.

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

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

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

SECTION B -- CBC/DIFFERENTIAL -- AUTOMATED

B1. Specimen date: ___ ___ / ___ ___ / ___ ___

B2. WBC ____ ____ . ____ ($10^3/\mu L$)

B3. RBC ____ ____ . ____ ($10^6/\mu L$)

B4. Hemoglobin ____ ____ . ____ (g/dL)

B5. Platelets ____ ____ ____ ($10^3/\mu L$)

B6. Lymphocytes a. ____ ____ . ____ % **and/or** b. ____ ____ . ____ ($10^3/\mu L$)

B7. Monocytes a. ____ ____ . ____ % **and/or** b. ____ ____ . ____ ($10^3/\mu L$)

B8. Neuts/Segs/Bands a. ____ ____ . ____ % **and/or** b. ____ ____ . ____ ($10^3/\mu L$)

SECTION C -- LYMPHOCYTE PHENOTYPING

C1. Specimen date: ___ ___ / ___ ___ / ___ ___

C2. Lymphocyte marker CD3/CD4 a. ____ ____ % **and** b. ____ ____ ____ ____ ____ (per μL)

C3. Lymphocyte marker CD3/CD8 a. ____ ____ % **and** b. ____ ____ ____ ____ ____ (per μL)

END OF FORM

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

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

A2. Visit number: 0 0

A3. Subject initials: ___. ___. ___.

A4. Form version: 0 1 / 1 5 / 9 6

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

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

SECTION B -- CBC/PLATELETS

B1. Specimen date: ___ ___ / ___ ___ / ___ ___

B2. WBC ____ ____ . ____ ($10^3/\mu L$)

B3. RBC ____ ____ . ____ ($10^6/\mu L$)

B4. Hemoglobin ____ ____ . ____ (g/dL)

B5. Platelets ____ ____ ____ ($10^3/\mu L$)

SECTION C -- LYMPHOCYTE PHENOTYPING

C1. Specimen date: ___ ___ / ___ ___ / ___ ___

C2. Lymphocyte marker CD3/CD4 a. ____ ____ % **and** b. ____ ____ ____ ____ ____ (per μL)

C3. Lymphocyte marker CD3/CD8 a. ____ ____ % **and** b. ____ ____ ____ ____ ____ (per μL)

END OF FORM

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

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

A2. Visit number: _0_ _0_

A3. Subject initials: ___. ___. ___.

A4. Form version: 0 8 / 0 1 / 9 6

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

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

SECTION B -- PLATELETS AND CBC WITH DIFFERENTIAL

B1. Specimen date: ___ ___ / ___ ___ / ___ ___

B2. WBC ____ ____ . ____ ($10^3/\mu L$)

B3. RBC ____ ____ . ____ ($10^6/\mu L$)

B4. Hemoglobin ____ ____ . ____ (g/dL)

B5. Platelets ____ ____ ____ ($10^3/\mu L$)

For Questions B6 through B11 the absolute differential is preferable to the percentage.
Record the percentage only if the absolute value is not available.

B6.	Neutrophils/Granulocytes	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %
B7.	Bands	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %
B8.	Lymphocytes	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %
B9.	Monocytes	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %
B10.	Eosinophils	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %
B11.	Basophils	a. ____ ____ . ____ ($10^3/\mu L$)	**or**	b. ____ ____ . ____ %

END OF FORM

BASELINE LOCAL LAB RESULTS – FM09DATA CODEBOOK

```
PUB_ID ------------------------------------------------------------ SUBJECT ID

                  type:  numeric (float)


                 range:  [1,531]                    units:  1
         unique values:  523                  coded missing:  0 / 523

                  mean:   265.262
             std. dev:   153.341

           percentiles:        10%       25%       50%       75%       90%
                               54       132       266       398       477


VISNUM ----------------------------------------------------------- A2.VISIT NUMBER
                  type:  string (str2)

         unique values:  1                    coded missing:  0 / 523

            tabulation:  Freq.  Value
                           523  "00"

VISNUM:
  1.  Since this form is only used at baseline visit (QU 00), this variable
      is always coded as 00.


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

                 range:  [12979,13362]              units:  1
         unique values:  3                    coded missing:  0 / 523

            tabulation:  Freq.   Numeric  Label
                           129     12979  07/15/95
                            75     13163  01/15/96
                           319     13362  08/01/96
```

CBC_DATE ---------- B1.CBC/PLATELET SPECIMEN DATE

type:	numeric (float)		
range:	[-20,304]	units:	1
unique values:	18	coded missing:	0 / 523

tabulation:	Freq.	Value
	1	-20
	1	-15
	2	-8
	3	-7
	1	-6
	1	-4
	5	-3
	22	-2
	106	-1
	336	0
	30	1
	4	2
	4	3
	3	4
	1	9
	1	24
	1	48
	1	304

CBC_DATE:

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)**

WBC ---------- B2.WBC (10^3/uL)

type:	numeric (float)		
range:	[.1,20.3]	units:	.1
unique values:	106	coded missing:	0 / 523
mean:	3.75583		
std. dev:	2.8221		

percentiles:	10%	25%	50%	75%	90%
	1.4	1.9	3	4.6	7.1

RBC ---------- B3.RBC (10^6/uL)

type:	numeric (float)		
range:	[.5,4]	units:	.1
unique values:	33	coded missing:	2 / 523
mean:	2.35777		
std. dev:	.578445		

percentiles:	10%	25%	50%	75%	90%
	1.6	2	2.4	2.8	3.1

HEMOGLOB ---------- B4.HEMOGLOBIN (g/dL)

type:	numeric (float)		
range:	[2.2,13.3]	units:	.1
unique values:	76	coded missing:	0 / 523
mean:	7.27878		
std. dev:	1.37883		

percentiles:	10%	25%	50%	75%	90%
	5.7	6.6	7.3	8	8.8

PLATELET ---------- B5.PLATELETS (10^3/uL)

type:	numeric (float)		
range:	[4,810]	units:	1
unique values:	290	coded missing:	9 / 523
mean:	213.603		
std. dev:	125.683		

percentiles:	10%	25%	50%	75%	90%
	71	118	186	290	385

LYMPHPER ---------- B6a.LYMPHOCYTE (%) [7/15/95]

type:	numeric (float)		
range:	[1,62]	units:	.1
unique values:	65	coded missing:	423 / 523
mean:	16.758		
std. dev:	12.6709		

percentiles:	10%	25%	50%	75%	90%
	4.3	8	13	25.25	33.8

LYMPHPER:
1. **Question B6.a. on form version 07/15/95**

```
LYMPH_UL ---------------------------------- B6b.LYMPHOCYTE (10^3/uL) [7/15/95]

                  type:  numeric (float)

                 range:  [.1,1.3]                    units:  .1
         unique values:  11                   coded missing:  474 / 523

            tabulation:  Freq.  Value
                            6        .1
                           12        .2
                            9        .3
                            2        .4
                            5        .5
                            3        .7
                            2        .8
                            4         1
                            3       1.1
                            1       1.2
                            2       1.3

LYMPH_UL:
  1.  Question B6.b. on form version 07/15/95


MONOPER ----------------------------------------- B7a.MONOCYTES (%) [7/15/95]
                  type:  numeric (float)

                 range:  [0,40]                      units:  .1
         unique values:  52                   coded missing:  423 / 523

                  mean:     9.014
             std. dev:    6.88912

           percentiles:        10%       25%       50%       75%       90%
                                2         5      7.95     11.75        18

MONOPER:
  1.  Question B7.a. on form version 07/15/95


MONO_UL ----------------------------------- B7b.MONOCYTES (10^3/uL) [7/15/95]
                  type:  numeric (float)

                 range:  [0,.7]                      units:  .1
         unique values:  8                    coded missing:  474 / 523

            tabulation:  Freq.  Value
                            2         0
                           15        .1
                           16        .2
                            9        .3
                            3        .4
                            2        .5
                            1        .6
                            1        .7
```

MONO_UL:

1. Question B7.b. on form version 07/15/95

NEUTSPER ---------- B8a.NEUTS/SEGS/BANDS (%) [7/15/95]

type:	numeric (float)		
range:	[22.7,97]	units:	.1
unique values:	73	coded missing:	424 / 523
mean:	67.5879		
std. dev:	17.8339		

percentiles:	10%	25%	50%	75%	90%
	41.1	55	70.4	81.6	88

NEUTSPER:
1. Question B8.a. on form version 07/15/95

NEUTS_UL ---------- B8b.NEUTS/SEGS/BANDS (10^3/uL) [7/15/95]

type:	numeric (float)		
range:	[.2,12.1]	units:	.1
unique values:	30	coded missing:	475 / 523
mean:	2.02292		
std. dev:	1.83758		

percentiles:	10%	25%	50%	75%	90%
	.5	.9	1.75	2.75	3.4

NEUTS_UL:
1. Question B8.b. on form version 07/15/95

LYMPH_DT ---------- C1.SPEC DATE - LYMPHOCYTE PHENOTYPING

type:	numeric (float)		
range:	[-2165,14]	units:	1
unique values:	51	coded missing:	347 / 523
mean:	-35.3011		
std. dev:	183.06		

percentiles:	10%	25%	50%	75%	90%
	-53	-6.5	0	0	1

LYMPH_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)

```
LYMPH_DZ -------------------------------- DATE IMPUTATION INDICATOR -- LYMPH_DT
                 type:  numeric (float)
                label:  LYMPH_DZ

                range:  [1,3]                       units:  1
        unique values:  2                    coded missing:  0 / 523

           tabulation:  Freq.   Numeric  Label
                          522         1  Date not imputed
                            1         3  July 1 imputed
```

LYMPH_DZ:
1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.

```
CD3_CD4P ---------------------------------- C2a.CD3/CD4 (%) [7/15/95 & 1/15/96]
                 type:  numeric (float)

                range:  [0,67]                      units:  1
        unique values:  27                   coded missing:  351 / 523

                 mean:   5.63372
            std. dev:   7.97215

          percentiles:        10%       25%       50%       75%       90%
                               1         1         3         6        14
```

CD3_CD4P:
1. Question C2.a. on form versions 07/15/95 and 01/15/96

```
CD3_CD4M ------------------------------- C2b.CD3/CD4 (/uL) [7/15/95 & 1/15/96]
                 type:  numeric (float)

                range:  [0,1425]                    units:  1
        unique values:  65                   coded missing:  353 / 523

                 mean:   45.8765
            std. dev:   127.161

          percentiles:        10%       25%       50%       75%       90%
                               1         5      11.5        40      99.5
```

CD3_CD4M:
1. Question C2.b. on form versions 07/15/95 and 01/15/96

```
CD3_CD8P ---------------------------------- C3a.CD3/CD8 (%) [7/15/95 & 1/15/96]

                  type:  numeric (float)


                 range:  [0,91]                       units:  1

         unique values:  65                   coded missing:  357 / 523

                  mean:    54.253
             std. dev:   17.7841

           percentiles:        10%       25%       50%       75%       90%
                               32        42        57        66        76
```

CD3_CD8P:
1. Question C3.a. on form versions 07/15/95 and 01/15/96

```
CD3_CD8M ------------------------------- C3b.CD3/CD8 (/uL) [7/15/95 & 1/15/96]
                  type:  numeric (float)

                 range:  [0,1673]                     units:  1
         unique values:  139                  coded missing:  359 / 523

                  mean:   322.317
             std. dev:   264.193

           percentiles:        10%       25%       50%       75%       90%
                               66       128     248.5       439       690
```

CD3_CD8M:
1. Question C3.b. on form versions 07/15/95 and 01/15/96

```
GRANULAB --------------------------------- B6a.NEUTRO/GRANUL (10^3/uL) [8/1/96]
                  type:  numeric (float)

                 range:  [.3,15.8]                    units:  .1
         unique values:  57                   coded missing:  361 / 523

                  mean:   2.72346
             std. dev:   2.45831

           percentiles:        10%       25%       50%       75%       90%
                               .8       1.3       1.9       3.2       5.8
```

GRANULAB:
1. Question B6.a on form version 08/01/96

```
GRANULPR ------------------------------------- B6b.NEUTRO/GRANUL (%) [8/1/96]

                  type:  numeric (float)

                 range:  [9,90]                       units:  .1
         unique values:  102                  coded missing:  350 / 523

                  mean:   59.4746
             std. dev:   18.1961

           percentiles:        10%       25%       50%       75%       90%
                               33        47      61.3        72      82.5

GRANULPR:
  1.  Question B6.b on form version 08/01/96


BANDSAB -------------------------------------- B7a.BANDS (10^3/uL) [8/1/96]
                  type:  numeric (float)

                 range:  [0,1]                        units:  .1
         unique values:  7                    coded missing:  481 / 523

            tabulation:  Freq.  Value
                            23      0
                             7     .1
                             5     .2
                             1     .3
                             3     .4
                             2     .8
                             1      1

BANDSAB:
  1.  Question B7.a on form version 08/01/96


BANDSPR ------------------------------------------------ B7b.BANDS (%) [8/1/96]
                  type:  numeric (float)

                 range:  [0,40]                       units:  .1
         unique values:  30                   coded missing:  385 / 523

                  mean:   6.10507
             std. dev:   8.62382

           percentiles:        10%       25%       50%       75%       90%
                                0         0         3         8        18

BANDSPR:
  1.  Question B7.b on form version 08/01/96
```

LYMPHABS ---------- B8a.LYMPHOCYTES (10^3/uL) [8/1/96]

type:	numeric (float)		
range:	[0,8]	units:	.1
unique values:	29	coded missing:	361 / 523
mean:	.828395		
std. dev:	.859616		

percentiles:	10%	25%	50%	75%	90%
	.2	.3	.65	.9	1.7

LYMPHABS:
1. Question B8.a on form version 08/01/96

LYMPHPRC ---------- B8b.LYMPHOCYTES (%) [8/1/96]

type:	numeric (float)		
range:	[1,73]	units:	.1
unique values:	99	coded missing:	349 / 523
mean:	22.9506		
std. dev:	15.3595		

percentiles:	10%	25%	50%	75%	90%
	6	10	18.9	33	46

LYMPHPRC:
1. Question B8.b on form version 08/01/96

MONOCABS ---------- B9a.MONOCYTES (10^3/uL)

type:	numeric (float)		
range:	[0,5]	units:	.1
unique values:	14	coded missing:	363 / 523

tabulation:	Freq.	Value
	4	0
	38	.1
	39	.2
	31	.3
	18	.4
	7	.5
	9	.6
	5	.7
	1	.8
	3	.9
	2	1
	1	1.1
	1	1.4
	1	5

MONOCABS:

1. Question B9.a on form version 08/01/96

MONOCPRC ---------- B9b.MONOCYTES (%)

type:	numeric (float)		
range:	[0,29]	units:	.1
unique values:	66	coded missing:	348 / 523

mean:	8.348
std. dev:	5.28265

percentiles:	10%	25%	50%	75%	90%
	3	4.9	7	11.6	16

MONOCPRC:
1. Question B9.b on form version 08/01/96

EOSINABS ---------- B10a.EOSINOPHILS (10^3/uL)

type:	numeric (float)		
range:	[0,1]	units:	.1
unique values:	9	coded missing:	375 / 523

tabulation:	Freq.	Value
	81	0
	38	.1
	11	.2
	5	.3
	5	.4
	3	.5
	2	.7
	1	.8
	2	1

EOSINABS:
1. Question B10.a on form version 08/01/96

EOSINPRC ---------- B10b.EOSINOPHILS (%)

type:	numeric (float)		
range:	[0,39]	units:	.1
unique values:	41	coded missing:	351 / 523

mean:	2.03605
std. dev:	4.24732

percentiles:	10%	25%	50%	75%	90%
	0	0	1	2	5

EOSINPRC:

1. Question B10.b on form version 08/01/96

BASOPHAB ---------- B11a.BASOPHILS (10^3/uL)

type:	numeric (float)		
range:	[0,.3]	units:	.1
unique values:	3	coded missing:	384 / 523

tabulation:

Freq.	Value
117	0
21	.1
1	.3

BASOPHAB:
1. Question B11.a on form version 08/01/96

BASOPHPR ---------- B11b.BASOPHILS (%)

type:	numeric (float)		
range:	[0,7]	units:	.1
unique values:	20	coded missing:	354 / 523

tabulation:

Freq.	Value
84	0
4	.1
7	.2
5	.3
8	.4
4	.5
3	.6
4	.7
2	.8
3	.9
29	1
2	1.1
1	1.2
2	1.5
1	1.6
1	1.8
6	2
1	3
1	4
1	7

BASOPHPR:
1. Question B11.b on form version 08/01/96