Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

# Form P001– Consent Confirmation Form

## Section A: GENERAL INFORMATION

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... PBSL

A3. Initials of person entering form: __ __ __

## Section B: CONSENT

B1. Has the patient signed a consent form? Yes.....1

B2. Date consent signed: __ __ / __ __ / __ __ __ __
M M D D Y Y Y Y

Platelet Dose Trial

# Form P001 QxQ – Consent Confirmation Form

Version A: 12/01/2003

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**Note: This is not a case report form to be completed by the site staff, rather, it is an online data entry confirmation that a patient has signed a consent form to participate in the Platelet Dose Trial**

**Purpose of this form:** The purpose of this form is to confirm that a patient (or the patient's legal guardian) and the Site Investigator have signed an Informed Consent document indicating the patient has agreed to participate in the Platelet Dose Trial.

**When to complete this form:** This online form is entered only after a patient (or their legal guardian) and the Site Investigator have signed an Informed Consent document.

## SECTION A: GENERAL INFORMATION

A1. Enter the patient's ID number.

A2. Enter the event code PBSL.

A3. Enter the initials of the person data entering the form.

## SECTION B: CONSENT

B1. Enter 1 (yes) – the patient (or their legal guardian) has signed an Informed Consent document.

B2. Record the date the patient (or their legal guardian) signed the Informed Consent document.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P002 – Eligibility Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __-- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... (PBSL)

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

| **Section B: INCLUSION CRITERIA** | **Yes** | **No** |
|---|---|---|
| B1. Patient has, or is expected to have, hypoproliferative thrombocytopenia, **and** is expected to have a platelet count ≤ 10,000 for ≥ 5 days, **and** be in the hospital for ≥ 5 days. | 1 | 2 |
| B2. Patient is undergoing hematopoietic stem cell transplantation<br>**AND/OR**<br>Patient has diagnosis of acute or chronic leukemia, non-Hodgkins or Hodgkins lymphoma, myeloma, myelodysplasia, or non-hematologic malignancy undergoing chemotherapy. | 1 | 2 |
| B3. PT, PTT and fibrinogen levels are as follows (*see Section E*):<br>a) PT ≤ 1.3 x the upper limit of normal for the laboratory<br>b) PTT ≤ 1.3 x the upper limit of normal for the laboratory<br>c) Fibrinogen ≥ 100mg/dL | 1 | 2 |
| ***Labs done within 72 hours prior to the date/time eligibility determined are acceptable*** | | |
| B4. Weight between 10kg and 120kg. | 1 | 2 |
| B5. During this hospitalization the patient has not yet received any platelet transfusions related to the current or planned course of therapy. | 1 | 2 |

| **Section C: EXCLUSION CRITERIA** | **Yes** | **No** |
|---|---|---|
| C1. Patient has evidence of ≥ Grade 2 bleeding while being assessed for study entry, as defined by the Platelet Dose Trial Bleeding Scale. | 1 | 2 |
| C2. Patient is receiving anti-thrombotic drugs. | 1 | 2 |
| C3. Patient will receive bedside leukoreduced platelet transfusions. | 1 | 2 |
| C4. Patient has current, or history of (within the previous 30 days), platelet transfusion refractoriness. | 1 | 2 |
| C5. Pre-enrollment lymphocytotoxic antibody screen (PRA) known to be ≥ 20% based on prior data. ***If antibody screen not available, answer No.*** | 1 | 2 |
| C6. Patient has, or has a history of, APML, ITP, TTP, or HUS. | 1 | 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section C: EXCLUSION CRITERIA, cont. | Yes | No |
|---|---|---|
| C7. Patient will be transfused at a platelet trigger of > 10,000 platelets/μl. | 1 | 2 |
| C8. Patient has recent history of major surgery (≤ 2 weeks prior to the date/time of eligibility determination). | 1 | 2 |
| C9. Patient is currently participating in a clinical trial involving platelet substitutes, platelet growth factors or pharmacologic agents intended to enhance or decrease platelet hemostatic function. | 1 | 2 |
| C10. Patient is pregnant. | 1 | 2 |
| C11. Patient was previously enrolled in this trial. | 1 | 2 |

**Section D: ELIGIBILITY STATUS**

D1. Are all questions in Section B answered YES? Yes .....1 No .....2

D2. Are all questions in Section C answered NO? Yes .....1 No .....2

D3. Date eligibility determined: __ __ / __ __ / __ __ __ __

D4. Time eligibility determined: ___ ___ : ___ ___

**Section E: ELIGIBILITY LABS**

Please provide the following information used to determine the patient's eligibility (question B3):

| Test | a. Date Collected | b. Time Collected *(24 hour clock)* | c. Value | d. Units |
|---|---|---|---|---|
| *INR is the preferred value – report PT only if INR is not available* | | | | |
| E1. PT / INR | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec ..... 1<br>INR ..... 2 |
| E2. PTT | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec |
| E3. Fibrinogen | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | mg/dL |

**Section F: SIGNATURE**

F1. Approved by PI or designee: Initials ____ ____ ____

F2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P002 – Eligibility Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __-- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... (PBSL)

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

| **Section B: INCLUSION CRITERIA** | **Yes** | **No** |
|---|---|---|
| B1. Patient has, or is expected to have, hypoproliferative thrombocytopenia, **and** is expected to have a platelet count ≤ 10,000 for ≥ 5 days, **and** be in the hospital for ≥ 5 days. | 1 | 2 |
| B2. Patient is undergoing hematopoietic stem cell transplantation<br>**AND/OR**<br>Patient has diagnosis of acute or chronic leukemia, non-Hodgkins or Hodgkins lymphoma, myeloma, myelodysplasia, or non-hematologic malignancy undergoing chemotherapy. | 1 | 2 |
| B3. PT, PTT and fibrinogen levels are as follows (*see Section E*):<br>a) PT ≤ 1.3 x the upper limit of normal for the laboratory<br>b) PTT ≤ 1.3 x the upper limit of normal for the laboratory<br>c) Fibrinogen ≥ 100mg/dL | 1 | 2 |
| ***Labs done within 72 hours prior to the date/time eligibility determined are acceptable*** | | |
| B4. Weight between 10kg and 135kg. | 1 | 2 |
| B5. During this hospitalization the patient has not yet received any platelet transfusions related to the current or planned course of therapy. | 1 | 2 |

| **Section C: EXCLUSION CRITERIA** | **Yes** | **No** |
|---|---|---|
| C1. Patient has evidence of ≥ Grade 2 bleeding while being assessed for study entry, as defined by the Platelet Dose Trial Bleeding Scale. | 1 | 2 |
| C2. Patient is receiving anti-thrombotic drugs. | 1 | 2 |
| C3. Patient will receive bedside leukoreduced platelet transfusions. | 1 | 2 |
| C4. Patient has current, or history of (within the previous 30 days), platelet transfusion refractoriness. | 1 | 2 |
| C5. Pre-enrollment lymphocytotoxic antibody screen (PRA) known to be ≥ 20% based on prior data. ***If antibody screen not available, answer No.*** | 1 | 2 |
| C6. Patient has, or has a history of, APML, ITP, TTP, or HUS. | 1 | 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section C: EXCLUSION CRITERIA, cont. | Yes | No |
|---|---|---|
| C7. Patient will be transfused at a platelet trigger of > 10,000 platelets/μl. | 1 | 2 |
| C8. Patient has recent history of major surgery (≤ 2 weeks prior to the date/time of eligibility determination). | 1 | 2 |
| C9. Patient is currently participating in a clinical trial involving platelet substitutes, platelet growth factors or pharmacologic agents intended to enhance or decrease platelet hemostatic function. | 1 | 2 |
| C10. Patient is pregnant. | 1 | 2 |
| C11. Patient was previously enrolled in this trial. | 1 | 2 |

**Section D: ELIGIBILITY STATUS**

D1. Are all questions in Section B answered YES? Yes ..... 1 No..... 2

D2. Are all questions in Section C answered NO? Yes ..... 1 No..... 2

D3. Date eligibility status determined: __ __ / __ __ / __ __ __ __

D4. Time eligibility status determined: ___ ___ : ___ ___

**Section E: ELIGIBILITY LABS**

Please provide the following information used to determine the patient's eligibility (question B3):

| Test | a. Date Collected | b. Time Collected *(24 hour clock)* | c. Value | d. Units |
|---|---|---|---|---|
| E1. PT | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec |
| E2. INR | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ • ___ ___ | INR |
| E3. PTT | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec |
| E4. Fibrinogen | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL |

**Section F: SIGNATURE**

F1. Approved by PI or designee: Initials ____ ____ ____

F2. Date approved: __ __ / __ __ / __ __ __ __

# Form P002 QxQ – Eligibility Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of the Eligibility Form is to document the eligibility status of the patient based on all inclusion and exclusion criteria. This form must be completed for every patient who signed an Informed Consent document.

**When to complete this form:** This form must be completed during the screening/eligibility phase of the study, after the patient has signed an Informed Consent and/or Assent Form, and before the patient is randomized.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: INCLUSION CRITERIA

B1. Indicate if the patient meets all 3 conditions. If patient does not meet all 3 conditions circle 2 (no).

B2. Indicate if patient is either undergoing hematopoietic stem cell transplant and/or has one of the listed diagnoses.

B3. Samples drawn within the 72 hours prior to eligibility determination may be used. If the patient has not had PT/INR, PTT and fibrinogen tests done within the previous 72 hours, draw blood for these tests and wait for results before determining patient's eligibility.

**All 3 of the following conditions must be met:**

1) PT must be within 1.3 times the upper limit of normal for the lab where the test was done
2) PTT must be within 1.3 times the upper limit of normal for the lab where the test was done
3) Fibrinogen must be greater than or equal to 100mg/dL

B4. Indicate if the patient weighs at least 10kg and no more than 120kg.

B5. During this hospitalization the patient has not yet received any platelet transfusions related to the current or planned course of therapy. If the patient has already had the first transfusion for this course of therapy during this hospitalization, circle 2 (No).

## SECTION C: EXCLUSION CRITERIA

C1. The patient is not eligible for this study if they have evidence of $\geq$ Grade 2 bleeding while being assessed for study entry as defined by the Platelet Dose Trial Bleeding Scale, available in the Platelet Dose Trial Protocol (Chapter 1 of the study Manual of Procedures).

C2. Indicate if the patient is receiving anti-thrombotic drugs.

C3. Indicate if the patient will receive bedside leukoreduced platelets.

C4. Indicate if the patient has present, or history of (within the previous 30 days), platelet transfusion refractoriness.

C5. Indicate if the patient has a known, pre-enrollment PRA $\geq$20% based on prior data. If antibody screen is not available, circle 2 (no).

C6. Indicate if the patient has, or has a history of acute promyelocytic leukemia (APML), idiopathic thromobocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP) or hemolytic-uremic syndrome (HUS).

**SECTION C: EXCLUSION CRITERIA cont.**

C7. Indicate if the patient will be transfused at a platelet trigger of > 10,000 platelets/μL.

C8. Indicate if the patient has had major surgery within the 2 weeks prior to the date/time of eligibility determination.

C9. Indicate if the patient is currently participating in a clinical trial involving any of the items listed.

C10. Indicate if the patient is pregnant. If unknown, draw blood for a pregnancy test and wait for the results before determining eligibility.

C11. Indicate if the patient was previously enrolled in this trial.

**SECTION D: ELIGIBILITY STATUS**

D1. Circle 1 (Yes) if all questions in Section B (B1 – B5) are answered YES.

D2. Circle 1 (Yes) if all questions in Section C (C1 – C11) are all answered NO.

D3. Enter the date eligibility was determined (i.e. all criteria on this form were evaluated).

D4. Enter the time eligibility was determined (i.e. all criteria on this form were evaluated).

**SECTION E: ELIGIBILITY LABS**

In this section, provide the lab results used to determine if the patient's PT/INR, PTT and Fibrinogen levels are within normal limits (inclusion criteria # B3). These tests must be done in the 72 hours prior to eligibility determination (as recorded in fields D3 and D4), and may be extracted from the patient's medical record. If the subject has not had these tests done within the 72 hours prior to eligibility determination, draw a blood sample for these tests and wait for the results to determine if the patient is eligible for the study.

E1a – E1d. Enter the date and time the specimen was collected, the result of the test, and circle the number that corresponds to the correct units (sec or INR). **Note: INR is the preferred value – report PT only if INR is not available.**

E2a – E2c. Enter the date and time the specimen was collected, and the result of the test.

E3a – E3c. Enter the date and time the specimen was collected, and the result of the test.

**SECTION F: SIGNATURE**

The Principal Investigator or their designee must approve the form.

F1. Enter the initials of the person approving the form.

F2. Record the date the form was approved.

Platelet Dose Trial

# Form P002 QxQ – Eligibility Form

Version B: 04/11/2005

**Purpose of this form:** The purpose of the Eligibility Form is to document the eligibility status of the patient based on all inclusion and exclusion criteria. This form must be completed for every patient who signed an Informed Consent document.

**When to complete this form:** This form must be completed during the screening/eligibility phase of the study, after the patient has signed an Informed Consent and/or Assent Form, and before the patient is randomized.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: INCLUSION CRITERIA

B1. Indicate if the patient meets all 3 conditions. If patient does not meet all 3 conditions circle 2 (no).

B2. Indicate if patient is either undergoing hematopoietic stem cell transplant and/or has one of the listed diagnoses.

B3. Samples drawn within the 72 hours prior to eligibility determination may be used. If the patient has not had PT/INR, PTT and fibrinogen tests done within the previous 72 hours, draw blood for these tests and wait for results before determining patient's eligibility.

**All 3 of the following conditions must be met:**

1) PT must be within 1.3 times the upper limit of normal for the lab where the test was done
2) PTT must be within 1.3 times the upper limit of normal for the lab where the test was done
3) Fibrinogen must be greater than or equal to 100mg/dL

B4. Indicate if the patient weighs at least 10kg and no more than 135kg.

B5. During this hospitalization the patient has not yet received any platelet transfusions related to the current or planned course of therapy. If the patient has already had the first transfusion for this course of therapy during this hospitalization, circle 2 (No).

## SECTION C: EXCLUSION CRITERIA

C1. The patient is not eligible for this study if they have evidence of $\geq$ Grade 2 bleeding while being assessed for study entry as defined by the Platelet Dose Trial Bleeding Scale, available in the Platelet Dose Trial Protocol (Chapter 1 of the study Manual of Procedures).

C2. Indicate if the patient is receiving anti-thrombotic drugs.

C3. Indicate if the patient will receive bedside leukoreduced platelets.

C4. Indicate if the patient has present, or history of (within the previous 30 days), platelet transfusion refractoriness.

C5. Indicate if the patient has a known, pre-enrollment PRA $\geq$20% based on prior data. If antibody screen is not available, circle 2 (no).

C6. Indicate if the patient has, or has a history of acute promyelocytic leukemia (APML), immune thromobocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP) or hemolytic-uremic syndrome (HUS).

**SECTION C: EXCLUSION CRITERIA cont.**

C7. Indicate if the patient will be transfused at a platelet trigger of > 10,000 platelets/μL.

C8. Indicate if the patient has had major surgery within the 2 weeks prior to the date/time of eligibility determination.

C9. Indicate if the patient is currently participating in a clinical trial involving any of the items listed.

C10. Indicate if the patient is pregnant. If unknown, perform a pregnancy test and wait for the results before determining eligibility.

C11. Indicate if the patient was previously enrolled in this trial.

**SECTION D: ELIGIBILITY STATUS**

D1. Circle 1 (Yes) if all questions in Section B (B1 – B5) are answered YES.

D2. Circle 1 (Yes) if all questions in Section C (C1 – C11) are all answered NO.

D3. Enter the date eligibility status was determined (i.e. all criteria on this form were evaluated).

D4. Enter the time eligibility status was determined (i.e. all criteria on this form were evaluated).

**SECTION E: ELIGIBILITY LABS**

In this section, provide the lab results used to determine if the patient's PT/INR, PTT and Fibrinogen levels are within normal limits (inclusion criteria # B3). These tests must be done in the 72 hours prior to eligibility determination (as recorded in fields D3 and D4), and may be extracted from the patient's medical record. If the subject has not had these tests done within the 72 hours prior to eligibility determination, draw a blood sample for these tests and wait for the results to determine if the patient is eligible for the study.

E1a – E1c. Enter the date and time the specimen was collected, and the result of the test.

E2a – E2c. Enter the date and time the specimen was collected, and the result of the test.

E3a – E3c. Enter the date and time the specimen was collected, and the result of the test.

E4a – E4c. Enter the date and time the specimen was collected, and the result of the test.

**SECTION F: SIGNATURE**

The Principal Investigator or their designee must approve the form.

F1. Enter the initials of the person approving the form.

F2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P003 – Randomization Form**

TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... (PBSL)

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

***This form should be completed only if the patient has signed a consent form and has screened eligible.***

**Section B: SUBJECT INFORMATION**

B1a. Weight in kilograms: ___ ___ ___ • ___ kilograms = pounds X 0.4536

B1b. Weight in pounds: ___ ___ ___ • ___ pounds = kilograms X 2.205

B2a. Height in centimeters: ___ ___ ___ • ___ centimeters = inches X 2.54

B2b. Height in inches: ___ ___ ___ • ___ inches = centimeters X 0.3937

**Section C: STRATIFICATION**

C1. Please indicate the patient's treatment category:

Autologous or syngeneic stem cell transplant ..... 1

Allogeneic stem cell transplant ..... 2

Chemotherapy for hematologic malignancy ..... 3

Chemotherapy for solid tumor ..... 4

**Section D: PLATELETS**

D1. What is the desired type of platelets for this patient? Apheresis ..... 1 Pooled whole blood derived platelets ..... 2

**Section E: SIGNATURE**

E1. Approved by PI or designee: Initials: ____ ____ ____

E2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P003 QxQ – Randomization Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to gather the information needed to randomize a patient and enter that information into the ADEPT data management system.

**When to complete this form:** This form is completed after the patient has signed consent (and/or assent form) and has screened eligible for the Platelet Dose Trial. The patient should be randomized no more than 72 hours prior to their first planned transfusion.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: SUBJECT INFORMATION

The information in section B will be used to calculate the patient's body surface area (BSA). The form requires the data to be entered in both Metric and English units to ensure the data are entered correctly. The formulas to convert the measurements between units are provided at the right of the question.

B1a – B1b. Record the patient's weight in kilograms and pounds. To convert pounds to kilograms, multiply the number of pounds by 0.4536. To convert kilograms to pounds, multiply the number of kilograms by 2.205.

B2a – B2b. Record the patient's height in centimeters and inches. To convert inches to centimeters, multiply the number of inches by 2.54. To convert centimeters to inches, multiply the number of centimeters by 0.3937.

Note: The DMS will check the height and weight by calculating BMI. During data entry you may be asked to double check the values and confirm that they have been entered correctly if they fail this validation.

## SECTION C: STRATIFICATION

C1. Circle the number that corresponds to the patient's treatment category. You must choose one treatment category only. Hematologic malignancy includes: lymphomas, mylodysplastic syndromes and multiple myeloma.

## SECTION D: PLATELETS

D1. Circle the number that corresponds to the desired type of platelets this patient will receive during the study. You must choose one type only.

## SECTION E: SIGNATURE

The Principal Investigator or their designee must approve the form.

E1. Enter the initials of the person approving the form.

E2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P004 – Baseline Demographics and Medical History** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... (PBSL)

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

**Section B: DEMOGRAPHICS**

B1. Date of Birth: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

B2. Gender:
Male.....1
Female.....2

B3. Ethnic Origin:
Hispanic/Latino ..... 1
Not Hispanic/Latino ..... 2
Not obtained/Unknown ..... -8
Refused ..... -7

| B4. Race: | Yes | No | Refused | Unknown/ Not Obtained |
|---|---|---|---|---|
| a. American Indian or Alaska Native | 1 | 2 | -7 | -8 |
| b. Asian | 1 | 2 | -7 | -8 |
| c. Black or African American | 1 | 2 | -7 | -8 |
| d. Native Hawaiian or Other Pacific Islander | 1 | 2 | -7 | -8 |
| e. White | 1 | 2 | -7 | -8 |
| f. Other | 1 | 2 **(C1)** | -7 **(C1)** | -8 **(C1)** |

B4f1. Specify Other _____

| **Section C: MEDICAL HISTORY** | **Yes** | **No** | |
|---|---|---|---|
| C1. Has the patient ever received a platelet transfusion prior to this episode of thrombocytopenia? | 1 | 2 | |
| C2. Has the patient ever received a red cell transfusion prior to this episode of thrombocytopenia? | 1 | 2 | |
| C3. Has the patient had a splenectomy? | 1 **(C4)** | 2 | |
| C3a. Is the patient's spleen enlarged? | 1 | 2 | |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| *Question C4 – C7a are for female patients only, if male skip to D1.* | Yes | No | Unknown |
|---|---|---|---|
| C4. Has the patient achieved menarche? | 1 | 2 **(D1)** | -8 |
| C5. Is the patient post-menopausal? | 1 **(C7)** | 2 | -8 |
| C6. Is the patient on hormonal therapy to eliminate/retard vaginal bleeding? | 1 | 2 | -8 |
| C7. Has the patient ever been pregnant? | 1 | 2 **(D1)** | -8 **(D1)** |

C7a. Number of pregnancies (including miscarriages and abortions): ____ ____

**Section D: PRIMARY DIAGNOSIS**

D1. Primary Diagnosis: ***(circle one number)***

Acute Lymphocytic Leukemia.....01
Acute Nonlymphocytic Leukemia .....02
Chronic Myelogenous Leukemia .....03
Chronic Lymphocytic Leukemia.....04
Chronic Myelomonocytic Leukemia.....05
Hairy Cell Leukemia .....06
Non-Hodgkin's Lymphoma .....07
Hodgkin's Lymphoma .....08
Myelodysplasia .....09
Myeloma .....10
Non-Hematopoietic Solid Tumor Carcinoma .....11
Non-Hematopoietic Solid Tumor Sarcoma .....12

Other.....99 **(D1a)**

D1a. Specify Other: _____

**Section E: IMMUNOHEMATOLOGY**

E1. Subject's Blood Group: A.....1 B ..... 2 O..... 3 AB ..... 4

E2. Subject's Rh Type: Positive ..... 1 Negative..... 2

E3. Did or will the patient receive a stem cell transplant? Yes ..... 1 No..... 2 **(F1)** Unknown .....-8 **(F1)**

E3a. Date of transplant (or planned date): __ __ / __ __ / __ __ __ __

E3b. Type of transplant: Cord Blood ..... 1 PBSC.....2 Marrow ..... 3

E3c. Is transplant autologous or syngeneic? Yes ..... 1 **(F1)** No .....2

E3d. Donor blood group: A.....1 B ..... 2 O..... 3 AB ..... 4

E3e. Related donor? Yes.....1 No..... 2

**Section F: SIGNATURE**

F1. Approved by PI or designee: Initials: ____ ____ ____

F2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P004 QxQ – Baseline Demographics and Medical History

Version A: 12/01/2003

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**Purpose of this form:** The purpose of this form is to obtain basic demographic information and medical history from the patient. Included in this form are questions about race/ethnicity, primary diagnosis and immunohematology.

**When to complete this form:** The Consent Form and/or Assent Form must be signed and the patient must be randomized prior to completing this form. This baseline form is completed on the same day the patient is randomized.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: DEMOGRAPHICS

Questions B1 through and including B4 must be self-reported or self-identified by the patient or the patient's legal guardian. This may be accomplished by asking the patient to circle the appropriate answers on the form or by a staff member conducting an interview with the patient.

B1. Record the patient's date of birth.

B2. Record the patient's gender.

B3. Record the patient's ethnic origin.

B4a-f. Record the patient's race. The patient may identify themselves as one or more than one race. If the patient provides a racial category not in this list, circle 'Yes' for other (B4f) and write the category in the line provided in B4f1.

## SECTION C: MEDICAL HISTORY

C1. Indicate if the patient has received a platelet transfusion prior to this episode of thrombocytopenia.

C2. Indicate if the patient has received a red cell transfusion prior to this episode of thrombocytopenia.

C3. Indicate if the patient has had a splenectomy. If 'Yes' (1) go to question C4.

C3a. Indicate if the patient's spleen is enlarged. Spleen size may be determined by palpation of the spleen, an image study is not required.

If the patient is male, skip questions C4 through C7a and go to question D1

C4. Indicate if the patient has achieved menarche, i.e. has had their first period. If no, go to question D1.

C5. Indicate if the patient is post-menopausal, i.e. no longer has a period. If yes, go to question C7.

C6. Indicate if the patient is on hormonal therapy to eliminate / retard vaginal bleeding.

C7. Indicate if the patient has ever been pregnant. If no or unknown, go to question D1.

C7a. Indicate the number of pregnancies the patient has had, including miscarriages and abortions.

## SECTION D: PRIMARY DIAGNOSIS

D1 – D1a. Indicate the patient's primary diagnosis by circling one number in the list provided. If the patient's primary diagnosis is not in the list provided circle 99 (other) and specify the diagnosis in the line provided in D1a, otherwise go to question E1.

## SECTION E: IMMUNOHEMATOLOGY

E1 – E2. Record the patient's blood group and Rh type.

E3. Indicate if the patient will be receiving a stem cell transplant, or if they have received a stem cell transplant within 14 days prior to being evaluated for eligibility. If no (2) or unknown (-8), skip to question F1.

E3a. Record the planned date of transplant, or the date the patient had the transplant.

E3b. Indicate the type of transplant the patient will receive, or received.

E3c. Indicate if the transplant is (was) autologous or syngeneic. If yes (1), skip to question F1.

E3d. Record the donor blood group

E3e. Indicate if the donor is related to the patient.

## SECTION F: SIGNATURE

The Principal Investigator or their designee must approve the form.

F1. Enter the initials of the person approving the form.

F2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P005 – Baseline Laboratory Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline.....PBSL

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: BASELINE LABORATORY TESTS**

*All of the following tests are required at baseline*

| | a.Test Done? | b. Date Collected | c.Time Collected *24-hour clock* | d. Value | e. Units | f. Site Sample Obtained From: |
|---|---|---|---|---|---|---|
| **Hemoglobin** | | | | | | |
| B1. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| **Hematocrit** | | | | | | |
| B2. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| **Platelet count** | | | | | | |
| B3. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| **PT / INR:** *INR is the preferred value – report PT only if INR is not available* | | | | | | |
| B4. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ •___ __ | sec..... 1<br>INR .... 2 | Central .....1<br>Peripheral ....2 |
| **PTT** | | | | | | |
| B5. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central .....1<br>Peripheral ....2 |
| **Fibrinogen** | | | | | | |
| B6. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | mg/dL | Central .....1<br>Peripheral ....2 |
| **Lymphocytotoxic Antibody Screen** | | | | | | |
| B7. | Yes.....1<br>No .....2 | __ __/__ __/__ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | %* | Not applicable |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P005 – Baseline Laboratory Form**

TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline ..... PBSL

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: BASELINE LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test result to report? Yes..... 1 No..... 2 **(B2)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test result to report? Yes..... 1 No.....2 **(B3)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |

***Continued on Next Page***

**Section B: BASELINE LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test result to report? Yes..... 1 No..... 2 **(B4)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 5. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 6. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |

B4. **PT/INR:** At least one test result to report? Yes..... 1 No.....2 **(B5)**

***INR is the preferred value – report PT only if INR is not available***

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec..... 1<br>INR..... 2 | Central ..... 1<br>Peripheral ..... 2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec..... 1<br>INR..... 2 | Central ..... 1<br>Peripheral ..... 2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec..... 1<br>INR..... 2 | Central ..... 1<br>Peripheral ..... 2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | sec..... 1<br>INR..... 2 | Central ..... 1<br>Peripheral ..... 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B5. **PTT:** At least one test result to report? Yes ..... 1 No ..... 2 **(B6)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central ..... 1<br>Peripheral ..... 2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central ..... 1<br>Peripheral ..... 2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central ..... 1<br>Peripheral ..... 2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central ..... 1<br>Peripheral ..... 2 |

B6. **Fibrinogen:** At least one test result to report? Yes..... 1 No.....2 **(B7)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central ..... 1<br>Peripheral ..... 2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central ..... 1<br>Peripheral ..... 2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central ..... 1<br>Peripheral ..... 2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central ..... 1<br>Peripheral ..... 2 |

B7. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes ..... 1 No ..... 2 **(C1)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | %* |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P005 – Baseline Laboratory Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: Baseline..... PBSL

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: BASELINE LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test result to report? Yes.....1 No .....2 **(B2)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test result to report? Yes ..... 1 No .....2 **(B3)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | % |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: BASELINE LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test result to report? Yes.....1 No.....2 **(B4)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 5. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 6. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |

B4. **PT/INR:** At least one test result to report? Yes..... 1 No .....2 **(B5)**

*You must report both PT and INR values for each test.*

| | a. Date Collected | b. Time Collected *24-hour clock* | c. PT Value (sec) | d. INR Value | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central ..... 1<br>Peripheral ..... 2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central ..... 1<br>Peripheral ..... 2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central ..... 1<br>Peripheral ..... 2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central ..... 1<br>Peripheral ..... 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B5. **PTT:** At least one test result to report? Yes .....1 No.....2 **(B6)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central .....1<br>Peripheral .....2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central .....1<br>Peripheral .....2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central .....1<br>Peripheral .....2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central .....1<br>Peripheral .....2 |

B6. **Fibrinogen:** At least one test result to report? Yes..... 1 No ..... 2 **(B7)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units | e. Site Sample Obtained From: |
|---|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central .....1<br>Peripheral .....2 |
| 2. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central .....1<br>Peripheral .....2 |
| 3. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central .....1<br>Peripheral .....2 |
| 4. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central .....1<br>Peripheral .....2 |

B7. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes..... 1 No ..... 2 **(C1)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | %* |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P005 QxQ – Baseline Laboratory Form

Version A: 12/01/2003

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**Purpose of this form:** The purpose of this form is to document a patient's baseline laboratory results.

**When to complete this form:** This form is completed after the patient has signed a Consent and/or an Assent Form, screened eligible and has been randomized. Baseline PT/INR, PTT and Fibrinogen tests must be the most recent test done within 72 hours prior to eligibility determination. The same PT/INR, PTT and Fibrinogen levels may have been reported on Form P002 (Eligibility Form). Please re-enter these lab values here, to record these values as the patient's baseline labs. The remaining baseline labs (hemoglobin, hematocrit, platelet count, and LCA test) must be done the same day the patient is randomized.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4 Enter the initials of the person completing the form.

## SECTION B: BASELINE LABORATORY TESTS

It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.

B1 – B7. Each question consists of 6 parts (questions a, b, c, d, e, and f).

Column A: Indicate if the test was done at baseline. If the lab was not done, answer 'No' by circling the number 2, and skip to the next question. Note: On data entry, you must provide an override reason why the required test was not done.
Column B: Record the date the specimen was collected.
Column C: Record the time the specimen was collected.
Column D: Record the lab value.
Column E: **For PT/INR only**: circle the number that corresponds to the correct units: sec or INR.
Column F: **For PT/INR, PTT and Fibrinogen**: circle the number that corresponds to the correct site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

# Form P005 QxQ – Baseline Laboratory Form



**Purpose of this form:** The purpose of this form is to document a patient's baseline laboratory results.

**When to complete this form:** This form is completed after the patient has signed a Consent and/or an Assent Form, screened eligible and been randomized. Baseline PT/INR, PTT and Fibrinogen tests must be the most recent test done within 72 hours prior to eligibility determination. The same PT/INR, PTT and Fibrinogen levels may have been reported on Form P002 (Eligibility Form). Please re-enter these lab values here, to record these values as the patient's baseline labs. The remaining required baseline labs (hemoglobin, hematocrit, platelet count, and LCA test) must be done the same day the patient is randomized. One result for each test is required at baseline, however, the results of **all** tests done on the patient's baseline day (after consent signed) must be reported. This version of Form P005 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: BASELINE LABORATORY TESTS

**It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.**

B1. Indicate if there is at least one Hemoglobin test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B2. Indicate if there is at least one Hematocrit test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B3. Indicate if there is at least one Platelet Count to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B4. Indicate if there is at least one PT/INR test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.
d: Circle the number that corresponds to the correct units: sec or INR.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B5. Indicate if there is at least one PTT test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there is at least one Fibrinogen test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there is a Lymphocytotoxic Antibody Screen result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

# Form P005 QxQ – Baseline Laboratory Form



**Purpose of this form:** The purpose of this form is to document a patient's baseline laboratory results.

**When to complete this form:** This form is completed after the patient has signed a Consent and/or an Assent Form, screened eligible and been randomized. Baseline PT/INR, PTT and Fibrinogen tests must be the most recent test done within 72 hours prior to eligibility determination. The same PT/INR, PTT and Fibrinogen levels may have been reported on Form P002 (Eligibility Form). Please re-enter these lab values here, to record these values as the patient's baseline labs. The remaining required baseline labs (hemoglobin, hematocrit, platelet count, and LCA test) must be done the same day the patient is randomized. One result for each test is required at baseline, however, the results of **all** tests done on the patient's baseline day (after consent signed) must be reported. This version of Form P005 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: BASELINE LABORATORY TESTS

**It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.**

B1. Indicate if there is at least one Hemoglobin test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B2. Indicate if there is at least one Hematocrit test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B3. Indicate if there is at least one Platelet Count to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

B4. Indicate if there is at least one PT/INR test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the PT value (sec).
d: Record the INR value.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B5. Indicate if there is at least one PTT test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there is at least one Fibrinogen test result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.
e: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there is a Lymphocytotoxic Antibody Screen result to report. If the answer is No (2) you must provide a reason a required baseline test was not done when completing data entry of the form. If Yes (1) complete the following:

a: Record the date the specimen was collected.
b: Record the time the specimen was collected.
c: Record the lab value.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P006 – Hemostatic Assessment Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline Assessment.....PBSL
Daily Assessment .....PHMA

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

**Section B: ASSESSMENT**

B1. Date of assessment __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

B2. Components of assessment:

B2a. Interview Yes.....1 No..... 2

B2b. Physical Assessment Yes.....1 No..... 2

B2c. Chart Review Yes.....1 No..... 2

*If one or more of the components of the assessment was not done, provide reason not done in comment (C2)*

B3. Initials of person completing physical assessment and interview: ___ ___ ___

B4. Time physical assessment and interview started: ___ ___ :___ ___ *(24 hour clock)*

| *Please indicate if the following have occurred within the assessment period (00:00 to 23:59 on date in B1).* ***(circle one number for each question)*** | **Yes** | **No** | **Not Assessed/ Unknown** | **Refused** | **N/A** |
|---|---|---|---|---|---|
| ***Oral and Nasal:*** | | | | | |
| B5. New petechiae of oral mucosa? | 1 | 2 | 3 | -7 | |
| B6. Oropharyngeal bleeding? | 1 | 2 **(B7)** | 3 **(B7)** | -7 **(B7)** | |
| B6a. Total duration of all episodes during assessment period > 30 minutes? | 1 | 2 | 3 | -7 | |
| B7. Epistaxis during assessment period? | 1 | 2 **(B8)** | 3 **(B8)** | -7 **(B8)** | |
| B7a. Total duration of all episodes during assessment period > 30 minutes? | 1 | 2 | 3 | -7 | |
| ***Skin, Soft Tissue, Musculoskeletal:*** | | | | | |
| B8. New petechiae present on skin? | 1 | 2 | 3 | -7 | |
| B9. New purpura present? | 1 | 2 **(B10)** | 3 **(B10)** | -7 **(B10)** | |
| B9a. Purpura > 1 inch diameter? | 1 | 2 | 3 | -7 | |
| B10. One or more spontaneous hematomas in soft tissue or muscle > 1 inch? | 1 | 2 | 3 | -7 | |
| B11. Spontaneous hematoma in deeper tissues? | 1 | 2 | 3 | -7 | |
| B12. Joint bleeding? | 1 | 2 | 3 | -7 | |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section B: ASSESSMENT (cont.) (*circle one number for each question*) | Yes | No | Not Assessed/ Unknown | Refused | N/A |
|---|---|---|---|---|---|
| ***Gastrointestinal / Genitourinary / Gynecologic:*** | | | | | |
| B13. Melanotic stool? | 1 | 2 | 3 | -7 | -1 |
| B14. Visible red blood in stool? | 1 | 2 | 3 | -7 | -1 |
| B15. Visible blood in emesis? | 1 | 2 | 3 | -7 | -1 |
| B16. Visible blood in nasogastric drainage tube? | 1 | 2 | 3 | -7 | -1 |
| B17. Visible blood in urine? | 1 | 2 | 3 | -7 | |
| B18. Abnormal vaginal bleeding [Unexpected bleeding out of normal cycle **OR** Bleeding heavier than normal **OR** Breakthrough bleeding (patient on hormonal therapy to prevent bleeding)]? | 1 | 2 **(B19)** | 3 **(B19)** | -7 **(B19)** | -1 **(B19)** |
| B18a. Is abnormal bleeding more than spotting? | 1 | 2 | 3 | -7 | |
| ***Pulmonary:*** | | | | | |
| B19. Hemoptysis (visible blood)? | 1 | 2 | 3 | -7 | |
| B20. Blood in broncho-pulmonary lavage? | 1 | 2 | 3 | -7 | -1 |
| B21. Blood tinged sputum? | 1 | 2 | 3 | -7 | |
| ***Body Cavity:*** | | | | | |
| B22. Visible blood in body cavity fluid with non-traumatic aspiration? | 1 | 2 | 3 | -7 | -1 |
| B23. Grossly bloody body cavity fluids with associated organ dysfunction with symptoms and/or need to intervene? | 1 | 2 | 3 | -7 | |
| ***Neurologic:*** | | | | | |
| B24. Retinal bleed? | 1 | 2 **(B25)** | 3 **(B25)** | -7 **(B25)** | |
| B24a. Visual Impairment? | 1 | 2 | 3 | -7 | |
| B25. Did patient have lumbar puncture? | 1 | 2 **(B26)** | 3 **(B26)** | -7**(B26)** | |
| B25a. >5 RBC/μL in CSF on microscopic analysis, in absence of traumatic tap? | 1 | 2 | 3 | -7 | |
| B25b. Visible red color in CSF, in absence of traumatic tap? | 1 | 2 | 3 | -7 | |
| B25c. Associated CNS symptoms? | 1 | 2 | 3 | -7 | |
| B26. Was imaging study performed? | 1 | 2 **(B27)** | 3 **(B27)** | -7 **(B27)** | |
| B26a. CNS bleeding present? | 1 | 2 | 3 | -7 | |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section B: ASSESSMENT (cont.) (*circle one number for each question*) | Yes | No | Not Assessed/ Unknown | Refused | N/A |
|---|---|---|---|---|---|
| ***Invasive Sites:*** | | | | | |
| B27. Active oozing at invasive site for a cumulative total of > 1 hour during assessment period? | 1 | 2 | 3 | -7 | |
| ***Hemodynamic Instability:*** | | | | | |
| B28. >50mmHg fall or >50% decrease in either systolic or diastolic blood pressure | 1 | 2 **(B29)** | 3 **(B29)** | -7 **(B29)** | |
| B28a. Associated heart rate increase ≥ 20% for 20 minutes? | 1 **(C1)** | 2 **(C1)** | 3 **(C1)** | -7 **(C1)** | |
| B29. >30mmHg fall or >30% decrease in either systolic or diastolic blood pressure | 1 | 2 | 3 | -7 | |

**Section C: END OF ASSESSMENT**

C1. Time physical assessment and interview completed: ___ ___ :___ ___ *(24 hour clock)*

C2. Comments on Assessment: (include reason if any component of the assessment was not completed)

_____

_____

_____

_____

**Section D: SIGNATURE**

D1. Approved by PI or designee: Initials: ____ ____ ____

D2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P006 – Hemostatic Assessment Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline Assessment.....PBSL
Daily Assessment .....PHMA

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: __ __ __

**Section B: ASSESSMENT**

B1. Date of assessment __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

B2. Components of assessment:

B2a. Interview Yes ..... 1 No ..... 2

B2b. Physical Assessment Yes ..... 1 No ..... 2

B2c. Chart Review Yes ..... 1 No ..... 2

*If one or more of the components of the assessment was not done, provide reason not done in comment (C2)*

B3. Initials of person completing physical assessment and interview: ___ ___ ___

B4. Time physical assessment and interview started: ___ ___ :___ ___ *(24 hour clock)*

| *Please indicate if the following have occurred within the assessment period (00:00 to 23:59 on date in B1).* ***(circle one number for each question)*** | **Yes** | **No** | **Not Assessed** | **Refused** | **Don't Know** |
|---|---|---|---|---|---|
| ***Oral and Nasal:*** | | | | | |
| B5. New petechiae of oral mucosa? | 1 | 2 | 3 | -7 | -8 |
| B6. Oropharyngeal bleeding? | 1 | 2 **(B7)** | 3 **(B7)** | -7 **(B7)** | -8 **(B7)** |
| B6a. Total duration of all episodes during assessment period > 30 minutes? | 1 | 2 | 3 | -7 | -8 |
| B7. Epistaxis during assessment period? | 1 | 2 **(B8)** | 3 **(B8)** | -7 **(B8)** | -8 **(B8)** |
| B7a. Total duration of all episodes during assessment period > 30 minutes? | 1 | 2 | 3 | -7 | -8 |
| ***Skin, Soft Tissue, Musculoskeletal:*** | | | | | |
| B8. New petechiae present on skin? | 1 | 2 | 3 | -7 | -8 |
| B9. New purpura present? | 1 | 2 **(B10)** | 3 **(B10)** | -7 **(B10)** | -8 **(B10)** |
| B9a. Purpura > 1 inch diameter? | 1 | 2 | 3 | -7 | -8 |
| B10. One or more spontaneous hematomas > 1 inch in soft tissue or muscle? | 1 | 2 | 3 | -7 | -8 |
| B11. Spontaneous hematoma in deeper tissues? | 1 | 2 | 3 | -7 | -8 |
| B12. Joint bleeding? | 1 | 2 | 3 | -7 | -8 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section B: ASSESSMENT (cont.) (*circle one number for each question*) | Yes | No | Not Assessed | Refused | Don't Know |
|---|---|---|---|---|---|
| ***Gastrointestinal / Genitourinary / Gynecologic:*** | | | | | |
| B13. Was there a stool specimen? | 1 | 2 **(B14)** | 3 **(B14)** | -7**(B14)** | -8 **(B14)** |
| B13a. Melanotic stool? | 1 | 2 | 3 | -7 | -8 |
| B13b. Visible red blood in stool? | 1 | 2 | 3 | -7 | -8 |
| B14. Was there emesis? | 1 | 2 **(B15)** | 3 **(B15)** | -7**(B15)** | -8 **(B15)** |
| B14a. Visible red blood in emesis? | 1 | 2 | 3 | -7 | -8 |
| B15. Does patient have a nasogastric drainage tube? | 1 | 2 **(B16)** | 3 **(B16)** | -7**(B16)** | -8 **(B16)** |
| B15a. Visible blood in nasogastric drainage tube? | 1 | 2 | 3 | -7 | -8 |
| B16. Was there a urine specimen? | 1 | 2 **(B17)** | 3 **(B17)** | -7**(B17)** | -8 **(B17)** |
| B16a. Visible blood in urine? | 1 | 2 | 3 | -7 | -8 |
| B17. Is the patient female? | 1 | 2 **(B18)** | 3 **(B18)** | -7**(B18)** | -8 **(B18)** |
| B17a. Abnormal vaginal bleeding [Unexpected bleeding out of normal cycle **OR** Bleeding heavier than normal **OR** Breakthrough bleeding (patient on hormonal therapy to prevent bleeding)]? | 1 | 2 **(B18)** | 3 **(B18)** | -7 **(B18)** | -8 **(B18)** |
| B17b. Is abnormal bleeding more than spotting? | 1 | 2 | 3 | -7 | -8 |
| ***Pulmonary:*** | | | | | |
| B18. Hemoptysis (visible blood)? | 1 | 2 | 3 | -7 | -8 |
| B19. Did patient have broncho-pulmonary lavage? | 1 | 2 **(B20)** | 3 **(B20)** | -7**(B20)** | -8 **(B20)** |
| B19a. Blood in broncho-pulmonary lavage? | 1 | 2 | 3 | -7 | -8 |
| B20. Blood tinged sputum? | 1 | 2 | 3 | -7 | -8 |
| ***Body Cavity:*** | | | | | |
| B21. Was there a non-traumatic aspiration? | 1 | 2 **(B22)** | 3 **(B22)** | -7**(B22)** | -8 **(B22)** |
| B21a. Visible blood in body cavity fluid with non-traumatic aspiration? | 1 | 2 | 3 | -7 | -8 |
| B22. Grossly bloody body cavity fluids <u>with</u> associated organ dysfunction with symptoms <u>and/or</u> need to intervene? | 1 | 2 | 3 | -7 | -8 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

| Section B: ASSESSMENT (cont.) (*circle one number for each question*) | Yes | No | Not Assessed | Refused | Don't Know |
|---|---|---|---|---|---|
| ***Neurologic:*** | | | | | |
| B23. Did patient have visual impairment? | 1 | 2 | 3 | -7 | -8 |
| B24. Did patient have a retinal exam? | 1 | 2 **(B25)** | 3 **(B25)** | -7**(B25)** | -8 **(B25)** |
| B24a. Did patient have a retinal bleed? | 1 | 2 | 3 | -7 | -8 |
| B25. Did patient have lumbar puncture? | 1 | 2 **(B26)** | 3 **(B26)** | -7**(B26)** | -8 **(B26)** |
| B25a. >5 RBC/μL in CSF on microscopic analysis, in absence of traumatic tap? | 1 | 2 | 3 | -7 | -8 |
| B25b. Visible red color in CSF, in absence of traumatic tap? | 1 | 2 | 3 | -7 | -8 |
| B25c. Associated CNS symptoms? | 1 | 2 | 3 | -7 | -8 |
| B26. Was imaging study for neurological indications performed? | 1 | 2 **(B27)** | 3 **(B27)** | -7 **(B27)** | -8 **(B27)** |
| B26a. CNS bleeding present? | 1 | 2 | 3 | -7 | -8 |
| ***Invasive Sites:*** | | | | | |
| B27. Active oozing at invasive site for a cumulative total of > 1 hour during assessment period? | 1 | 2 | 3 | -7 | -8 |
| ***Hemodynamic Instability:*** | | | | | |
| B28. >50mmHg fall or >50% decrease in either systolic or diastolic blood pressure | 1 | 2 **(B29)** | 3 **(B29)** | -7 **(B29)** | -8 **(B29)** |
| B28a. Associated heart rate increase ≥ 20% for 20 minutes? | 1 **(C1)** | 2 **(C1)** | 3 **(C1)** | -7 **(C1)** | -8 **(C1)** |
| B29. >30mmHg fall or >30% decrease in either systolic or diastolic blood pressure | 1 | 2 | 3 | -7 | -8 |

**Section C: END OF ASSESSMENT**

C1. Time physical assessment and interview completed: ___ ___ :___ ___ *(24 hour clock)*

C2. Comments on Assessment: (include reason if any component of the assessment was not completed)

_____

_____

**Section D: SIGNATURE**

D1. Approved by PI or designee: Initials: ____ ____ ____

D2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P006 QxQ – Hemostatic Assessment Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to obtain objective information about the occurrence of bleeding during the assessment period.

**When to complete this form:** This form is completed at baseline (the day the patient is randomized) and everyday after randomization while the patient participates in the study, including the end of study (last day).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. Circle the correct event: if the assessment is the baseline assessment for the patient circle PBSL. If the assessment is being done as part of the daily measures, circle PHMA.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: ASSESSMENT

B1. Record the date of assessment

B2a-c. Indicate the components of assessment completed during the entire assessment period. Answer yes or no for each question. If one or more of the components was not done, provide the reason in question C2.

B3. The protocol requires that a full head-to-toe assessment and interview of the patient be done at least once per assessment period. Record the initials of the staff member completing the required physical assessment and interview.

B4. Record the time the physical assessment and interview of the patient was started using a 24-hour clock (hh:mm).

**Questions B5 to B29**: Circle one number for each item unless directed to skip over an item by the question number in **BOLD** following the number you circle. The assessment time period begins at 00:00 and ends at 23:59 (11:59pm) each day. **It is important that the information recorded on this form reflects only what took place during that time period.**

**General Instructions**: If you are able to evaluate the bleeding indicated in each question, circle **1** (yes) to indicate that bleeding occurred in the assessment period or **2** (No) if that bleeding did not occur. If the patient refuses the completion of any measurement, circle **–7** (refused). If the staff member is unable to complete any measurement or is not able to ascertain if the bleeding occurred from the chart review circle **3** (not done or unknown).

B5. New petechiae of the oral mucosa during the assessment period?

B6. Oropharyngeal bleeding in the assessment period? If No, Unknown, or Refused, go to question B7.

B6a. Total duration of all episodes of oropharyngeal bleeding during the assessment period greater than 30 minutes?

B7. Epistaxis during the assessment period? If No, Unknown, or Refused, go to question B8.

B7a. Total duration of all episodes of epistaxis during the assessment period greater than 30 minutes?

B8. New petechiae on the skin during the assessment period?

B9. New purpura during the assessment period? If No, Unknown, or Refused, go to question B10.

B9a. Is the Purpura greater than 1 inch in diameter?

B10. Evidence of one or more spontaneous hematomas in soft tissue or muscle that are greater than 1 inch?

B11. Spontaneous hematoma in the deep tissue during the assessment period?

B12. Joint bleeding (as confirmed by aspiration, imaging study, or other accepted technique) during the assessment period?

B13. Melanotic stool during the assessment period?

B14. Visible red blood in stool during the assessment period?

B15. Visible blood in emesis during assessment period? If there was no emesis during assessment period, circle **–1** (N/A)

B16. Visible blood in nasogastric drainage tube during assessment period. If patient does not have nasogastric tube, circle **–1** (N/A).

B17. Visible blood in urine during assessment period?

B18. Did the patient have any abnormal vaginal bleeding during the assessment period? Abnormal vaginal bleeding is defined as any one of the following:

- Unexpected bleeding out of normal cycle
- Bleeding heavier than normal
- Breakthrough bleeding while patient is on hormonal therapy to prevent bleeding

If the patient is male circle **–1** (N/A). If No, Unknown, Refused, or N/A go to question B19.

B18a. Was the abnormal bleeding during the assessment period more than spotting?

B19. Hemoptysis (visible blood) during the assessment period?

B20. Blood in broncho-pulmonary lavage during assessment period? If patient did not have lavage, circle **–1** (N/A).

B21. Blood tinged sputum during assessment period?

B22. Visible blood in body cavity fluid with non-traumatic aspiration? If patient did not have aspiration, circle **–1** (N/A).

B23. Grossly bloody body cavity fluids with associated organ dysfunction with symptoms and/or need to intervene?

B24. Retinal bleeding during assessment period? If No, Unknown, or Refused go to question B25.

B24a. Visual impairment with retinal bleed during assessment period?

B25. Was a lumbar puncture performed during the assessment period? If No, Unknown, or Refused go to question B26.

B25a. Does report show >5 red blood cells/μL in CSF on microscopic analysis, in absence of traumatic tap?

B25b. Visible red color in CSF, in absence of traumatic tap?

B25c. CNS symptoms with non-traumatic bloody lumbar puncture?

B26. Imaging study performed during the assessment period? If No, Unknown, or Refused go to question B27.

B26a. Report of CNS bleeding on imaging study?

B27. Active oozing at an invasive/insertion site for a cumulative total of >1 hour during the assessment period?

B28. Did the patient experience a >50mmHg fall or >50% decrease in either systolic or diastolic blood pressure during the assessment period? If No, Unknown, or Refused go to question B29.

B28a. In addition to blood pressure changes identified in B28, was there an associated heart rate increase of ≥ 20% for at least 20 minutes? After answering this question, skip to question C1.

B29. Did the patient experience a >30mmHg fall or >30% decrease in either systolic or diastolic blood pressure during the assessment period?

## SECTION C: END OF ASSESSMENT

C1. Indicate the time the required head-to-toe physical assessment and interview of the patient was completed using a 24-hour clock.

C2. Provide comments or clarification of the assessment; for example, additional information about hemostatic instability. If applicable, include the reason one or more of the components of the assessment were not completed. If there is no comment, enter a **–1** (N/A). A maximum of 250 characters is allowed.

## SECTION D: SIGNATURE

The Principal Investigator or their designee must approve the form.

D1. Enter the initials of the person approving the form.

D2. Record the date the form was approved.

Platelet Dose Trial

# Form P006 QxQ – Hemostatic Assessment Form

Version B: 10/22/2004

**Purpose of this form:** The purpose of this form is to obtain objective information about the occurrence of bleeding during the assessment period.

**When to complete this form:** This form is completed at baseline (the day the patient is randomized) and everyday after randomization while the patient participates in the study, including the end of study (last day).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. Circle the correct event: if the assessment is the baseline assessment for the patient circle PBSL. If the assessment is being done as part of the daily measures, circle PHMA.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: ASSESSMENT

B1. Record the date of assessment

B2a-c. Indicate the components of assessment completed during the entire assessment period. Answer yes or no for each question. If one or more of the components was not done, provide the reason in question C2.

B3. The protocol requires that a full head-to-toe assessment and interview of the patient be done at least once per assessment period. Record the initials of the staff member completing the required physical assessment and interview.

B4. Record the time the physical assessment and interview of the patient was started using a 24-hour clock (hh:mm).

**Questions B5 to B29**: Circle one number for each item unless directed to skip over an item by the question number in **BOLD** following the number you circle. The assessment time period begins at 00:00 and ends at 23:59 (11:59pm) each day. **It is important that the information recorded on this form reflects only what took place during that time period.**

**General Instructions**: The definitions of the available codes are as follows. By circling one of the codes, the DCC will interpret your answer to each question as follows:

**1 (Yes)** = Item was assessed, answer is positive
**2 (No)** = Item was assessed, answer is negative
**3 (Not Assessed)** = Item was not assessed
**-7 (Refused)** = Patient refused to allow assessment of this item
**-8 (Don't Know)** = Item was assessed, but insufficient information available to determine if the answer is positive or negative

B5. New petechiae of the oral mucosa during the assessment period?

B6. Oropharyngeal bleeding in the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B7.

B6a. Total duration of all episodes of oropharyngeal bleeding during the assessment period greater than 30 minutes?

B7. Epistaxis during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B8.

B7a. Total duration of all episodes of epistaxis during the assessment period greater than 30 minutes?

B8. New petechiae on the skin during the assessment period?

B9. New purpura during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B10.

B9a. Is the Purpura greater than 1 inch in diameter?

B10. Evidence of one or more spontaneous hematomas greater than 1 inch in soft tissue or muscle?

B11. Spontaneous hematoma in the deep tissue during the assessment period?

B12. Joint bleeding (as confirmed by aspiration, imaging study, or other accepted technique) during the assessment period?

B13. Was there a stool specimen during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B14

B13a. Melanotic stool during the assessment period?

B13b. Visible red blood in stool during the assessment period?

B14. Was there emesis during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B15.

B14a. Visible blood in emesis during assessment period?

B15. Does the patient have a nasogastric drainage tube? If No, Not Assessed, Refused or Don't Know, go to question B16.

B15a. Visible blood in nasogastric drainage tube during assessment period.

B16. Was there a urine specimen during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B17.

B16a. Visible blood in urine during assessment period?

B17. Is the patient female? If No, Not Assessed, Refused or Don't Know, go to question B18.

B17a. Did the patient have any abnormal vaginal bleeding during the assessment period? Abnormal vaginal bleeding is defined as any one of the following:

- Unexpected bleeding out of normal cycle
- Bleeding heavier than normal
- Breakthrough bleeding while patient is on hormonal therapy to prevent bleeding

B17b. Was the abnormal bleeding during the assessment period more than spotting?

B18. Hemoptysis (visible blood) during the assessment period?

B19. Did the patient have a broncho-pulmonary lavage during assessment period? If No, Not Assessed, Refused or Don't Know, go to question B20.

B19a. Blood in broncho-pulmonary lavage during assessment period?

B20. Blood tinged sputum during assessment period?

B21. Was there a non-traumatic aspiration during assessment period? If No, Not Assessed, Refused or Don't Know, go to question B22.

B21a. Visible blood in body cavity fluid with non-traumatic aspiration?

B22. Grossly bloody body cavity fluids with associated organ dysfunction with symptoms and/or need to intervene?

B23. Did the patient have visual impairment during assessment period?

B24. Was there a retinal exam during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B25.

B24a. Retinal bleeding during assessment period?

B25. Was a lumbar puncture performed during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B26.

B25a. Does report show >5 red blood cells/μL in CSF on microscopic analysis, in absence of traumatic tap?

B25b. Visible red color in CSF, in absence of traumatic tap?

B25c. CNS symptoms with non-traumatic bloody lumbar puncture?

B26. Imaging study performed during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B27.

B26a. Report of CNS bleeding on imaging study?

B27. Active oozing at an invasive/insertion site for a cumulative total of >1 hour during the assessment period?

B28. Did the patient experience a >50mmHg fall or >50% decrease in either systolic or diastolic blood pressure during the assessment period? If No, Not Assessed, Refused or Don't Know, go to question B29.

B28a. In addition to blood pressure changes identified in B28, was there an associated heart rate increase of ≥ 20% for at least 20 minutes? After answering this question, skip to question C1.

B29. Did the patient experience a >30mmHg fall or >30% decrease in either systolic or diastolic blood pressure during the assessment period?

## SECTION C: END OF ASSESSMENT

C1. Indicate the time the required head-to-toe physical assessment and interview of the patient was completed using a 24-hour clock.

C2. Provide comments or clarification of the assessment; for example, additional information about hemostatic instability. If applicable, include the reason one or more of the components of the assessment were not completed. If there is no comment, enter a **–1** (N/A). A maximum of 250 characters is allowed.

## SECTION D: SIGNATURE

The Principal Investigator or their designee must approve the form.

D1. Enter the initials of the person approving the form.

D2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P008 – Data on Transfused Product (Platelets and Granulocytes)**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event. Trans: Plts and Grans ..... (PPLT)

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: PRODUCT INFORMATION**

B1a. Date product sent for transfusion: __ __ / __ __ / __ __ __ __

B1b. Time product sent: __ __ : __ __ *(24 hour clock)*

| | | | | |
|---|---|---|---|---|
| B2. Unit ID number | _____ | _____ | _____ | _____ |
| B3. Type of product *(see codes page 2)* | ___ ___ | ___ ___ | ___ ___ | ___ ___ |
| B3a. Number of concentrates/donors | ___ ___ N/A.... -1 | ___ ___ N/A .... -1 | ___ ___ N/A ....-1 | ___ ___ N/A.... -1 |
| B4. ABO Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type |
| B5. Leukoreduced | Yes.....1 No..... 2 | Yes ..... 1 No .....2 | Yes.....1 No .....2 | Yes.....1 No..... 2 |
| B6. Vol reduced | Yes.....1 No .... 2 | Yes ..... 1 No.....2 | Yes.....1 No .....2 | Yes.....1 No..... 2 |
| B7. Storage duration* | ___ ___ N/A.... -1 | ___ ___ N/A .... -1 | ___ ___ N/A ....-1 | ___ ___ N/A.... -1 |
| B8. Plt concentration at collection** | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L |
| B9. Volume of unit | __ __ __ ml.....1 g.....2 | __ __ __ ml..... 1 g ..... 2 | __ __ __ ml.....1 g.....2 | __ __ __ ml .... 1 g ..... 2 |
| B10. Plt concentration at issue | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L |
| B11. Lab equipment used to measure count *(see lab equip codes)* | ___ ___ ___ | ___ ___ ___ | ___ ___ ___ | ___ ___ ___ |
| B11a. If B11 = 999, specify equipment: | _____ | _____ | _____ | _____ |

**Enter number of days. Record days for pooled concentrates only if all same age, else circle –1*

***Record for apheresis platelets only*

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

| TYPE OF PRODUCT CODES |
|---|
| **01** = Granulocytes |
| **02** = Apheresis Platelets |
| **03** = Pooled Whole Blood Derived Platelets |
| **04** = HLA- or Crossmatch-Selected Apheresis Platelets |
| **05** = HLA- or Crossmatch-Selected Whole Blood Derived Platelets |

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P008 – Data on Transfused Product (Platelets and Granulocytes)** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event. Trans: Plts and Grans ..... PPLT

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: PRODUCT INFORMATION**

| | | | |
|---|---|---|---|
| B1a. Date product sent for transfusion: | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |
| B1b. Time product sent: | __ __ : __ __ *24 hour clock* | __ __ : __ __ *24 hour clock* | __ __ : __ __ *24 hour clock* |
| B2. Unit ID number | _____ | _____ | _____ |
| B3. Type of product *(see codes page 2)* | ___ ___ | ___ ___ | ___ ___ |
| B3a. Number of concentrates/donors | ___ ___ • ___ NA-1 | ___ ___ • ___ NA-1 | ___ ___ • ___ NA-1 |
| B4. ABO Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type | ☐1 A ☐2 B ☐3 AB ☐4 O ☐5 Mixed Type |
| B5. Leukoreduced | Yes.....1 No..... 2 | Yes.....1 No..... 2 | Yes..... 1 No..... 2 |
| B6. Vol reduced | Yes.....1 No .... 2 | Yes.....1 No..... 2 | Yes..... 1 No..... 2 |
| B7. Storage duration* | ___ ___ N/A ....-1 | ___ ___ N/A ....-1 | ___ ___ N/A.....-1 |
| B8. Plt concentration at collection** | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L |
| B9. Volume of unit | __ __ __ ml ..... 1 g ..... 2 | __ __ __ ml ..... 1 g ..... 2 | __ __ __ ml..... 1 g ..... 2 |
| B10. Plt concentration at issue | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L | __ __ __ __ x $10^9$/L |
| B11. Lab equipment used to measure count (see lab equip codes) | ___ ___ ___ | ___ ___ ___ | ___ ___ ___ |
| B11a. If B11 = 999, specify equipment: | _____ | _____ | _____ |

**Enter number of days. Record days for pooled concentrates only if all same age, else circle –1*

***Record for apheresis platelets only*

***Continued on Next Page***

_ _ __ -- __ __ __ __ -- __ __ __ -- __

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

| TYPE OF PRODUCT CODES |
|---|
| **01** = Granulocytes |
| **02** = Apheresis Platelets |
| **03** = Pooled Whole Blood Derived Platelets |
| **04** = HLA- or Crossmatch-Selected Apheresis Platelets |
| **05** = HLA- or Crossmatch-Selected Whole Blood Derived Platelets |

Platelet Dose Trial

# Form P008 QxQ – Data on Transfused Product (Platelets and Granulocytes)

Version A: 12/01/2003

---

**Purpose of this form:** The purpose of this form is to document the product information of the platelets or granulocytes ordered for one transfusion episode.

**When to complete this form:** This form is completed for each platelet or granulocyte transfusion episode ordered for a patient. A transfusion episode is defined as: all platelet or granulocyte products ordered by a patient's physician at one time (i.e. one order).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: PRODUCT INFORMATION

B1a – B1b. Enter the date and time the product was released from the blood bank to the patient for transfusion.

**Answer questions B2 – B11a (one column) for each unit of the transfusion that has been prepared for the patient. If the transfusion episode consists of more than 4 units, staple an additional copy of Form P008 to the original page and continue recording the units on the additional copy.**

B2. Record the unit ID number (can be a combination of ID numbers, and is a unique identifier for this bag/unit).

B3. Record the type of product using the Product Codes on page 2:
- If the unit contains granulocytes, the product code **= 01**
- If the unit contains apheresis platelets, the product code **= 02**
- If the unit contains pooled whole blood derived platelets, the product code **= 03**
- If the unit contains HLA- or Crossmatch-selected apheresis platelets, the product code **= 04**
- If the unit contains HLA- or Crossmatch-selected whole blood derived platelets, the product code **= 05**

B3a. Enter the number of concentrates/donors that were used for this unit. If this is not a pooled product, circle **–1** (N/A)

B4. Indicate the ABO type of the product. (Data entry: enter the number to the right of the check box.)

B5. Indicate if the product is leukoreduced.

B6. Indicate if the product is volume reduced.

B7. Enter the storage duration of the product in number of whole days, where Day 0 = day of collection. For pooled products, only enter the storage duration if all pooled concentrates were the same age. Otherwise, circle –1 (N/A).

**NOTE: The platelet concentrations must be reported as: # x $10^9$/L. This unit - $10^9$/L - is the same as K/microliter.**

B8. This question is for apheresis platelets only. Enter the platelet concentration of the product at collection. If not an apheresis product, skip to question B9.

B9. Enter the volume of the unit in milliliters or grams and **circle the number corresponding to the correct units**. The volume of the unit should be measured after all processing is complete.

B10. Enter the platelet concentration of the product at issue – i.e. after all processing is complete and the same day the product is sent to the patient for transfusion.

B11. Enter the lab equipment code for the equipment used to measure the platelet concentration at issue. Select the appropriate code from the Code List for Form P008 – Data on Transfused Product (separate sheet).

B11a. If the code in B11 = 999 (other), write in the type of equipment in the space provided.

**SECTION C: SIGNATURE**

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P008 QxQ – Data on Transfused Product (Platelets and Granulocytes)

Version B: 04/11/2005

---

**Purpose of this form:** The purpose of this form is to document the product information of the platelets or granulocytes ordered for one transfusion episode.

**When to complete this form:** This form is completed for each platelet or granulocyte transfusion episode ordered for a patient. A transfusion episode is defined as: all platelet or granulocyte products ordered by a patient's physician at one time (i.e. one order).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: PRODUCT INFORMATION

**Answer questions B1a – B11a (one column) for each unit of the transfusion that has been prepared for the patient. If the transfusion episode consists of more than 3 units, staple an additional copy of Form P008 to the original page and continue recording the units on the additional copy.**

B1a. Enter the date each unit was released from the blood bank to the patient for transfusion.

B1b. Enter the time each unit was released from the blood bank to the patient for transfusion.

B2. Record the unit ID number (can be a combination of ID numbers, and is a unique identifier for this bag/unit).

B3. Record the type of product using the Product Codes on page 2:
- If the unit contains granulocytes, the product code **= 01**
- If the unit contains apheresis platelets, the product code **= 02**
- If the unit contains pooled whole blood derived platelets, the product code **= 03**
- If the unit contains HLA- or Crossmatch-selected apheresis platelets, the product code **= 04**
- If the unit contains HLA- or Crossmatch-selected whole blood derived platelets, the product code **= 05**

B3a. Enter the number of concentrates/donors that were used for this unit. If this is not a pooled product, circle **–1** (N/A)

B4. Indicate the ABO type of the product. (Data entry: enter the number to the right of the check box.)

B5. Indicate if the product is leukoreduced.

B6. Indicate if the product is volume reduced.

B7. Enter the storage duration of the product in number of whole days, where Day 0 = day of collection. For pooled products, only enter the storage duration if all pooled concentrates were the same age. Otherwise, circle –1 (N/A).

**NOTE: The platelet concentrations must be reported as: # x $10^9$/L. This unit - $10^9$/L - is the same as K/microliter.**

B8. This question is for apheresis platelets only. Enter the platelet concentration of the product at collection. If not an apheresis product, skip to question B9.

B9. Enter the volume of the unit in milliliters or grams and **circle the number corresponding to the correct units**. The volume of the unit should be measured after all processing is complete.

B10. Enter the platelet concentration of the product at issue – i.e. after all processing is complete and the same day the product is sent to the patient for transfusion.

B11. Enter the lab equipment code for the equipment used to measure the platelet concentration at issue. Select the appropriate code from the Code List for Form P008 – Data on Transfused Product (separate sheet).

B11a. If the code in B11 = 999 (other), write in the type of equipment in the space provided.

**SECTION C: SIGNATURE**

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P009 – Platelet and Granulocyte Transfusion Administration Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: Trans: Plts and Grans.....PPLT

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: ADMINISTRATION INFORMATION**

B1. Type of Transfusion: Platelets.....1 Granulocytes..... 2

B2. Indication for transfusion ***(circle one)***

Prophylaxis for low platelets.....1

Therapeutic for active bleeding .....2

Prophylaxis or therapeutic for invasive, surgical procedure.....3

Other..... 99➔➔ B2a. Specify: _____

| | | | | |
|---|---|---|---|---|
| B3: Unit ID number | _____ | _____ | _____ | _____ |
| B4. Start date | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ |
| B5. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B6. Finish date | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ |
| B7. Finish time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B8: Transfusion status *(see codes below)* | ____ ____ | ____ ____ | ____ ____ | ____ ____ |
| B8a. If status = 99, specify reason: | _____ | _____ | _____ | _____ |
| B9. If status = 03, 04, or 99, enter volume of unit transfused | ml .. 1<br>___ ___ ___ g .... 2 | ml ... 1<br>___ ___ ___ g ..... 2 | ml ... 1<br>___ ___ ___ g ..... 2 | ml ... 1<br>___ ___ ___ g .... 2 |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**TRANSFUSION FINAL STATUS CODES**

**01** = Unit Not Given to Patient
**02** = Transfusion of Unit Completed
**03** = Transfusion of Unit Discontinued Due to Transfusion Reaction
**04** = Transfusion of Unit Discontinued Due to Failure to Flow
**99** = Transfusion of Unit Discontinued Due to OTHER Reason

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P009 – Platelet and Granulocyte Transfusion Administration Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: Trans: Plts and Grans..... PPLT

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: ADMINISTRATION INFORMATION**

B1. Type of Transfusion: Platelets..... 1 Granulocytes .....2

B2. Indication for transfusion ***(circle one)***

Prophylaxis for low platelets .....1

Therapeutic for active bleeding.....2

Prophylaxis or therapeutic for invasive, surgical procedure .....3

Other .....99➔➔ B2a. Specify: _____

| | | | |
|---|---|---|---|
| B3. Unit ID number | _____ | _____ | _____ |
| B4. Start date | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ |
| B5. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B6. Finish date | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ |
| B7. Finish time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B8: Transfusion status *(see codes below)* | ____ ____ | ____ ____ | ____ ____ |
| B8a. If status = 99, specify reason: | _____ | _____ | _____ |
| B9. If status = 03, 04, or 99, enter volume of unit transfused | ml...1<br>___ ___ ___ g ....2 | ml .. 1<br>___ ___ ___ g .... 2 | ml.. 1<br>___ ___ ___ g.... 2 |

B10. Was there a transfusion related event of grade ≥ 1 (see P012)? Yes .....1 No.....2

*If yes, please complete a Form P012 for this transfusion.*

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**TRANSFUSION FINAL STATUS CODES**

**01** = Unit Not Given to Patient
**02** = Transfusion of Unit Completed
**03** = Transfusion of Unit Discontinued Due to Transfusion Reaction
**04** = Transfusion of Unit Discontinued Due to Failure to Flow
**99** = Transfusion of Unit Discontinued Due to OTHER Reason

Platelet Dose Trial

# Form P009 QxQ – Platelet and Granulocyte Transfusion Administration Form

Version A: 12/01/2003

---

**Purpose of this form:** The purpose of this form is to document the administration of platelets or granulocytes during one transfusion episode.

**When to complete this form:** This form is completed for each platelet or granulocyte transfusion episode. A transfusion episode is defined as: all platelet or granulocyte products ordered by a patient's physician at one time (i.e. one order).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: ADMINISTRATION INFORMATION

B1. Identify the type of transfusion.

B2. Circle the number that corresponds to the reason the patient is receiving this transfusion. If "other", circle 99 and write in the reason in the line provided in B2a.

B3 – B9. Answer questions B3 – B9 (one column) for each unit of the transfusion that has been delivered for the patient. If the transfusion episode consists of more than 4 units, staple an additional copy of Form P009 to the original page and continue recording the units on the additional copy.

B3. Record the unit ID number (bag number). This is a site-specific unique identifier for a particular bag/unit. This number must match the Unit ID number on the corresponding Forms P009 and P012.

B4. Record the date transfusion of this unit was started.

B5. Record the time transfusion of this unit was started.

B6. Record the date the transfusion of this unit was finished or stopped.

B7. Record the time the transfusion was finished or stopped.

B8. Indicate the final status of the transfusion by writing in a code number from the list of codes at the bottom of the form:

- If the transfusion unit was ordered and delivered, but the unit was not given to patient, the status code **= 01**
- If the transfusion was completed, and a complete unit was transfused, the status code **= 02**
- If the transfusion was discontinued due to a transfusion reaction, the status code **= 03**
- If the transfusion was discontinued due to Failure to Flow, the status code **= 04**
- If the transfusion was discontinued due to an "Other" reason, the status code **= 99**

B8a. If the status code = 99, record the reason the transfusion was discontinued in the line provided.

B9. If less than the entire unit was given to the patient (i.e. the status code = 03, 04 or 99), enter the volume that was transfused (in grams or mls). **Circle the number that corresponds to the correct units**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

# Form P009 QxQ – Platelet and Granulocyte Transfusion Administration Form

Version B: 04/11/2005

**Purpose of this form:** The purpose of this form is to document the administration of platelets or granulocytes during one transfusion episode.

**When to complete this form:** This form is completed for each platelet or granulocyte transfusion episode. A transfusion episode is defined as: all platelet or granulocyte products ordered by a patient's physician at one time (i.e. one order).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: ADMINISTRATION INFORMATION

B1. Identify the type of transfusion.

B2. Circle the number that corresponds to the reason the patient is receiving this transfusion. If "other", circle 99 and write in the reason in the line provided in B2a.

**Answer questions B3 – B9 (one column) for each unit of the transfusion that has been delivered for the patient. If the transfusion episode consists of more than 3 units, staple an additional copy of Form P009 to the original page and continue recording the units on the additional copy.**

B3. Record the unit ID number (bag number). This is a site-specific unique identifier for a particular bag/unit. This number must match the Unit ID number on the corresponding Forms P009 and P012.

B4. Record the date transfusion of this unit was started.

B5. Record the time transfusion of this unit was started.

B6. Record the date the transfusion of this unit was finished or stopped.

B7. Record the time the transfusion was finished or stopped.

B8. Indicate the final status of the transfusion by writing in a code number from the list of codes at the bottom of the form:

- If the transfusion unit was ordered and delivered, but the unit was not given to patient, the status code **= 01**
- If the transfusion was completed, and a complete unit was transfused, the status code **= 02**
- If the transfusion was discontinued due to a transfusion reaction, the status code **= 03**
- If the transfusion was discontinued due to Failure to Flow, the status code **= 04**
- If the transfusion was discontinued due to an "Other" reason, the status code **= 99**

B8a. If the status code = 99, record the reason the transfusion was discontinued in the line provided.

B9. If less than the entire unit was given to the patient (i.e. the status code = 03, 04 or 99), enter the volume that was transfused (in grams or mls). **Circle the number that corresponds to the correct units**.

B10. Indicate if there was a transfusion related event of grade $\geq$ 1 during or within 4 hours of this transfusion episode. If yes, then you must complete a Form P012. For a list of transfusion related events that must be reported for this trial review Form P012.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P010 – Daily Red Cell Transfusion Log** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: Trans: RBCs ..... (PRBC)

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: RED CELL TRANSFUSION LOG**

B1. Date of transfusions: __ __ / __ __ / __ __ __ __

| | | | | |
|---|---|---|---|---|
| B2. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B3. Were RBCs leukoreduced? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No..... 2 | Yes..... 1 No .....2 |
| B4. ABO group of RBC unit | A ..... 1 B .....2<br>AB..... 3 O.....4 | A.....1 B..... 2<br>AB.....3 O..... 4 | A.....1 B..... 2<br>AB .....3 O ..... 4 | A ..... 1 B.....2<br>AB ..... 3 O .....4 |
| B5. Rh type of RBC unit | Positive ..... 1<br>Negative ..... 2 | Positive..... 1<br>Negative ..... 2 | Positive..... 1<br>Negative..... 2 | Positive .....1<br>Negative.....2 |
| B6. Reason RBC transfusion given *(see codes below)* | ____ ____ | ____ ____ | ____ ____ | ____ ____ |
| B6a. If reason = 99, specify reason: | _____ | _____ | _____ | _____ |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**REASON RBC TRANSFUSION GIVEN CODES**

**01** = Acute Bleeding
**02** = Anemia
**99** = Other

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P010 – Daily Red Cell Transfusion Log** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Trans: RBCs ..... PRBC

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: RED CELL TRANSFUSION LOG**

B1. Date of transfusions: __ __ / __ __ / __ __ __ __

| | | | |
|---|---|---|---|
| B2. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B3. Were RBCs leukoreduced? | Yes..... 1 No..... 2 | Yes ..... 1 No ..... 2 | Yes..... 1 No..... 2 |
| B4. ABO group of RBC unit | A ..... 1 B..... 2<br>AB ..... 3 O ..... 4 | A..... 1 B ..... 2<br>AB..... 3 O..... 4 | A ..... 1 B..... 2<br>AB ..... 3 O ..... 4 |
| B5. Rh type of RBC unit | Positive ..... 1<br>Negative..... 2 | Positive..... 1<br>Negative ..... 2 | Positive ..... 1<br>Negative..... 2 |
| B6. Reason RBC transfusion given *(see codes below)* | ____ ____ | ____ ____ | ____ ____ |
| B6a. If reason = 99, specify reason: | _____ | _____ | _____ |
| B7. Was there a transfusion related event of grade ≥ 1 (see P012)?* | Yes..... 1 No..... 2 | Yes ..... 1 No ..... 2 | Yes..... 1 No..... 2 |

**If yes, please complete a Form P012 for the appropriate transfusion.*

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**REASON RBC TRANSFUSION GIVEN CODES**

**01** = Acute Bleeding
**02** = Anemia
**99** = Other

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P010 – Daily Red Cell Transfusion Log** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Trans: RBCs ..... PRBC

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: RED CELL TRANSFUSION LOG**

B1. Start date of transfusion episodes: __ __ / __ __ / __ __ __ __

| | Transfusion Episode a | Transfusion Episode b | Transfusion Episode c |
|---|---|---|---|
| B2. Start time of transfusion episode | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B3. Number of RBC units in transfusion episode | _____ _____ | _____ _____ | _____ _____ |
| B4. Were all RBC units leukoreduced? | Yes..... 1<br>No ..... 2 | Yes .... 1<br>No ..... 2 | Yes .....1<br>No.....2 |
| B5. Reason RBC transfusion given *(see codes below)* | _____ _____ | _____ _____ | _____ _____ |
| B5a. If reason = 99, specify reason: | _____ | _____ | _____ |
| B6. Completion date of transfusion episode | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ | __ __/__ __/__ __ __ __ |
| B7. Completion time of transfusion episode | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B8. Was there a transfusion related event of grade ≥ 1 (see P012)?* | Yes..... 1<br>No ..... 2 | Yes .... 1<br>No ..... 2 | Yes .....1<br>No.....2 |

**If yes, please complete a Form P012 for the appropriate transfusion.*

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**REASON RBC TRANSFUSION GIVEN CODES**

**01** = Acute Bleeding
**02** = Anemia
**99** = Other

Platelet Dose Trial

# Form P010 QxQ – Daily Red Cell Transfusion Log

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document the administration of red cells on one calendar day the patient is in the study.

**When to complete this form:** This form is completed once a day, each day the patient receives a red blood cell (RBC) transfusion. Do not complete this form if the patient did not receive any red blood cell transfusions.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: RED CELL TRANSFUSION LOG

B1. Enter the date the RBC transfusions documented on this form were given to the patient.

Answer questions B2 – B6a (one column) for each red cell transfusion during one calendar day. If the patient receives more than 4 RBC transfusions in one calendar day, staple an additional copy of Form P010 to the original page and continue recording the transfusions on the additional copy.

B2. Record the time the transfusion was started.

B3. Indicate if the RBCs were leukoreduced.

B4. Identify the ABO group of the RBCs transfused.

B5. Identify the Rh type of the RBCs transfused.

B6. Indicate the reason the RBCs were given to the patient using the codes at the bottom of the page.

- If the RBC transfusion was given for acute bleeding, the reason code **= 01**
- If the RBC transfusion was given for anemia, the reason code **= 02**
- If the RBC transfusion was given for an “Other” reason, the reason code **= 99**

B6a. If the reason code in question B6 is 99, use the space provided to record why the transfusion was given.

## SECTION C: SIGNATURE

The Principal Investigator or designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P010 QxQ – Daily Red Cell Transfusion Log

Version B: 04/11/2005

**Purpose of this form:** The purpose of this form is to document the administration of red cells on one calendar day the patient is in the study.

**When to complete this form:** This form is completed once a day, each day the patient receives a red blood cell (RBC) transfusion. Do not complete this form if the patient did not receive any red blood cell transfusions.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: RED CELL TRANSFUSION LOG

B1. Enter the date the RBC transfusions documented on this form were given to the patient.

**Answer questions B2 – B7(one column) for each red cell transfusion during one calendar day. If the patient receives more than 3 RBC transfusions in one calendar day, staple an additional copy of Form P010 to the original page and continue recording the transfusions on the additional copy.**

B2. Record the time the transfusion was started.

B3. Indicate if the RBCs were leukoreduced.

B4. Identify the ABO group of the RBCs transfused.

B5. Identify the Rh type of the RBCs transfused.

B6. Indicate the reason the RBCs were given to the patient using the codes at the bottom of the page.

- If the RBC transfusion was given for acute bleeding, the reason code **= 01**
- If the RBC transfusion was given for anemia, the reason code **= 02**
- If the RBC transfusion was given for an "Other" reason, the reason code **= 99**

B6a. If the reason code in question B6 is 99, use the space provided to record why the transfusion was given.

B7. Indicate if there was a transfusion related event of grade $\geq$ 1 during or within 4 hours of this transfusion. If yes, then you must complete a Form P012. For a list of transfusion related events that must be reported for this trial review Form P012.

## SECTION C: SIGNATURE

The Principal Investigator or designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P010 QxQ – Daily Red Cell Transfusion Log

Version C: 12/15/2005

**Purpose of this form:** The purpose of this form is to document the administration of red cell transfusions begun on one calendar day the patient is in the study.

**When to complete this form:** This form is completed once a day, each day at least one red blood cell (RBC) transfusion order is given for the patient. Do not complete this form if there were no red blood cell transfusions begun on that day.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: RED CELL TRANSFUSION LOG

**Note:** A RBC transfusion episode is defined as one order of red cells. A RBC transfusion episode may consist of one unit or multiple units of RBCs.

B1. Enter the start date of the RBC transfusion episodes documented on this form. This date will be the same as the order date for the RBC if the RBC transfusion episode was started on the same day the RBCs were ordered. If the transfusion episode was not started until the next calendar day, record the date the transfusion episode was started. For example, if an RBC transfusion of 2 units was ordered on 12/15/2005 and the first unit of the transfusion was started on 12/15/2005, B1 is 12/15/2005. If an RBC transfusion of 2 units was ordered on 12/15/2005 and the first unit of the transfusion was started on 12/16/2005, B1 is 12/16/2005.

**Note:** Answer questions B2 – B7 (one column) for each RBC transfusion episode that was initiated on the calendar day indicated in question B1. If the patient receives more than 3 RBC transfusions in one calendar day, staple an additional copy of Form P010 to the original page and continue recording the transfusions (i.e. more than 3 separate orders for RBC transfusions) on the additional copy.

B2. Record the start time of the transfusion episode.

B3. Indicate the number of RBC units in the transfusion episode.

B4. Indicate if all of the RBC units in the transfusion episode were leukoreduced.

B5. Indicate the reason the RBC transfusion episode was ordered for the patient using the codes at the bottom of the page.

- If the RBC transfusion was ordered for acute bleeding, the reason code **= 01**
- If the RBC transfusion was ordered for anemia, the reason code **= 02**
- If the RBC transfusion was ordered for an "Other" reason, the reason code **= 99**

B5a. If the reason code in question B5 is 99, use the space provided to record why the transfusion was ordered.

B6. Record the completion date of the transfusion episode.

B7. Record the completion time of the transfusion episode.

**Note**: If the RBC units that make up this transfusion episode were given at different times, record in B7 the date and time that the last unit of the episode was completed.

B7. Indicate if there was a transfusion related event of grade $\geq$ 1 during or within 4 hours after the end of this transfusion. If yes, then you must complete a Form P012. For a list of transfusion related events that must be reported for this trial, review Form P012.

## SECTION C: SIGNATURE

The Principal Investigator or designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P011 – Daily Other Blood Product Transfusion Log** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: Trans: Other Bld Prod ..... POTH

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: OTHER BLOOD PRODUCT TRANSFUSION LOG**

B1. Date of transfusions or transplant: __ __ / __ __ / __ __ __ __

| | | | | |
|---|---|---|---|---|
| B2. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B3. Type of product transfused? | FFP .....1<br>Cryoprecipitate....2<br>Transplant.....3 **(C1)**<br>Other.....99 | FFP.....1<br>Cryoprecipitate ...2<br>Transplant .....3 **(C1)**<br>Other .....99 | FFP .....1<br>Cryoprecipitate... 2<br>Transplant..... 3 **(C1)**<br>Other ..... 99 | FFP.....1<br>Cryoprecipitate ...2<br>Transplant.....3 **(C1)**<br>Other.....99 |
| B3a. If product = 99, specify product given | _____ | _____ | _____ | _____ |
| B4. # of units transfused | ____ ____ | ____ ____ | ____ ____ | ____ ____ |
| B5. Given for acute bleeding? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No.....2 | Yes..... 1 No .....2 |
| B6. Given for abnormal PT/INR? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No.....2 | Yes..... 1 No .....2 |
| B7. Given for abnormal PTT? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No.....2 | Yes..... 1 No .....2 |
| B8. Given for abnormal fibrinogen? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No.....2 | Yes..... 1 No .....2 |
| B9. Given for other reason? | Yes .... 1 No ..... 2 | Yes .....1 No..... 2 | Yes .....1 No.....2 | Yes..... 1 No .....2 |
| B9a. If other reason specify: | _____ | _____ | _____ | _____ |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P011 – Daily Other Blood Product Transfusion Log** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Trans: Other Bld Prod ..... POTH

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: OTHER BLOOD PRODUCT TRANSFUSION LOG**

B1. Date of transfusions or transplant: __ __ / __ __ / __ __ __ __

| | | | |
|---|---|---|---|
| B2. Start time | ___ ___ : ___ ___ | ___ ___ : ___ ___ | ___ ___ : ___ ___ |
| B3. Type of product transfused? | FFP ..... 1 **(B4)**<br>Cryoprecipitate ... 2 **(B4)**<br>Other ..... 99 | FFP ..... 1 **(B4)**<br>Cryoprecipitate ... 2 **(B4)**<br>Other ..... 99 | FFP ..... 1 **(B4)**<br>Cryoprecipitate ... 2 **(B4)**<br>Other ..... 99 |
| B3a. If product = 99, specify product given | _____ | _____ | _____ |
| B4. # of units transfused | ____ ____ | ____ ____ | ____ ____ |
| B5. Given for acute bleeding? | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |
| B6. Given for abnormal PT/INR? | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |
| B7. Given for abnormal PTT? | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |
| B8. Given for abnormal fibrinogen? | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |
| B9. Given for other reason? | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |
| B9a. If other reason specify: | _____ | _____ | _____ |
| B10. Was there a transfusion related event of grade $\geq$ 1 (see P012)?* | Yes .....1 No .....2 | Yes .....1 No .....2 | Yes .... 1 No .....2 |

**If yes, please complete a Form P012 for the appropriate transfusion.*

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

# Form P011 QxQ – Other Blood Product Transfusion Log

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document the administration of other blood products (not platelets, granulocytes or red cells) on one calendar day of the study.

**When to complete this form:** This form is completed once a day, each day the patient receives an "other" type of transfusion or transplant (not platelets, granulocytes or red blood cells). If the patient does not receive an "other" type of transfusion or transplant do not complete this form.

## SECTION A: GENERAL INFORMATION

A1. Affix patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: OTHER BLOOD PRODUCT TRANSFUSION LOG

B1. Enter the date the "other" transfusions or transplant documented on this form were given to the patient.

B2 – B9a. Answer all questions B2 – B9a (one column) for each transfusion administered during one calendar day. If the patient receives more than 4 transfusions in one calendar day, staple an additional copy of Form P011 to the original page and continue recording the transfusions on the additional copy. ***Note**: if this form is filled out to document a transplant, fill out fields B1, B2 and B3 only, then skip to question C1; a form P012 does not need to be completed for a transplant.*

B2. Record the time the transfusion or transplant was started.

B3. Circle the number that corresponds to the type of transfusion the patient received. If the patient received a transplant, circle number **3** and skip to question C1.

B3a. If 99 (other) is circled in B3, write in the type of transfusion the patient received in the space provided.

B4. Identify the number of units transfused.

B5. Was the transfusion given for acute bleeding?

B6. Was the transfusion given for abnormal PT/INR?

B7. Was the transfusion given for abnormal PTT?

B8. Was the transfusion given for abnormal fibrinogen?

B9. Was the transfusion given for any other reason? If no (2) skip to C1. If yes (1), go to B9a.

B9a. If B9 is Yes (1), write in the reason the transfusion was given to the patient.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P011 QxQ – Other Blood Product Transfusion Log

Version B: 04/11/2005

**Purpose of this form:** The purpose of this form is to document the administration of other blood products (not platelets, granulocytes or red cells) on one calendar day of the study.

**When to complete this form:** This form is completed once a day, each day the patient receives an "other" type of transfusion (not platelets, granulocytes or red blood cells). If the patient does not receive an "other" type of transfusion do not complete this form.

## SECTION A: GENERAL INFORMATION

A1. Affix patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: OTHER BLOOD PRODUCT TRANSFUSION LOG

B1. Enter the date the "other" transfusions documented on this form were given to the patient.

**Answer all questions B2 – B9a (one column) for each transfusion administered during one calendar day. If the patient receives more than 3 transfusions in one calendar day, staple an additional copy of Form P011 to the original page and continue recording the transfusions on the additional copy.**

B2. Record the time the transfusion was started.

B3. Circle the number that corresponds to the type of transfusion the patient received.

B3a. If 99 (other) is circled in B3, write in the type of transfusion the patient received in the space provided.

B4. Identify the number of units transfused.

B5. Was the transfusion given for acute bleeding?

B6. Was the transfusion given for abnormal PT/INR?

B7. Was the transfusion given for abnormal PTT?

B8. Was the transfusion given for abnormal fibrinogen?

B9. Was the transfusion given for any other reason? If no (2), skip to B10. If yes (1), go to B9a.

B9a. If B9 is Yes (1), write in the reason the transfusion was given to the patient.

B10. Indicate if there was a transfusion related event of grade $\geq$ 1 during or within 4 hours of this transfusion. If yes, then you must complete a Form P012. For a list of transfusion related events that must be reported for this trial review Form P012.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P012 – Transfusion Related Events**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ --__ __ __ -- __

A2. Initials of person completing form: __ __ __

A3. Event: Trans: Plts and Grans .....PPLT
Trans: RBCs.....PRBC
Trans: Other Bld Prod .....POTH

**Section B: TRANSFUSION RELATED EVENTS**

B1. Date of transfusion start: __ __ / __ __ / __ __ __ __

B1a. Time of transfusion start: ___ ___ : ___ ___ *(24 hour clock)*

B2. Date of transfusion finish: __ __ / __ __ / __ __ __ __

B2a. Time of transfusion finish: ___ ___ : ___ ___ *(24 hour clock)*

B3a. Type of product: _____

B3b. Unit ID number(s): _____

B4. Did the patient experience any transfusion related event? Yes.....1 No.....2 **(C1)**

| EVENT | GRADE 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| B5. **Allergic reaction/ Hypersensitivity** | ☐0 None | ☐1 transient flushing or rash | ☐2 rash, flushing, urticaria, dyspnea | ☐3 symptomatic bronchospasm, with or without urticaria; parenteral medication(s), indicated; allergy-related edema/ angioedema, hypotension | ☐4 anaphylaxis |
| B6. **Sinus bradycardia** | ☐0 None | ☐1 asymptomatic, intervention not indicated | ☐2 non-urgent medical intervention indicated | ☐3 symptomatic and incompletely controlled medically, or controlled with device (e.g. pacemaker) | ☐4 life-threatening (e.g. arrhythmia associated with CHF, hypotension syncope, shock) |
| B7. **Sinus tachycardia** | ☐0 None | ☐1 asymptomatic, intervention not indicated | ☐2 non-urgent medical intervention indicated | ☐3 symptomatic and incompletely controlled medically, or controlled with device (e.g. pacemaker) | ☐4 life-threatening (e.g. arrhythmia associated with CHF, hypotension syncope, shock) |

__ __ -- __ __ __ __ -- __ __ __ -- __

| EVENT | GRADE 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| B8. **Hypertension** | ☐0 None | ☐1 asymptomatic, transient (<24hrs) increase by >20mmHg (diastolic) or to >150/100* if previously WNL; intervention not indicated | ☐2 recurrent or persistent (>24hrs) symptomatic increase by >20mmHg (diastolic) or to >150/100* if previously WNL; monotherapy may be indicated | ☐3 requiring more than one drug or more intensive therapy than previously | ☐4 Life-threatening consequences (e.g. hypertensive crisis) |
| **Note: For pediatric patients, use age and sex appropriate normal values > 95th percentile ULN.* | | | | | |
| B9. **Hypotension** | ☐0 None | ☐1 changes, intervention not indicated | ☐2 brief (<24hrs) fluid replacement or other therapy; no physiologic consequences | ☐3 sustained (≥24hrs) therapy, resolves without persisting physiologic consequences | ☐4 shock (acidemia; impairment of vital organ function) |
| B10. **Dyspnea** (shortness of breath) | ☐0 Normal | ☐1 dyspnea on exertion, but can walk 1 flight of stairs without stopping | ☐2 dyspnea on exertion but unable to walk 1 flight of stairs or 1 city block (0.1km) without stopping | ☐3 dyspnea with ADL | ☐4 dyspnea at rest; intubation/ventilator indicated |
| B11. **Hypoxia** | ☐0 Normal | — | ☐2 decreased $O_2$ saturation with exercise (e.g. pulse oximeter<88%); intermittent supplemental oxygen | ☐3 decreased $O_2$ saturation at rest; continuous oxygen indicated | ☐4 life-threatening; intubation or ventilation indicated |
| B12. **Wheezing** | ☐0 None | ☐1 asymptomatic | ☐2 symptomatic not interfering with function | ☐3 symptomatic interfering with function | ☐4 life-threatening |
| B13. **Cough** | ☐0 None | ☐1 symptomatic, non-narcotic medication only indicated | ☐2 symptomatic and narcotic medication indicated | ☐3 Operative intervention indicated | ☐4 life-threatening (e.g. hemodynamic instability or ventilatory support indicated) |

__ __ -- __ __ __ __ -- __ __ __ -- __

| EVENT | GRADE 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| B14. **Hemolysis** | ☐0 None | ☐1 laboratory evidence of hemolysis only (direct antiglobulin test [DAT, Coombs'] schistocytes) | ☐2 evidence of red cell destruction and ≥ 2gm decrease in hemoglobin, no transfusion | ☐3 transfusion or medical intervention (e.g. steroids) indicated | ☐4 catastrophic consequences of hemolysis (e.g. renal failure, hypotension, bronchospasm) |
| B15. **Rigors, chills** | ☐0 None | ☐1 mild requiring symptomatic treatment (e.g., blanket) or non-narcotic medication | ☐2 severe and/or prolonged, requiring narcotic medication | ☐3 not responsive to narcotic medication | — |
| B16. **Fever** | ☐0 None | ☐1 38.0 – 39.0°C (100.4 – 102.2°F) | ☐2 >39.0 – 40.0°C (>102.2 – 104.0°F) | ☐3 >40.0°C (>104.0°F) for ≤24 hours | ☐4 >40.0°C (>104.0°F) for >24 hours |
| *Note: The temperature measurements listed above are oral or tympanic* | | | | | |
| B17. **Infection** | ☐0 None | — | ☐2 localized, local intervention indicated | ☐3 IV antibiotic, antifungal, or antiviral intervention indicated, interventional radiology or operative intervention indicated | ☐4 life-threatening consequences (e.g. septic shock, hypotension, acidosis, necrosis) |

B18. Did the patient experience a Grade 4 transfusion-related event (questions B5-B17)? Yes.....1 No..... 2

**If Yes (1) report the Grade 4 event on a Serious Adverse Event Form (Form P085)**

B19. Comment: _____

_____

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P012 QxQ – Transfusion Related Events

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document the occurrence of transfusion related events during and within 4 hours after a transfusion is completed or discontinued while a patient is in this study. The signs and symptoms identified on this form include most of the expected and common adverse events associated with transfusions.

**When to complete this form:** This form is completed after every transfusion the patient receives while on the study. The form must include all transfusion related events that occur during, or within 4 hours after the transfusion episode is completed or discontinued.
**Note:** All Grade 4 events must also be reported on a Serious Adverse Event Form (P085).

**Relationship to other study forms:** There must be one Form P012 for each P009, P010 and P011 completed and entered into the data management system. All Grade 4 events must also be reported on a Serious Adverse Event Form (P085).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. Enter the initials of the person completing the form.

A3. Circle the PPLT if the transfusion related to this form was either Platelets or Granulocytes. Circle PRBCs if the transfusion related to this form was Red Blood Cells. Circle POTH if the transfusion related to this event was "other blood product". **Data Entry:** Enter the form in the event matching the code that is circled.

## SECTION B: TRANSFUSION RELATED EVENTS

B1- B1a. Enter the date and time the transfusion was started.

B2- B2a. Enter the date and time the transfusion was finished or discontinued.

B3a- B3b. Enter the type of product transfused, and the unit number(s) of the product transfused.

B4. Did the patient experience a transfusion related event following this transfusion episode? If No, skip to question C1.

For each question B5-B17 check the box that best corresponds to the event grade that the patient experienced during or within 4 hours after the transfusion was completed or discontinued. If the patient did not experience a particular event, check the box marked Grade 0 (none or normal). Check only one box per item. **Data Entry**: enter the number to the right of the checked box.

B5. Allergy Reaction / Hypersensitivity

B6. Sinus bradycardia

B7. Sinus tachycardia

**Form P012 QxQ – Transfusion Related Events**

Version A: 12/01/2003

For each question B5-B17 check the box that best corresponds to the event grade that the patient experienced during or within 4 hours after the transfusion was completed or discontinued. If the patient did not experience a particular event, check the box marked Grade 0 (none or normal). Check only one box per item. **Data Entry**: enter the number to the right of the checked box.

**Note:** All Grade 4 events must also be reported on a Serious Adverse Event Form (P085).

B8. Hypertension WNL= within normal limits

Pediatric values:

Grade 1: Asymptomatic, transient (<24hrs) BP increase >Upper Limit of Normal (ULN); intervention not indicated
Grade 2: Recurrent or persistent (>24hrs) BP >ULN; monotherapy may be indicated
Grade 3: Same as adult
Grade 4: Same as adult

B9. Hypotension

B10. Dyspnea (difficulty breathing): ADL = activities of daily living

B11. Hypoxia

B12. Wheezing

B13. Cough

**Blood Pressure Levels for the 95th Percentiles of Blood Pressure for Girls and Boys Aged 1 to 17 Years, 95th Percentile of Height**

| | Boys | | Girls | |
|---|---|---|---|---|
| Age, y | SBP | DBP | SBP | DBP |
| 1 | 106 | 59 | 107 | 60 |
| 2 | 110 | 63 | 109 | 65 |
| 3 | 113 | 67 | 110 | 68 |
| 4 | 115 | 71 | 111 | 71 |
| 5 | 116 | 74 | 113 | 73 |
| 6 | 117 | 76 | 114 | 75 |
| 7 | 119 | 78 | 116 | 76 |
| 8 | 120 | 80 | 118 | 78 |
| 9 | 121 | 81 | 120 | 79 |
| 10 | 123 | 82 | 122 | 80 |
| 11 | 125 | 83 | 124 | 81 |
| 12 | 127 | 83 | 126 | 82 |
| 13 | 130 | 84 | 128 | 84 |
| 14 | 132 | 85 | 130 | 85 |
| 15 | 135 | 86 | 131 | 86 |
| 16 | 138 | 87 | 132 | 86 |
| 17 | 140 | 89 | 132 | 86 |

For each question B5-B17 check the box that best corresponds to the event grade that the patient experienced during or within 4 hours after the transfusion was completed or discontinued. If the patient did not experience a particular event, check the box marked Grade 0 (none or normal). Check only one box per item. **Data Entry**: enter the number to the right of the checked box.

**Note:** All Grade 4 events must also be reported on a Serious Adverse Event Form (P085).

B14. Hemolysis

B15. Rigors, chills

B16. Fever. The temperature measurements listed on the form are oral or tympanic.

B17. Infection

B18. Indicate if a Grade 4 transfusion-related event was reported on this form. If yes, the event must be reported to the DCC immediately, and a Serious Adverse Event form (P085) must be completed and sent to the DCC within 48 hours.

B19. Space is provided for a comment or additional explanation of any transfusion-related event. If there is no comment, write **–1**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P013 – Stem Cell Transplant Log**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Trans: Other Bld Prod.....POTH

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: TRANSPLANT LOG**

| | | | |
|---|---|---|---|
| B1. Start Date: | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y |
| B2. Start time: | ___ ___ : ___ ___<br>*(24 hour clock)* | ___ ___ : ___ ___<br>*(24 hour clock)* | ___ ___ : ___ ___<br>*(24 hour clock)* |
| B3. Product Type? | Fresh (non-Cryo) .....1 **(B4)**<br>Cryo-preserved .....2 **(C1)**<br>Other.....99 | Fresh (non-Cryo)..... 1 **(B4)**<br>Cryo-preserved ..... 2 **(C1)**<br>Other.....99 | Fresh (non-Cryo) ..... 1 **(B4)**<br>Cryo-preserved..... 2 **(C1)**<br>Other .....99 |
| B3a. If B3 = 99, specify other: | _____ | _____ | _____ |
| B4. End Date: | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y | __ __ / __ __ / __ __ __ __<br>M M D D Y Y Y Y |
| B5. End time: | ___ ___ : ___ ___<br>*(24 hour clock)* | ___ ___ : ___ ___<br>*(24 hour clock)* | ___ ___ : ___ ___<br>*(24 hour clock)* |
| B6. Volume of unit | ml.....1<br>____ ____ ____ g ..... 2 | ml.....1<br>____ ____ ____ g.....2 | ml ..... 1<br>____ ____ ____ g ..... 2 |
| B7. Plt concentration at issue | ___ ___ ___ ___ x $10^9$/L | ___ ___ ___ ___ x $10^9$/L | ___ ___ ___ ___ x $10^9$/L |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P013 QxQ – Stem Cell Transplant Log

Version A: 02/10/2005

**Purpose of this form:** The purpose of this form is to document the administration of a stem cell transplant while the patient is enrolled in the Platelet Dose Trial.

**When to complete this form:** This form is completed if and when a patient receives a stem cell transplant while they are enrolled in the Platelet Dose Trial. Only one form P013 can be completed per patient. Therefore, transplant units given on multiple days must all be recorded on one Form P013.

## SECTION A: GENERAL INFORMATION

A1. Affix patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: TRANSPLANT LOG

**Answer all questions in section B (one column) for each Fresh (non-Cryopreserved) or "other" transplant unit administered to the patient. If the patient receives more than 3 transplant units while enrolled in the Trial, staple an additional copy of Form P013 to the original page and continue recording the units on the additional copy.**

B1. Enter the date when the administration of this transplant unit to the patient was started. Record the date as mm/dd/yyyy.

B2. Record the time the administration of this transplant unit was started using a 24-hour clock.

B3. Circle the number that corresponds to the type of transplant product the patient received. If the patient received a Fresh (non-Cryopreserved) transplant please go to question B4. If the patient received a Cryo-preserved transplant please go to question C1.

B3a. If B3 = 99 (other), write in the type of product.

B4. Enter the date when the administration of this transplant unit was completed. Record the date as mm/dd/yyyy.

B5. Record the time the administration of this transplant unit was completed using a 24-hour clock.

B6. Enter the volume of the unit in milliliters or grams and **circle the number corresponding to the correct units**. The volume of the unit should be measured after the product is prepared and all processing is complete.

B7. Enter the platelet concentration of the product at issue – i.e. after all processing is complete and the same day the product is sent to the patient for transfusion.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P015 – Daily Laboratory Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Daily Labs ..... PLAB

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: DAILY LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

| | 1. Test Done? | 2. Time Collected *24-hour clock* | 3. Value | 4. Units | 5. Site Sample Obtained From: |
|---|---|---|---|---|---|
| **Hemoglobin** | | | | | |
| B1a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| B1b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| B1c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| **Hematocrit** | | | | | |
| B2a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| B2b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| B2c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| **Platelet count** | | | | | |
| B3a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| B3b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| B3c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

| | 1. Test Done? | 2. Time Collected *24-hour clock* | 3. Value | 4. Units | 5. Site Sample Obtained From: |
|---|---|---|---|---|---|
| **PT / INR** | *INR is the preferred value – report PT only if INR is not available* | | | | |
| B4a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central .....1<br>Peripheral .....2 |
| B4b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central .....1<br>Peripheral .....2 |
| B4c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central .....1<br>Peripheral .....2 |
| **PTT** | | | | | |
| B5a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central .....1<br>Peripheral .....2 |
| B5b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central .....1<br>Peripheral .....2 |
| B5c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central .....1<br>Peripheral .....2 |
| **Fibrinogen** | | | | | |
| B6a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central .....1<br>Peripheral .....2 |
| B6b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central .....1<br>Peripheral .....2 |
| B6c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central .....1<br>Peripheral .....2 |
| **Lymphocytotoxic Antibody Screen** | | | | | |
| B7a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | %* | Not applicable |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P015 – Daily Laboratory Form**

TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Daily Labs ..... PLAB

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: DAILY LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test done today? Yes..... 1 No.....2 **(B2)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test done today? Yes..... 1 No.....2 **(B3)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | % |

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__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test done today? Yes..... 1 No.....2 **(B4)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 2. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 3. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 4. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 5. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 6. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |

B4. **PT/INR:** At least one test done today? Yes..... 1 No.....2 **(B5)**

***INR is the preferred value – report PT only if INR is not available***

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 2. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 3. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 4. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B5. **PTT:** At least one test done today? Yes.....1 No.....2 **(B6)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |

B6. **Fibrinogen:** At least one test done today? Yes.....1 No.....2 **(B7)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |

B7. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes.....1 No.....2 **(C1)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ | %* |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P015 – Daily Laboratory Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Daily Labs..... (.. PLAB)

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: DAILY LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test done today? Yes ..... 1 No .....2 **(B2)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test done today? Yes ..... 1 No .....2 **(B3)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | % |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test done today? Yes ..... 1 No .....2 **(B4)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 5. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 6. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |

B4. **PT/INR:** At least one test done today?
*You must report both PT and INR values for each test.* Yes ..... 1 No .....2 **(B5)**

| | a. Time Collected *24-hour clock* | b. PT Value (sec) | c. INR Value | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central..... 1<br>Peripheral..... 2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central..... 1<br>Peripheral..... 2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central..... 1<br>Peripheral..... 2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central..... 1<br>Peripheral..... 2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B5. **PTT:** At least one test done today? Yes.....1 No.....2 **(B6)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |

B6. **Fibrinogen:** At least one test done today? Yes.....1 No.....2 **(B7)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |

B7. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes.....1 No .....2 **(C1)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ | %* |

*Percent panel reactivity

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P015 QxQ – Daily Laboratory Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document a patient's daily laboratory results.

**When to complete this form:** This form is completed every day the patient is in the study starting the day after the patient is randomized and continuing until, but not including, the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient for these labs.

**It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.**

## SECTION B: DAILY LABORATORY TESTS

B1a – B7a. Each day the patient remains in the study, the following lab tests are required: hemoglobin, hematocrit and Platelet count. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done as part of the patient's standard care must be reported each day. Space has been provided to record 3 results for each lab per day (except LCA). If the patient has a particular lab done more than 3 times during one day complete a second Form P015 with these additional results, and fax the form to the DCC.

Each question consists of 5 parts (columns 1, 2, 3, 4, and 5).

Column 1: Indicate if the test was done on the date recorded in question A5. If the lab was not done, answer 'No' by circling the number 2, and skip to the next lab test. **Note:** On data entry, you must provide an override reason why a required test was not done.

Column 2: Record the time the specimen was collected.

Column 3: Record the lab value.

Column 4: **For PT/INR only**: circle the number that corresponds to the correct units: sec or INR.

Column 5: **For PT/INR, PTT and Fibrinogen**: circle the number that corresponds to the correct site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P015 QxQ – Daily Laboratory Form

Version B: 08/18/2004

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**Purpose of this form:** The purpose of this form is to document a patient's daily laboratory results.

**When to complete this form:** This form is completed every day the patient is in the study starting the day after the patient is randomized and continuing until, but not including, the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient for these labs.

## SECTION B: DAILY LABORATORY TESTS

### It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.

Each day the patient remains in the study, the following lab tests are required: hemoglobin, hematocrit and Platelet count. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done as part of the patient's standard care must be reported each day. This version of Form P015 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

B1. Indicate if there was at least one Hemoglobin test done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B2. Indicate if there was at least one Hematocrit test done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B3. Indicate if there was at least one Platelet Count done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the time the specimen was collected.
b: Record the lab value.

B4. Indicate if there was at least one PT/INR test done today. If yes, complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
c: Circle the number that corresponds to the correct units: sec or INR.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B5. Indicate if there was at least one PTT test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there was at least one Fibrinogen test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there was a Lymphocytotoxic Antibody Screen test done today. If Yes (1) complete the following:

a: Record the time the specimen was collected.
b: Record the lab value.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P015 QxQ – Daily Laboratory Form

Version C: 12/10/2004

**Purpose of this form:** The purpose of this form is to document a patient's daily laboratory results.

**When to complete this form:** This form is completed every day the patient is in the study starting the day after the patient is randomized and continuing until, but not including, the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient for these labs.

## SECTION B: DAILY LABORATORY TESTS

### It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.

Each day the patient remains in the study, the following lab tests are required: hemoglobin, hematocrit and Platelet count. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done as part of the patient's standard care must be reported each day. This version of Form P015 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

B1. Indicate if there was at least one Hemoglobin test done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B2. Indicate if there was at least one Hematocrit test done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B3. Indicate if there was at least one Platelet Count done today. If the answer is No (2) you must provide a reason a required daily test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the time the specimen was collected.
b: Record the lab value.

B4. Indicate if there was at least one PT/INR test done today. If yes, complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the PT value (sec).
c: Record the INR value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B5. Indicate if there was at least one PTT test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there was at least one Fibrinogen test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there was a Lymphocytotoxic Antibody Screen test done today. If Yes (1) complete the following:

a: Record the time the specimen was collected.
b: Record the lab value.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P024 – Anti-Thrombotic and Fibrinolytic Inhibitor Medication Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: End of study ..... (PEOS)

A3. Date form completed: __ __ / __ __ / __ __ __ __
M M D D Y Y Y Y

A4. Initials of person completing form: ___ ___ ___

**Section B: ANTI-THROMBOTIC AND FIBRINOLYTIC INHIBITOR MEDICATIONS**

| | B1. Code | B2. Name of Medication | B3. Dose | B4. Date Started | B5. Date Ended or Changed |
|---|---|---|---|---|---|
| a. | __ __ __ | _____ | _____ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |
| b. | __ __ __ | _____ | _____ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |
| c. | __ __ __ | _____ | _____ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |
| d. | __ __ __ | _____ | _____ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |
| e. | __ __ __ | _____ | _____ | __ __ / __ __ / __ __ __ __ | __ __ / __ __ / __ __ __ __ |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P024 QxQ – Anti-Thrombotic and Fibrinolytic Inhibitor Medication Form

Version A: 12/01/2003

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**Purpose of this form:** The purpose of this form is to document information about anti-thrombotic or fibrinolytic inhibitor medications, if the patient is started on one of these types of medications while they are enrolled in the study.

**When to complete this form:** This form is completed if and when a patient is started on an anti-thrombotic or fibrinolytic inhibitor medication while they are enrolled in the Platelet Dose Trial. This form must be updated if the dose is changed, or the medication use is discontinued while the patient is on the study. While this form will be completed and updated throughout the patient's time on the study, it may be data entered when the patient reaches the end of the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: ANTI-THROMBOTIC AND FIBRINOLYTIC INHIBITOR MEDICATIONS

Answer questions B1-B5 (one row) for each anti-thrombotic or fibrinolytic inhibitor medication given to the patient while they are in the study. If a medication dose is changed, record this on a new row of the table as if it is a separate medication. If the patient is started on more than 5 medications, or has more than 5 medication changes, staple an additional copy of Form P024 to the original page and continue recording the medications on the additional copy.

B1. Record the medication code from the list of codes provided.

B2. Record the name of the medication.

B3. Record the dose of the medication given to the patient.

B4. Record the date the medication was started.

B5. Record the date the medication was stopped or changed. If the patient remains on the medication when they reach the end of their participation in the study, enter 01/01/0101 (N/A) as the end date.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P025 – End of Study Laboratory Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: End of Study ..... PEOS

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: END OF STUDY LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

| | 1. Test Done? | 2. Time Collected *24-hour clock* | 3. Value | 4. Units | 5. Site Sample Obtained From: |
|---|---|---|---|---|---|
| **Hemoglobin** | | | | | |
| B1a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| B1b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| B1c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL | Not applicable |
| **Hematocrit** | | | | | |
| B2a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| B2b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| B2c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ • ___ | % | Not applicable |
| **Platelet count** | | | | | |
| B3a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| B3b. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| B3c. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ | Not applicable |
| **Lymphocytotoxic Antibody Screen** | | | | | |
| B4a. | Yes.....1 No .....2 | ___ ___ : ___ ___ | ___ ___ ___ | %* | Not applicable |

*Percent panel reactivity

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: DAILY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

| | 1. Test Done? | 2. Time Collected *24-hour clock* | 3. Value | 4. Units | 5. Site Sample Obtained From: |
|---|---|---|---|---|---|
| **PT / INR** | *INR is the preferred value – report PT only if INR is not available* | | | | |
| B5a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central.....1<br>Peripheral .....2 |
| B5b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central.....1<br>Peripheral .....2 |
| B5c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central.....1<br>Peripheral .....2 |
| **PTT** | | | | | |
| B6a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central.....1<br>Peripheral .....2 |
| B6b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central.....1<br>Peripheral .....2 |
| B6c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ • __ | sec | Central.....1<br>Peripheral .....2 |
| **Fibrinogen** | | | | | |
| B7a. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central.....1<br>Peripheral .....2 |
| B7b. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central.....1<br>Peripheral .....2 |
| B7c. | Yes.....1<br>No .....2 | __ __ : __ __ | __ __ __ | mg/dL | Central.....1<br>Peripheral .....2 |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P025 – End of Study Laboratory Form**

TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: End of Study ..... PEOS

A3. Date form completed: __ __ / __ __ / __ __ __ __

A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: END OF STUDY LABORATORY TESTS**

*Record all values obtained each calendar day. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test done today? Yes..... 1 No.....2 **(B2)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test done today? Yes..... 1 No.....2 **(B3)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | % |

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__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: END OF STUDY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test done today? Yes..... 1 No.....2 **(B4)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 2. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 3. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 4. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 5. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |
| 6. | __ __ : __ __ | __ __ __ | x $10^3/\mu L$ |

B4. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes .....1 No .....2 **(B5)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | __ __ : __ __ | __ __ __ | %* |

*Percent panel reactivity

B5. **PT/INR:** At least one test done today? Yes..... 1 No.....2 **(B6)**

***INR is the preferred value – report PT only if INR is not available***

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 2. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 3. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |
| 4. | __ __ : __ __ | __ __ • __ __ | sec .....1<br>INR..... 2 | Central..... 1<br>Peripheral..... 2 |

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__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: END OF STUDY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B6. **PTT:** At least one test done today? Yes.....1 No.....2 **(B7)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |

B7. **Fibrinogen:** At least one test done today? Yes.....1 No.....2 **(C1)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P025 – End of Study Laboratory Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __ A2. Event: End of Study ..... PEOS

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

A5. Collection date: __ __ / __ __ / __ __ __ __

**Section B: END OF STUDY LABORATORY TESTS**

*Record all values obtained on last calendar day in study. Highlighted lines are required.*

B1. **Hemoglobin:** At least one test done today? Yes ..... 1 No ..... 2 **(B2)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | g/dL |

B2. **Hematocrit:** At least one test done today? Yes ..... 1 No ..... 2 **(B3)**

| | **a. Time Collected** *24-hour clock* | **b. Value** | **c. Units** |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | % |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | % |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: END OF STUDY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B3. **Platelet Count:** At least one test done today? Yes.....1 No .....2 **(B4)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units |
|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 5. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |
| 6. | ___ ___ : ___ ___ | ___ ___ ___ | x $10^3/\mu L$ |

B4. **Lymphocytotoxic Antibody Screen:** Was an LCA test done today? Yes.....1 No .....2 **(B5)**

| | a. Date Collected | b. Time Collected *24-hour clock* | c. Value | d. Units |
|---|---|---|---|---|
| 1. | __ __ / __ __ / __ __ __ __ | ___ ___ : ___ ___ | ___ ___ ___ | %* |

*Percent panel reactivity

B5. **PT/INR:** At least one test done today?

*You must report both PT and INR values for each test.* Yes.....1 No .....2 **(B6)**

| | a. Time Collected *24-hour clock* | b. PT Value (sec) | c. INR Value | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central.....1<br>Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central.....1<br>Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central.....1<br>Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ ___ | ___ • ___ ___ | Central.....1<br>Peripheral.....2 |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: END OF STUDY LABORATORY TESTS (cont.)**
*Record all values obtained each calendar day as part of routine care*

B6. **PTT:** At least one test done today? Yes.....1 No.....2 **(B7)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ • ___ | sec | Central.....1 Peripheral.....2 |

B7. **Fibrinogen:** At least one test done today? Yes.....1 No.....2 **(C1)**

| | a. Time Collected *24-hour clock* | b. Value | c. Units | d. Site Sample Obtained From: |
|---|---|---|---|---|
| 1. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 2. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 3. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |
| 4. | ___ ___ : ___ ___ | ___ ___ ___ ___ | mg/dL | Central.....1 Peripheral.....2 |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P025 QxQ – End of Study Laboratory Form

Version A: 12/01/2003

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**Purpose of this form:** The purpose of this form is to document a patient's end of study laboratory results.

**When to complete this form:** This form is completed on the last day the patient is in the study. The required end of study labs must be drawn the morning of the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient.

## SECTION B: END OF STUDY LABORATORY TESTS

**It is important that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.**

B1a – B7c. Hemoglobin, hematocrit, morning platelet count and Lymphocytotoxic antibody screen (LCA) are required at the end of study. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done at the end of the study (on the last day the patient is in the study) as part of the patient's standard care must be reported. Space has been provided to record 3 results for each lab (except LCA). If the patient has a particular lab done more than 3 times during the last day on study, complete a second Form P025 with these additional results, and fax the form to the DCC.

Each question consists of 5 parts (columns 1, 2, 3, 4, and 5).

- Column 1: Indicate if the test was done on the date recorded in question A5. If the lab was not done, answer 'No' by circling the number 2, and skip to the next lab test. **Note**: On data entry, you must provide an override reason why a required test was not done.
- Column 2: Record the time the specimen was collected.
- Column 3: Record the lab value.
- Column 4: **For PT/INR only**: circle the number that corresponds to the correct units: sec or INR.
- Column 5: **For PT/INR, PTT and Fibrinogen**: circle the number that corresponds to the correct site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P025 QxQ – End of Study Laboratory Form

Version B: 08/18/2004

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**Purpose of this form:** The purpose of this form is to document a patient's end of study laboratory results.

**When to complete this form:** This form is completed on the last day the patient is in the study. The required end of study labs must be drawn the morning of the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient for these labs.

## SECTION B: DAILY LABORATORY TESTS

### It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.

Hemoglobin, hematocrit, morning platelet count and Lymphocytotoxic antibody screen (LCA) are required at the end of study. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done at the end of the study (on the last day the patient is in the study) as part of the patient's standard care must be reported. This version of Form P025 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

B1. Indicate if there was at least one Hemoglobin test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B2. Indicate if there was at least one Hematocrit test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B3. Indicate if there was at least one Platelet Count done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the time the specimen was collected.
b: Record the lab value.

B4. Indicate if there was a Lymphocytotoxic Antibody Screen test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following:

a: Record the date the specimen was collected.
b. Record the time the specimen was collected.
c: Record the lab value.

B5. Indicate if there was at least one PT/INR test done today. If yes, complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
c: Circle the number that corresponds to the correct units: sec or INR.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there was at least one PTT test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there was at least one Fibrinogen test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Platelet Dose Trial

# Form P025 QxQ – End of Study Laboratory Form

Version C: 12/10/2004

**Purpose of this form:** The purpose of this form is to document a patient's end of study laboratory results.

**When to complete this form:** This form is completed on the last day the patient is in the study. The required end of study labs must be drawn the morning of the patient's last day on the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

A5. Enter the date the blood was drawn (collected) from the patient for these labs.

## SECTION B: DAILY LABORATORY TESTS

### It is required that the laboratory measurements recorded on this form are in the units that have been pre-printed on the form.

Hemoglobin, hematocrit, morning platelet count and Lymphocytotoxic antibody screen (LCA) are required at the end of study. These required tests (rows) are highlighted in gray. In addition, the results of **all** hemoglobin, hematocrit, platelet count, PT/INR, PTT, fibrinogen and Lymphocytotoxic antibody screens (LCA) done at the end of the study (on the last day the patient is in the study) as part of the patient's standard care must be reported. This version of Form P025 allows an unlimited number of test results for these labs done each day (except LCA) to be reported on one electronic case report form.

B1. Indicate if there was at least one Hemoglobin test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B2. Indicate if there was at least one Hematocrit test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.

B3. Indicate if there was at least one Platelet Count done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following for each platelet count:

a: Record the time the specimen was collected.
b: Record the lab value.

B4. Indicate if there was a Lymphocytotoxic Antibody Screen test done today. If the answer is No (2) you must provide a reason a required end of study test was not done when completing data entry of the form. If Yes (1) complete the following:

a: Record the date the specimen was collected.
b. Record the time the specimen was collected.
c: Record the lab value.

B5. Indicate if there was at least one PT/INR test done today. If yes, complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the PT value (sec).
c: Record the INR value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B6. Indicate if there was at least one PTT test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

B7. Indicate if there was at least one Fibrinogen test done today. If Yes (1) complete the following for each test result:

a: Record the time the specimen was collected.
b: Record the lab value.
d: Circle the number that corresponds to the site where the sample was obtained – central or peripheral. If unknown, write in **–8**.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P026 – End of Study Report** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __ A2. Event: End of study..... PEOS

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y) A4. Initials of person completing form: __ __ __

**Section B: END OF STUDY REPORT**

B1. Primary reason for end of study: ***(please circle one)***

Patient (or guardian) decision to withdraw.....01

Physician decision to withdraw patient .....02

No platelet transfusion for 10 days after last transfusion.....03

30 days after first transfusion.....04

Patient discharged from hospital.....05

Patient randomized, never received transfusion, 30 days post randomization.....06

Study terminated early.....07

Death .....08

Other.....99 **(B1a)**

B1a. Specify other_____

B2. Study end date : __ __ / __ __ / __ __ __ __

B3. Comment: _____

_____

_____

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P026 QxQ – End of Study Report

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document that a patient has reached the end of the study, and to identify the primary reason for the end of study.

**When to complete this form:** This form is completed when the patient reaches the end of study for one of the reasons listed in section B. This form is to be completed for every patient randomized into the study.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: END OF STUDY REPORT

B1. Indicate the primary reason the patient's participation in the study has ended by circling one number:

- **01:** The patient (or their guardian) withdrew themselves from the study, no longer wanted study staff to evaluate their medical status, collect data, and/or no longer agreed to receive the platelet dose to which they were randomized.
- **02:** The patient's physician withdrew the patient from the study
- **03:** The patient has not had a platelet transfusion for 10 days since their last platelet transfusion
- **04:** 30 days have elapsed since the patient's first platelet transfusion
- **05:** Patient discharged from the hospital
- **06:** Patient randomized, never received transfusion, 30 days post randomization
- **07:** Study terminated early
- **08:** Patient died while on study
- **99:** Patient has reached the end of study for an "other" reason. Specify reason in question B1a.

B2. Record the date of the last day the patient was in the study.

B3. If applicable, provide an additional comment to explain the reason the patient's participation in the study has ended. If available, please provide the reason the patient (or guardian) or patient's physician decided to withdraw the patient from the study. If there is no comment, enter a **–1** (N/A)

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P027 – Transfusion Checklist**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: End of study..... PEOS

A3. Date randomized: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. End of study date: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

| B1. Date on Study | B2. Platelets | | B3.Granulocytes | | B4. Red Cells | | B5. Other | |
|---|---|---|---|---|---|---|---|---|
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |
| | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ | Yes$_1$ | No$_2$ |

Platelet Dose Trial

# Form P027 QxQ – Transfusion Checklist

Version A: 12/01/2003

---

**Purpose of this form:** The purpose of this form is to report if a patient received a type of transfusion each day they were enrolled in the study.

**When to complete this form:** This form is a log to be completed each day while a patient is in the study. If the patient is in the study for more than 23 days, staple an additional copy of Form P027 to the original, and continue recording the days on the additional copy. The form(s) must be completed and sent to the Data Coordinating Center for data entry when the patient reaches the end of study. Data entry of this form will only occur at the Data Coordinating Center.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the patient was randomized.

A4. Record the date the patient reached the end of study.

## SECTION B: CHECKLIST

B1. Write in the dates for each day the patient is on study. The first date is the day they are randomized (A3). The last date is the day the patient reaches the end of study (A4).

B2. Indicate if the patient received at least one platelet transfusion on the date in B1.

B3. Indicate if the patient received at least one granulocyte transfusion on the date in B1.

B4. Indicate if the patient received at least one red cell transfusion on the date in B1.

B5. Indicate if the patient received at least one other transfusion on the date in B1.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P071 – Urine Hemoglobin Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline.....PBSL
Daily Urine Hemoglobin.....PURH

A3. Date form completed: __ __/ __ __/ __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: URINE HEMOGLOBIN RESULTS**

B1. Date of urine specimens __ __/ __ __/ __ __ __ __

B2. Was there at least one urine specimen today? Yes.....1 No.....2 **(C1)**

B3. Was there at least one urine specimen tested today? Yes.....1 No.....2 **(C1)**

| Number | B4. Time of Specimen *(24 hour clock)* | B5. Result *(see codes below)* | B6. RBC Number *(complete only if result code=90)* |
|---|---|---|---|
| 1 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 2 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 3 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 4 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 5 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 6 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 7 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |
| 8 | ___ ___ : ___ ___ | ____ ____ | ___ ___ ___ ___ ___ ___ / HPF |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**URINE HEMOGLOBIN RESULT CODES**

**00** = Negative or None
**10** = Positive (no amount specified)
**20** = Trace
**30** = 1+ / Small
**40** = 2+ / Moderate
**50** = 3+ / Large / Gross
**90** = Specimen tested by lab, RBC result obtained

Platelet Dose Trial

# Form P071 QxQ – Urine Hemoglobin Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document all of a patient's urine hemoglobin results during one calendar day the patient is in the study.

**When to complete this form:** This form is completed at baseline (the day the patient is randomized) and every day the patient remains in the study once they are randomized. This form should be completed daily even if the tests are not performed. One test per day is required. However, all urine hemoglobin tests performed on a patient must be reported (i.e. if they have more than one urine tested a day, submit the results of all tests).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. This form is filled out at baseline, and every day that the patient remains in the study once they are randomized. Circle PBSL to indicate the baseline test. Circle PURH to indicate it is a daily urine hemoglobin.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: URINE HEMOGLOBIN RESULTS

B1. Record the date of urine specimens.

B2. Indicate if the patient produced at least one urine specimen today. If No (2), skip to question C1.

B3. Indicate if at least one urine specimen was tested today. If No (2), skip to question C1.

B4 – B6. For each urine specimen tested, record the time of the specimen and the test result. To record the result of the test, write in **one** number from the list of Urine Hemoglobin Result Codes at the bottom of the form that best matches the result of the test. If the specimen was tested by a laboratory, and not a urine dipstick test, record the result as code **90**, and enter the number of red cells in question B6.

**00**: Negative or None
**10**: Positive (no amount specified)
**20**: Trace
**30**: 1+ / Small
**40**: 2+ / Moderate
**50**: 3+ / Large / Gross
**90**: Specimen tested by lab, RBC result obtained

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

TMH-01

**Form P072 – Stool Guaiac Form**

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __ -- __ __ __ __ -- __ __ __ -- __

A2. Event: Baseline.....PBSL
Daily Stool Guaiac....PSTG

A3. Date form completed: __ __/ __ __/ __ __ __ __

A4. Initials of person completing form: ___ ___ ___

**Section B: STOOL GUAIAC RESULTS**

B1. Date of stool specimens __ __/ __ __/ __ __ __ __

B2. Was there at least one stool specimen today? Yes.....1 No.....2 **(C1)**

B3. Was there at least one stool specimen tested today? Yes.....1 No.....2 **(C1)**

| Number | B4. Time of Specimen *(24 hour clock)* | B5. Result *(see codes below)* | |
|---|---|---|---|
| 1 | ___ ___ : ___ ___ | ____ ____ | |
| 2 | ___ ___ : ___ ___ | ____ ____ | |
| 3 | ___ ___ : ___ ___ | ____ ____ | |
| 4 | ___ ___ : ___ ___ | ____ ____ | |
| 5 | ___ ___ : ___ ___ | ____ ____ | |
| 6 | ___ ___ : ___ ___ | ____ ____ | |
| 7 | ___ ___ : ___ ___ | ____ ____ | |
| 8 | ___ ___ : ___ ___ | ____ ____ | |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**STOOL GUAIAC RESULT CODES**

**00** = Negative

**10** = Positive

Platelet Dose Trial

# Form P072 QxQ – Stool Guaiac Form

Version A: 12/01/2003

---

**Purpose of this form:** The purpose of this form is to document all of a patient's stool guaiac results during one calendar day the patient is in the study.

**When to complete this form:** This form is completed at baseline (the day the patient is randomized) and every day the patient remains in the study once they are randomized. This form should be completed daily even if the tests are not performed. One test per day is required. However, all stool guaiac tests performed on a patient must be reported (i.e. if they have more than one stool sample tested a day, submit the results of all tests).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. This form is filled out at baseline, and every day that the patient remains in the study once they are randomized. Circle PBSL to indicate baseline. Circle PSTG to indicate daily stool guaiac.

A3. Enter the date the form was completed.

A4. Enter the initials of the person completing the form.

## SECTION B: STOOL GUAIAC RESULTS

B1. Record the date of stool specimens.

B2. Indicate if the patient produced at least one stool specimen today. If No (2), skip to question C1.

B3. Indicate if at least one stool specimen was tested today. If No (2), skip to question C1.

B4 – B5. For each stool sample tested, record the time of specimen and the result. To record the result of the test, write in a code number from the list of Stool Guaiac Result Codes at the bottom of the form:

**00**: Negative
**10**: Positive

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P085 – Serious Adverse Event Report** TMH-01

**SECTION A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __ A2. Event: Adverse Event ..... (PADV)

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y) A4. Initials of person completing form: ___ ___ ___

***REPORTING INSTRUCTIONS: All serious adverse events must be documented using this form. The Principal Investigator (or designee in their absence) must notify the DCC of the event by telephone or e-mail within 24 hours and fax the form to the DCC within 48 hours. A separate form must be used to report each serious adverse event.***

**Section B: SERIOUS ADVERSE EVENT DESCRIPTION**

B1. Event number: ___ ___

B2. Type of Report:

Initial .....1

Follow-up .....2

B3. Event code (**circle one**):

Transient ischemic attack.....01

Myocardial infarction .....02

Stroke.....03

Graft-versus-Host disease.....04

Venocclusive disease of the liver .....05

Seizure .....06

TRALI .....07

Death.....08➔➔➔ **SKIP TO QUESTION B5**

Other .....99➔➔➔ B3a. Specify _____

B4. Date serious adverse event began: __ __ / __ __ / __ __ __ __

B5. Did the adverse event result in any of the following: *(**answer all questions**)*

| | | | |
|---|---|---|---|
| a. Death | Yes..... 1 | No..... 2 | |
| b. Life-threatening event | Yes..... 1 | No..... 2 | |
| c. Hospitalization or prolongation of existing hospitalization | Yes..... 1 | No..... 2 | |
| d. Congenital anomaly/birth defect | Yes..... 1 | No..... 2 | |
| e. Persistent significant disability/incapacity | Yes..... 1 | No..... 2 | |

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section B: SERIOUS ADVERSE EVENT DESCRIPTION (cont.)**

B6. Relationship of adverse event to:

| | Unrelated | Unlikely | Possible | Probable | Definite |
|---|---|---|---|---|---|
| a. Transfusion | 1 | 2 | 3 | 4 | 5 |
| b. Underlying disease | 1 | 2 | 3 | 4 | 5 |
| c. Bleeding | 1 | 2 | 3 | 4 | 5 |

B7. Event Status:

Resolved, no sequelae ..... 1 **(B9)**

Resolved with sequelae..... 2 **(B9)**

Continuing..... 3 **(B10)**

Disability ..... 4 **(B10)**

Death ..... 5 **(B8)**

Unknown at this time..... 6 **(B10)**

B8. Date of death: __ __ / __ __ / __ __ __ __ **(B10)**

B9. Date serious adverse event resolved: __ __ / __ __ / __ __ __ __

B10. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.

_____

_____

_____

_____

_____

_____

*Principal Investigator (or designated Co-Investigator) must approve form.*

**Section C: SIGNATURE**

C1. Approved by PI or Co-Investigator: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Platelet Dose Trial

# Form P085 QxQ – Serious Adverse Event Report

Version A: 12/01/2003

**Purpose of this form:** The Serious Adverse Event form is used to record information on all Serious Adverse Events.

**Reporting Procedures / When to complete this form:** This form must be completed for events that occur while the patient is part of the Platelet Dose Trial. A serious adverse event must be reported to the Data Coordinating Center via telephone or email within 24 hours and via fax within 48 hours of learning of the event using whatever information is available.

The first time that information about the event is reported, question B2 must be coded as 1 (Initial). Complete information about its relationship to the study, hospitalization, serious adverse event outcome, or actions taken to treat the serious adverse event may not be available for some time. Each time an update to the serious adverse event is submitted, question B2 must be coded as 2 (Follow-up).

**Definitions: Adverse Event**: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure regardless of whether or not it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable, or definite).

A **serious adverse event** is any untoward medical occurrence that:

- Results in death,
- Is life-threatening (there is a risk of death at the time of the event),
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, OR
- Results in a congenital anomaly / birth defect.

**Relationship to Transfusion Related Events Form (P012):** If the patient experiences a Grade 4 transfusion related event during or within 4 hours following a transfusion as reported on Form P012, it must be reported on the Serious Adverse Event Form (P085).

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: SERIOUS ADVERSE EVENT (SAE) DESCRIPTION

B1. Enter the event number: Number each **new** SAE the patient experiences sequentially.

B2. Circle 1 if this is the initial reporting of the adverse event. Circle 2 if this is a follow up report (i.e. an initial report has already been filed)

B3. Circle one event code from the list provided. If code 99 (Other) is circled, specify the event in the space provided in question B3a

B4. Enter the date the SAE began or occurred.

B5a-e. Indicate if the SAE resulted in any of the events listed by answering all questions Yes or No.

B6a-c. Circle the code describing the relationship of the adverse event to the **transfusion** (B6a), **underlying disease** (B6b) and **bleeding** (B6c).

Circle code **1** (unrelated) for B6a if the patient did not have a transfusion, or for B6c if the patient did not have any bleeding.

**Adverse Event Relationship Definitions**

1. **Unrelated:** The adverse event is **clearly NOT related** to the study drug/device/treatment(s).
2. **Unlikely:** The adverse event is **doubtfully related** to the study drug/device/treatment(s).
3. **Possible:** The adverse event **may be related** to the study drug/device/treatment(s).
4. **Probable:** The adverse event is **likely related** to the study drug/device/treatment(s).
5. **Definite:** The adverse event is **clearly related** to the study drug/device/treatment(s).

B7. Using the definitions below, choose one event status for this adverse event.
If choosing “resolved, no sequelae” or “resolved with sequelae”, skip to question **B9**
If choosing “continuing”, “disability” or “unknown”, skip to **B10**
If choosing “death”, proceed to question **B8**.

**Adverse Event Outcome Definitions**

1. **Resolved, no sequelae:** After the adverse event ends, the patient returns to pre-adverse event status.
2. **Resolved with sequelae:** After the adverse event ends, the patient does not return to pre-adverse event status.
3. **Continuing:** The adverse event is still ongoing at the time of the report.
4. **Disability:** An adverse event that has caused a substantial disruption of the person’s ability to conduct normal life functions.
5. **Death:** The patient dies as a result of the adverse event, or the event was death.
6. **Unknown at this time:** Sufficient information is not available to determine a final event status.

B8. Enter the date of death and then skip to question **B10**.

B9. Enter the date the serious adverse event was resolved.

B10. Provide a brief description of the clinical presentation, treatment (including medications and other therapies or procedures that were initiated to treat this condition), evolution of the event and any other assessments that help explain the event. If the outcome of the SAE was death, write the cause of death.

## SECTION C: SIGNATURE

The Principal Investigator or their designated Co-Investigator must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

## SOURCE DOCUMENTS AND MAILING INFORMATION:

If this is the first time that the SAE is being reported (B2 = 1), then this form must be completed and faxed to the DCC within 48 hours. Send copies of all relevant source documents as soon as they become available. Black out all identifying patient information, such as name and medical record number, and replace with the Platelet Dose Trial ID number.

When additional source documents and information about this SAE are obtained, complete a new Form P085, indicate in question B2 that it is a follow-up report, and submit it to the DCC with the additional relevant source documents.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P089 – Serious Adverse Event Review** TMH-01

**SECTION A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Adverse Event.....(PADV)

A3. Date of review: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of reviewer: ___ ___ ___

**Section B: SERIOUS ADVERSE EVENT REVIEW**

B1. Event number: ___ ___

B2. Type of Report:

Initial.....1

Follow-up.....2

B3. Event code as reported on P085 (**circle one**):

Transient ischemic attack.....01

Myocardial infarction.....02

Stroke.....03

Graft-versus-Host disease.....04

Veno-Occlusive disease of the liver.....05

Seizure.....06

TRALI.....07

Death.....08

Other.....99➔➔➔ B3a. Specify _____

B4. Date Form P085 completed: __ __ / __ __ / __ __ __ __

B5. Did SAE meet criteria for review by second Medical Monitor? Yes..... 1 No.....2 **(B6)**

B5a. Did second Medical Monitor review this SAE? Yes..... 1 No.....2

B5b. Was SAE reported to NHLBI promptly? Yes..... 1 No.....2 **(B6)**

B5c. Date SAE reported to NHLBI: __ __ / __ __ / __ __ __ __

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

B6. Do you agree with site's designation of relationship of SAE to transfusion, underlying disease and bleeding? Yes ..... 1**(B8)** No ..... 2

B7. If you do not agree, indicate relationship of adverse event to:

| | Unrelated | Unlikely | Possible | Probable | Definite |
|---|---|---|---|---|---|
| a. Transfusion | 1 | 2 | 3 | 4 | 5 |
| b. Underlying disease | 1 | 2 | 3 | 4 | 5 |
| c. Bleeding | 1 | 2 | 3 | 4 | 5 |

B8. Comment:

_____

_____

_____

_____

**Section C: SIGNATURE**

C1. Medical Monitor: Initials: ____ ____ ____

C2. Date signed: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P090 – Disclosure of Treatment Arm** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Miscellaneous.....PMSC

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: ___ ___ ___

**Section B: DISCLOSURE OF TREATMENT ARM**

B1. Who was told treatment arm?

| | Yes | No |
|---|---|---|
| a. Patient | 1 | 2 |
| b. Treating physician | 1 | 2 |
| c. Site staff | 1 | 2 |

B2. Reason for disclosure of treatment arm:

Patient request.....01

Physician request.....02

Error .....03

Other .....99➔➔➔ B2a. Specify: _____

B3. Provide a brief description of how and/or why the disclosure occurred and include the initials of the site staff that were told the treatment arm.

_____

_____

_____

B4. Date of disclosure: __ __ / __ __ / __ __ __ __

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

# Form P090 QxQ – Disclosure of Treatment Arm

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document when and how patients and/or study staff were told the patient's treatment group assignment.

**When to complete this form:** This form may be completed anytime after randomization. It must be completed as soon as study staff are made aware that a patient and/or staff member was told the patient's treatment group assignment.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: DISCLOSURE OF TREATMENT ARM

B1a-c. Complete each question. Circle Yes (1) if the individual listed was told the patient's treatment arm and No (2) if they were not.

B2 – B2a. Circle the number that best describes the reason the individual(s) was told the patient's treatment arm. Circle only one number. If 99 (other), indicate the reason in the space provided in question B2a.

B3. Provide a brief description of how and or why the disclosure occurred. Include the initials of the site staff that were told the patient's treatment arm.

B4. Enter the date the disclosure occurred.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P091 – Protocol Violation/Unusual Event Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Miscellaneous.....PMSC

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: ___ ___ ___

**Section B: PROTOCOL VIOLATION/ UNUSUAL EVENT**

B1. Describe Unusual Event or Protocol Violation:

_____

_____

_____

_____

_____

B1a. Code ____ ____ ____ ***DCC use only***

B2. Describe action taken (if any):

_____

_____

_____

B2a. Code ____ ____ ____ ***DCC use only***

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P091 – Protocol Violation/Unusual Event Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Event: Miscellaneous .....PMSC

A3. Date form completed: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

A4. Initials of person completing form: ___ ___ ___

**Section B: PROTOCOL VIOLATION/ UNUSUAL EVENT**

B1. Reporting a trigger change for prophylactic platelet transfusions? Yes .....1 No.....2 **(B2)**

B1a. Date of trigger change: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

B1b. Time of trigger change: ___ ___ : ___ ___ *24-hour clock*

B1c. Trigger changed to: ____ ____ ____ x $10^3$ /µL

B2. Reporting a dose change for prophylactic platelet transfusions? Yes .....1 No.....2 **(B3)**

B2a. Type of dose change ***(circle one)***

One-time request for non-study dose.....1 **(B2b)**

Non-study dose ordered until further notice .....2 **(B2b)**

Study dose resumed.....3 **(B2b)**

Non-study dose given to patient due to error .....4 **(B2b)**

Other .....99 **(B2a1)**

B2a1. Specify: _____

B2b. Date of dose change: __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

B2c. Time of dose change: ___ ___ : ___ ___ *24-hour clock*

B3. Reporting any other Unusual Event or Protocol Violation? Yes .....1 No.....2

***Continued on Next Page***

__ __ -- __ __ __ __ -- __ __ __ -- __

**Section C: DESCRIPTION**

C1. Describe Unusual Event(s) or Protocol Violation(s) and any action taken:

_____

_____

_____

_____

_____

_____

C1a. Code ____ ____ ____ ***DCC use only***

C1b. Code ____ ____ ____ ***DCC use only***

C1c. Code ____ ____ ____ ***DCC use only***

**Section D: SIGNATURE**

D1. Approved by PI or designee: Initials: ____ ____ ____

D2. Date approved: __ __ / __ __ / __ __ __ __

# Form P091 QxQ – Protocol Violation / Unusual Event Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document any protocol violation or unusual event.

**When to complete this form:** This form may be completed anytime during the study. It must be completed as soon as study staff are made aware that a protocol violation or unusual event has occurred.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: PROTOCOL VIOLATION / UNUSUAL EVENT

B1. Describe the unusual event or protocol violation.

B1a. The DCC will complete this question. If data entry occurs at the site, enter a –1 for this question.

B2. Describe what action was taken as a result of the protocol violation or unusual event.

B2a. The DCC will complete this question. If data entry occurs at the site, enter a –1 for this question.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

# Form P091 QxQ – Protocol Violation / Unusual Event Form

Version B: 04/11/2005

**Purpose of this form:** The purpose of this form is to document any protocol violation or unusual event.

**When to complete this form:** This form may be completed anytime during the study. It must be completed as soon as study staff are made aware that a protocol violation or unusual event has occurred.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: PROTOCOL VIOLATION / UNUSUAL EVENT

B1. Indicate whether or not you are reporting a trigger change for a prophylactic platelet transfusion. If no, skip to question B2.

B1a. Indicate the date that the trigger change was ordered.

B1b. Indicate the time that the trigger change was ordered. If you do not know what time it was ordered please data enter this field as -9 (Missing).

B1c. Indicate what the trigger was changed to for all prophylactic platelet transfusions.

B2. Indicate whether or not you are reporting a dose change for prophylactic platelet transfusions. If no, skip to question B3.

B2a. Circle the type of dose change that was ordered. You may only choose one answer. If you answer 1 (One time request for non-study dose), 2 (Non-study dose ordered until further notice), 3 (Study dose resumed), or 4 (Non-study dose given to patient due to error) skip to question B2b. If you choose 99 (Other), specify the type of dose change in the space provided.

B2b. Indicate the date that the dose change was ordered.

B2c. Indicate the time that the dose change was ordered. If you do not know what time it was changed please data enter this field as -9 (Missing).

B3. Indicate if you are reporting any other unusual events or protocol violations. If yes, you must provide an explanation of the event in question C1.

## SECTION C: DESCRIPTION

C1. Describe any unusual events or protocol violations as well as any action taken in this section in regard to the events reported on the form. If question B3 is answered as yes, then you must write a brief description of the unusual event or protocol violation.

C1a. The DCC will complete this question. If data entry occurs at the site, enter a –1 for this question.

C1b. The DCC will complete this question. If data entry occurs at the site, enter a –1 for this question.

C1c. The DCC will complete this question. If data entry occurs at the site, enter a –1 for this question.

## SECTION D: SIGNATURE

The Principal Investigator or their designee must approve the form.

D1. Enter the initials of the person approving the form.

D2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Platelet Dose Trial

**Form P099– Missing Daily and End of Study Information Form** TMH-01

**Section A: GENERAL INFORMATION**

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __ A2. Event: Miscellaneous ..... (PMSC)

A3. Date form completed: __ __ / __ __ / __ __ __ __ A4. Initials of person completing form: ___ ___ ___

**Section B: MISSING INFORMATION**

B1. Date form missing / not completed: __ __ / __ __ / __ __ __ __

| Data Collection Form: | | | a. Missed? Yes | a. Missed? No | b. Reason code | c. Specify reason if 99 (Other) coded |
|---|---|---|---|---|---|---|
| B2. | Form P006 | Hem.Assess | 1 | 2 | ___ ___ | _____ |
| B3. | Form P071: | Urine Hb | 1 | 2 | ___ ___ | _____ |
| B4. | Form P072 | Stool Guaiac | 1 | 2 | ___ ___ | _____ |
| B5. | Form P008: | Transf Platelets | 1 | 2 | ___ ___ | _____ |
| B6. | Form P009 | Transf Admin | 1 | 2 | ___ ___ | _____ |
| B7. | Form P010: | Red Cell Log | 1 | 2 | ___ ___ | _____ |
| B8. | Form P011 | Other Product | 1 | 2 | ___ ___ | _____ |
| B9. | Form P012: | Transf Event | 1 | 2 | ___ ___ | _____ |
| B10 | Form P015 | Daily Labs | 1 | 2 | ___ ___ | _____ |
| B11. | Form P025: | End Study Labs | 1 | 2 | ___ ___ | _____ |
| B12 | Form P026 | End Study Rpt | 1 | 2 | ___ ___ | _____ |

**Section C: SIGNATURE**

C1. Approved by PI or designee: Initials: ____ ____ ____

C2. Date approved: __ __ / __ __ / __ __ __ __

**REASON FORM MISSING CODES**

**01** = Patient not available for evaluation

**02** = Patient refused to complete measure

**03** = Lab problem / error

**04** = Staff not available to complete measure

**99** = Other reason, specify

# Form P099 QxQ – Missing Daily and End of Study Information Form

Version A: 12/01/2003

**Purpose of this form:** The purpose of this form is to document that a daily or end of study case report form was not completed, and is confirmed missing (will never be completed).

**When to complete this form:** This form is completed at the any point while the patient is in the study (after randomization) if a daily or end of study case report form listed is missed.

- A case report form is considered missing when required data was not collected during the time the patient was in the study.
- A case report form is only considered missing for the reasons coded at the bottom of the form (patient not available, patient refuses to allow data collection, lab error, staff not available, other).
- A case report form is not "missing" if there was no event on a given day that would result in a form being completed by the staff.
    - For example, if the patient did not have a transfusion during day 4, we would not expect forms P008 and P009.
- A case report form is not "missing" if an evaluation was done, but no results were obtained.
    - For example, if a research nurse establishes that a patient does not have a stool specimen on day 6, this information should be captured on a Form P072.

## SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided. If the label is not available, record the patient number legibly.

A2. The response is pre-circled on the form; there is no need to circle anything.

A3. Record the date the form was completed by a Platelet Dose Trial staff member.

A4. Enter the initials of the person completing the form.

## SECTION B: MISSING INFORMATION

B1. Enter the date the form is missing, i.e. the date the data should have been collected, but was missed.

B2 – B12 For questions B2 through B12, indicate if the form was missed by circling 1 (Yes) or 2 (No) for each question. If the form was missed, identify the reason the form was missed by writing in a Reason Code from the list at the bottom of the page. If you choose the code 99 (other), write in the reason on the line provided.

## SECTION C: SIGNATURE

The Principal Investigator or their designee must approve the form.

C1. Enter the initials of the person approving the form.

C2. Record the date the form was approved.

Transfusion Medicine/Hemostasis Clinical Trials Network

Site Management

# Form SP02 – Platelet QC Data Form

**Section A: GENERAL INFORMATION**

A1. Site ID: ____ ____ ____ ____

A2. Site Name: _____

**Section B: QUALITY CONTROL DATA**

B1. Will your site use whole blood derived platelets? Yes ..... 1 No .....2 **(End)**

Please provide the following information. This form must be updated every time new or updated QC data is obtained and used to determine the dose of whole blood derived platelets.

| | B2a-b. Mean | B2c. Start Date QC Data Used | B2d.Staff Initials | Reported to DCC |
|---|---|---|---|---|
| 1. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 2. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 3. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 4. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 5. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 6. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 7. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 8. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 9. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 10. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 11. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |
| 12. | ___ ___ ___ . ___ ___ x 10 — — | __ __ / __ __ / __ __ __ __ | ___ ___ ___ | ☐ |

Transfusion Medicine/Hemostasis Clinical Trials Network

# Form SP02 QxQ – Platelet QC Data Form

Version A: 03/12/2004

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**Purpose of this form:** The purpose of this form is to collect the quality control (QC) data that sites will use to prepare a dose of whole blood derived platelets.

**When to complete this form:** This form is completed at the start of a site's participation in the Platelet Dose study, and is updated each time the site receives new platelet QC data.

## Section A: General Information

A1: Affix the Site ID label in the space provided. If the label is not available, record the Site ID number legibly.

A2: Record the name of the site.

## Section B: Quality Control Data

B1. Indicate if your site will use whole blood derived platelets for the Platelet Dose Trial. If no (2), the form is complete, and no further information is required.

At the beginning of the study, and each time your site receives new platelet QC data, a new row must be completed, and the form must be faxed to the DCC. If all rows are completed, start a new form SP02 and continue to record the platelet QC data.

B2a-b: The QC mean. Be sure to write in the appropriate exponent.

B2c: Indicate the date your site started to use this platelet QC mean to prepare doses of whole blood derived platelets.

B2d: Write in the initials of the person completing this row.

Use the check box to indicate that the form has been faxed to the DCC once the row was completed.

Transfusion Medicine/Hemostasis Clinical Trials Network

Site Management

# Form SP03 – "Morning" Platelet Count Form

**Section A: GENERAL INFORMATION**

A1. Site ID: ____ ____ ____ ____

A2. Site Name: _____

**Section B: DEFINING MORNING PLATELET COUNTS**

B1. Identify the time at which your site's "day" starts for obtaining a morning platelet count and deciding whether to give a prophylactic platelet transfusion. *Note: The first platelet count obtained at or after the time identified in B1 will be considered the morning platelet count for each 24 hour period (unless modified per B2).*

___ ___ : ___ ___
*24-hour clock*

B2. If the first count obtained at or after the time identified in B1 is the post-transfusion count for a prior transfusion, should we also consider it to be the morning count for that day? *Note: If an additional platelet count would be obtained and used as the "morning count" answer "No". In that case, the next platelet count obtained that is not a post transfusion count would then be considered the "morning" count.*

Yes .....1 No .....2

B3. Provide effective date for information provided in B1 and B2:

__ __ / __ __ / __ __ __ __
*M M D D Y Y Y Y*

B4. Initials of person providing information:

_____ _____ _____

***Note: Hemostatic assessments must still be done by calendar day, 00:00 to 23:59.***

Transfusion Medicine/Hemostasis Clinical Trials Network

Site Management

# Form SP03 – "Morning" Platelet Count Form

**Section A: GENERAL INFORMATION**

A1. Site ID: ____ ____ ____ ____

A2. Site Name: _____

**Section B: DEFINING MORNING PLATELET COUNTS**

B1. Identify the time at which your site's "day" starts for obtaining a morning platelet count and deciding whether to give a prophylactic platelet transfusion. *Note: The first platelet count obtained at or after the time identified in B1 will be considered the morning platelet count for each 24 hour period (unless modified per B2).*

___ ___ : ___ ___
*24-hour clock*

B2. If the first count obtained at or after the time identified in B1 is the post-transfusion count for a prior transfusion, should we also consider it to be the morning count for that day? *Note: If an additional platelet count would be obtained and used as the "morning count" answer "No". In that case, the next platelet count obtained that is not a post transfusion count would then be considered the "morning" count.*

Yes .....1 No .....2

B3. Provide effective date for information provided in B1 and B2:

__ __ / __ __ / __ __ __ __
*M M D D Y Y Y Y*

B4. Initials of person providing information:

_____ _____ _____

***Note: Hemostatic assessments must still be done by calendar day, 00:00 to 23:59.***

**Form SP03 QxQ – "Morning" Platelet Count Form**

Version A: 06/23/2005

**Purpose of this form:** The purpose of this form is to identify the time that a "day" will start for obtaining a morning platelet count at each site.

**When to complete this form:** This form is completed at the start of a site's participation in the Platelet Dose study, and a new form is to be submitted each time the start time changes.

**Section A: General Information**

A1: Record the Site ID number legibly.

A2: Record the name of the site.

**Section B: Morning Platelet Count**

B1. Identify the time at which your site's "day" starts for obtaining a morning platelet count and deciding whether to give a prophylactic platelet transfusion. Record the time using a 24-hour clock: 00:00 to 23:59. The first platelet count obtained at or after the time identified in B1 will be considered the morning platelet count for each 24 hour period (unless modified per B2).

B2. Answer Yes (1) if the first count obtained at or after the time identified in B1 will be considered the morning count even if it is the post-transfusion count for a prior transfusion. Answer No (2) if an additional platelet count would be obtained and used as the "morning count". If the answer selected is No (2), the next platelet count obtained that is not a post transfusion count would then be considered the "morning" count.

B3. Provide the effective date for the information provided in B1 and B2.

B4. Provide the initials of the person submitting the information contained on this form.

| Date and Time | Events | Comments / Action |
|---|---|---|
| **Example 1**: Answer for B1 is **03:00** and answer for B2 is **Yes** (24 hour period is 03:00 7/1/2005 to 02:59 7/2/2005) | | |
| 7/1/2005 03:30 | Platelet Count | Morning count (whether or not it is also a post-transfusion count). **Action**: If <= 10K, give a platelet transfusion between now and 02:59 on 7/2/2005. If > 10K, per Protocol no prophylactic platelet transfusion should be given before the next 24-hour period's morning count. |
| **Example 2**: Answer for B1 is **03:00** and answer for B2 is **No** (24 hour period is 03:00 7/1/2005 to 02:59 7/2/2005) | | |
| 6/30/2005 23:45 | Platelet Transfusion Ends | (from previous 24-hour period) |
| 7/1/2005 03:30 | Platelet Count 15K | Post-transfusion count, not considered morning count. Another count must be drawn. |
| 7/1/2005 03:45 | Platelet Count | Morning count. **Action:** If <= 10K, give a platelet transfusion between now and 02:59 on 7/2/2005. If > 10K, per Protocol no prophylactic platelet transfusion should be given before the next 24-hour period's morning count. |
| **Example 3**: Answer for B1 is **03:00** and answer for B2 is **No** (24 hour period is 03:00 7/1/2005 to 02:59 7/2/2005) | | |
| 6/30/2005 23:45 | Platelet Transfusion Ends | (from previous 24-hour period) |
| 7/1/2005 03:30 | Platelet Count 9K | Post-transfusion count, not morning count. |
| 7/1/2005 04:00-04:50 | Platelet Transfusion | Doctor DOES order another platelet transfusion because count did not rise above 10K. |
| 7/1/2005 05:00 | Platelet Count 15K | Post-transfusion count, not morning count. |
| 7/1/2005 05:15 | Platelet Count | Morning count. **Action**: If <= 10K, give a platelet transfusion between now and 02:59 on 7/2/2005. If > 10K, per Protocol no prophylactic platelet transfusion should be given before the next 24-hour period's morning count. |

***NOTE: THIS FORM APPLIES TO LABORATORY DATA ONLY. HEMOSTATIC ASSESSMENTS MUST STILL BE DONE BY CALENDAR DAY, 00:00 TO 23:59.***