ATTACHMENT E

JUSTIFICATION FOR NBCUS QUESTIONS SORTED BY DOMAIN

A. Collection and Processing in the United States:

- Provide accurate national estimates of blood collections in the United States
- Identify important trends in the US blood supply
- Provide comparisons with previous measurements
- Only source of accurate information on the US blood supply

1. Does your institution collect blood from donors?

2. How many collection procedures (and for automated collections, how many products?) were successfully completed by your institution in each of the following categories in 2006?

Manual Whole Blood Collections (# of Procedures)

a. Community (Non directed allogeneic donations)
b. Autologous
c. Directed

Automated Collections (# of Procedures & # of Products)

1) Red Cell Pheresis

a. Allogeneic red cells
b. Autologous red cells
c. Directed red cells
d. Concurrent plasma
e. Concurrent plasma – jumbo

2) Platelet Pheresis

a. Single Donor Platelets
b. Concurrent Plasma
c. Concurrent Plasma –jumbo
d. Concurrent red cells

3) Plasma Pheresis

a. Source
b. Jumbo FFP (>400 ml)
c. FFP

3. In 2006, how many autologous and directed units of red cells and whole blood were crossed over to the community supply?

4. How many units of the following were produced from whole blood?
   a. FFP
   b. Plasma, Frozen within 24 hours
   c. Plasma cryoprecipitate reduced
   d. Jumbo size (> 400 ml)

5. How many units were processed by your institution in each of the following categories in 2006?
   a. Number of whole blood units processed for distribution as whole blood
   b. Number of red cell units processed

6. How many whole blood and red cells units (combined) were released for distribution?

7. Of the following components, how many units were produced by your institution in 2006?
   a. Plasma for further manufacture
   b. Whole blood derived platelets
   c. Apheresis platelets from single collections
   d. Apheresis platelets produced from double collections
   e. Apheresis platelets from triple collections
   f. Cryoprecipitate
   g. Granulocytes

B. Donor Information:

- Accurate data on blood donors by donation status on a national scale
- Help study the impact of deferrals on the US blood supply

1. From how many of the following types of donors did you successfully collect in 2006?
   a. First time allogeneic donors
   b. Repeat allogeneic donors

2. In 2006, how many donors were deferred before donating?

3. In 2006, how many donors were deferred before donating based on their response to the question regarding history of Chagas' disease?

4. How many donations were from repeat allogeneic donors?

C. Track utilization by non-hospital and military installations:

- Provide a complete and accurate picture of blood usage
- Assess its impact on the shrinking margin between supply and demand.

1. Do you issue blood to home transfusion services, free standing surgery centers or other off-site non-hospital transfusion services, such as dialysis centers?

2. If yes, how many units of:
    a. RBCs
    b. Platelets
    c. FFP

3. Do you issue blood for use by military installations?

4. If yes, how many units of:
    a. RBCs
    b. Platelets
    c. FFP
    d. Cryoprecipitate

D. Transfusions - Whole Blood and Red Blood Cells Transfused:

- Provide accurate estimates of WB and RBC transfusions in the United States
- Identify important trends in blood usage in U.S.
- Provide comparisons with previous measurements
- Only source of accurate information on blood usage in U.S.
- First and only national assessment of hospital departmental blood utilization

1. Is your institution directly involved in the transfusion of blood to patients or does it serve as a transfusion service for another institution that transfuses blood?

2. In 2006, how many units of allogeneic whole blood and red cells (WB/RBCs) did your institution transfuse either directly or as a transfusion service for another institution?

Total # of Units Transfused
Total # of Recipients

3. Indicate below the total number of WB/RBC units transfused in each of the following categories and report the number of recipients of these units.

	Directed units transfused to the intended patient	Units transfused to pediatric patients (overlap possible)	Autologous units transfused to autologous donor
a. Number of units			
b. Number of recipients			

4. What percentage of blood usage in your facility goes to the following departments:

a. surgery - general
b orthopedic surgery
c. cardiac surgery
d. trauma/ER
e. oncology
f. transplantation services
g. obstetrics/gynecology
h. pediatrics/ neonatology
i. nephrology/dialysis
j. hematology

5. Indicate below how many irradiated, leukoreduced, and leukofiltered units of each of the following components your institution transfused, either directly or as a transfusion service for another institution in 2006:

	I. Components irradiated ▼	II. Components leukoreduced before or after storage (not at bedside) ▼	III. Components leukofiltered at the bedside ▼
a. WB/RBCs			
b. Whole blood derived platelets			
c. Apheresis platelets			
d. Other blood component units, including pediatric units			

E. Non-Red Blood Cell Components Transfused:

- Provide accurate estimates of non-red blood cell components transfused in the United States
- Identify important trends in component usage in U.S.

- Provide comparisons with previous measurements
- Only source of accurate information on component usage in U.S.
- First and only assessment of hospital utilization of IVIG – a blood derivative frequently in short supply nationally

1. In 2006, how many units of each of the following components did your institution transfuse, either directly or as a transfusion service for another institution?
    a. Whole blood derived platelets (individual concentrates, not pools)
    b. Apheresis platelet packs – full dose ($\geq 3X10^{11}$)
    c. FFP
    d. Plasma, frozen within 24 hours
    e. Jumbo plasma (>400 ml)
    f. Plasma Cryoprecipitate reduced
    g. Pediatric size (100ml) single donor and/or fresh frozen plasma
    h. Cryoprecipitate AHF transfusion
    i. Cryoprecipitate used for fibrin sealant
    j. Granulocyte units

2. What volume of plasma is most commonly transfused during a single transfusion episode at your institution?

3. How many units of IVIG were used by your institution?

4. In 2006, how many therapeutic platelet doses were transfused?
    a. As plateletpheresis products
    b. As whole blood derived platelets

5. If you indicated a quantity above, what is the usual (most common) dosage at your institution of whole blood units from which dose was derived?

F. Blood Utilization Efficiency:

- Data will evaluate the efficiency of delivering appropriate products when needed
- Critical in assessment of availability

1. How many total units of red cells, O positive red cells, and O negative red cells (allogeneic, non-directed) were outdated in 2006?

2. How many units in each of the following categories were outdated in 2006?
    a. Whole blood
    b. Whole blood derived plasma
    c. Apheresis plasma
    d. Whole blood derived platelets
    e. Apheresis platelets

f. Cryoprecipitate
g. Directed units
h. Autologous units

3. How many WB/RBC crossmatch procedures were performed at your facility in 2006 by any method?

4. What percentage of crossmatch procedures performed would you estimate used electronic crossmatch?

5. What percentage of crossmatch procedures would you estimate were performed serologically?

G. Intraoperative Autologous Blood Recovery & Bloodless surgery:

- Such procedures may result in a reduction of the demand for allogeneic blood
- Important to understand how widely such programs are implemented since they impact blood use

1. Does your hospital use intra-operative autologous blood recovery therapies?

2. Does your institution have an established "bloodless" surgery program (with a dedicated coordinator)?

H. Component Modification – Irradiation & Leokoreduction:

- Blood components are irradiated to prevent graft versus host disease in immunosuppressed patients
- Blood components are leukoreduced to remove leukocyte-associated infectious agents and to avoid alloimmunization in transfusion recipients.
- Data will provide comparisons with previous measurements and identify trends
- Data will evaluate move towards universal leukoreduction
- Data will demonstrate where these important processing steps are occurring (blood center vs. hospital)
- Important implications in shaping policy regarding TRALI

1. For each of the following categories, how many units did your institution collect/prepare/modify to achieve <u>pre-storage leukoreduction</u> in 2006?

a. Red cells/whole blood
b. Whole blood derived platelets
c. Apheresis platelets
d. Other component units, including pediatric units

I. Safety:

- Information is needed to monitor data related to safety of the donor population and donated blood and blood components
- Public meeting discussions often come to an impasse because of a lack of quantitative data
- DHHS and FDA require quantitative data to inform their decision making process
- Calculate overall loss due to infectious disease screening
- Research has shown an association between age of PRBC and mortality
- Bacteria is the most common infectious disease agent transmitted by blood
- Presents a greater threat to public health than viruses since viral transmission risk is greatly minimized by improved screening methods
- Platelets are particularly vulnerable because they have to be stored at room temperature

1. What was the total number of allogeneic units (non-directed and directed combined) discarded in 2006 for any abnormal test results?

2. For all tested donations collected by your facility in 2006, indicate the number of repeat reactive and confirmed positive first- time allogeneic donors by infectious disease marker below:

a. Anti-HIV-1/HIV-2
b. Anti-HTLV-I/II
c. Anti-HCV
d. Anti-HBc
e. HBsAg
f. Serological test for Syphilis
g. HIV-1 NAT (antibody negative)
h. HCV NAT (antibody negative)
i. Undifferentiated NAT (if HIV-1 and HCV discriminatory negative when applicable)
j. WNV NAT
k. HBV NAT

3. For all tested donations collected by your facility in 2006, indicate the number of repeat reactive and confirmed positive repeat allogeneic donors by infectious disease marker below:

a. Anti-HIV-1/HIV-2
b. Anti-HTLV-I/II
c. Anti-HCV
d. Anti-HBc
e. HBsAg
f. Serological test for Syphilis
g. HIV-1 NAT (antibody negative)
h. HCV NAT (antibody negative)
i. Undifferentiated NAT (if HIV-1 and HCV discriminatory negative when applicable)
j. WNV NAT
k. HBV NAT

4. What is the average age of a unit transfused at your institution?
   a. Red blood cells
   b. Whole blood derived platelets
   c. 5 Day apheresis platelets
   d. 7 Day apheresis platelets

5. Are diversion devices used when collecting:
   a. Apheresis platelets?
   b. Whole blood?

6. Does your institution perform bacteria testing?

7. Indicate what methods are used by your institution to limit/detect bacterial contamination?

	Culture based method	Swirling	pH	Glucose	Other	None
a. Apheresis Platelets?						
b. WB Derived Platelets, singly?						
c. WB Derived Platelets, pooled?						

6. How many confirmed positives and false positives were detected by method?

Method	Number tested	# Confirmed Positive	# False Positive
a. Culture-based Methods			
b. Alternative Method			

J. Therapeutic Phlebotomy:

- Compares with same question from previous NBCUS surveys
- Provides better understanding of clinical practice
- Allows understanding of where therapeutic phlebotomy is being provided (blood center or hospital) and for what disease classes it is being predominantly used

1. Does your institution perform therapeutic apheresis procedures?

2. How many therapeutic apheresis procedures did you perform for the following indications in 2006:
   a. Thrombotic Thrombocytopenia Purpura (TTP)
   b. Guillain-Barré
   c. Multiple sclerosis
   d. Sickle cell disease
   e. Myasthenia gravis
   f. Hemochromatosis

g. Chronic Inflammatory Demyelinating Plyradiculoneuropathy
h. Goodpasture's syndrome
i. Other

K. Disaster Planning:

- Since 9/11 there have been many changes in approaches to blood safety and supply
- This data will assist in disaster planning and emergency preparedness
- Allows assessment of tissue availability in case of radiation threat

1. At your facility, how many units of group O red cells do you use or ship on an average day?

2. What is the average number of units in your hospital's emergency trauma inventory (O positive and O negative units)?

3. At your facility, what is the maximum number of units of group O positive and group O negative red cells in uncrossmatched inventory considered to be "critically low"?

4. At your facility, what is the minimum number of units of group O positive and group O negative red cells in uncrossmatched inventory considered to be "ideal"?

5. Do you maintain an inventory of human skin?

6. What was your average daily inventory of human skin in 2006?

L. Blood Inventory Shortages:

- Assess shortages
- Understand impact of shortages on scheduling and other direct effects on patients
- Assist in evaluation of BASIS system

1. How many days in 2006 was elective surgery postponed due to actual blood inventory shortages?

2. If any, how many surgeries were postponed?

3. On how many days was your regular or standing order incomplete?

4. On how many days in 2006 were you unable to meet other non-surgical blood requests (e.g. red cells, platelets)?

M. Component Costs:

- Address the critical need for representative and reliable data describing transfusion-related healthcare costs

1. What was the average dollar amount your institution paid per unit in 2006 for the following components:

a. Plasma for transfusion frozen within 24 hours of phlebotomy
b. Red cells, leukofiltered
c. Whole blood derived platelets, not leukoreduced, not irradiated
d. Apheresis platelets platelets, leukoreduced
e. Cryoprecipitate
f. Hematopoietic Progenitor Cells –Apheresis
g. Hematopoietic Progenitor Cells – Marrow
h. Hematopoietic Progenitor Cells – Cord

N. Cellular Therapy Products – Collections & Processing:

- Because of continued interest in hematopoietic transplantation and novel cellular therapies, data on collection, processing, and infusion of different cellular therapy products is critical
- Data will provide comparisons so that trends can be identified
- Identifies product type more clearly. Distinguishes between auto and allo (predicting current practice and trends); more accurately describes reporting data; adds credibility to data as it facilitates user reporting – clarifies definitions.
- In the past, respondents answers did not "make as much sense" as one might think as it was difficult to discern whether reported data was processed in house or shipped or vice versa such as the case might be if one were to collect more than processed or infused, etc. Assists, in companion with question 2, in determining products and for what they are used. Ex. A facility may collect HPC-A for shipment out only but collect and process all HPC-M in house.
- These questions have been reviewed by the CT Committee (composed of experts such as technologists, apheresis staff, laboratory directors, medical directors and transplant physicians within the field of cellular therapy) and determined to be the minimum number, design and content to provide meaningful data. The questions are not overly burdensome as most collection, processing and infusion facilities track these on a monthly or annual basis for regulatory and workload recording (staffing justification). IND products are reported separately to FDA, IRB and others so this info is also readily available. Most facilities have this information in a spreadsheet or database and estimates of reporting time is 0.5 hr for this section if the person is knowledgeable in the area.

1. Does your institution collect, process, issue, or infuse hematopoietic progenitor cells (HPCs) or other cell therapy (CT) products?

2. Do you collect products for third party vendors (including cord blood banks NMDP, other suppliers of cellular therapy products)

3. If yes, how many did you collect in 2006:

	HPC-A	HPC-M	HPC-C	Other
<10 per year				
10-100 per year				
100-500 per year				
>500 per year				

4. How many of each of the following product types were collected/processed at your institution in 2006?

	I. *COLLECTED* Autologous ▼	I. *COLLECTED* Allogeneic ▼	II. *PROCESSED** *See Glossary ▼
a. Peripheral blood progenitor cell collections (HPC-A)			
b. Bone marrow collections (HPC-M)			
c. Cord blood collections (HPC-C)			
d. Donor Lymphocyte infusion (or unmanipulated non-mobilized peripheral blood mononuclear cells)			
e. Hematopoietic stem/progenitor cells, expanded			
f. Immunotherapies (natural killer cells, dendritic cells, T cells, other)			
g. Nonhematopoietic stem cells (mesenchymal stem cells (or multipotent stromal cells per ISCT recommendations),other)			
h. Other products, specify: _____			

O. Cellular Therapy Products – Infusions:

- Identifies product type more clearly. Distinguishes between auto and allo (predicting current practice and trends); more accurately describes reporting data; adds credibility to data as it facilitates user reporting – clarifies definitions.

1. Indicate the number of infusion episodes and the number of patient recipients of cell therapies by product type.

	I. Autologous Infusions		II. Allogeneic Infusions	
	Total # of episodes ▼	Total # of patients ▼	Total # of episodes ▼	Total # of patients ▼
a. Peripheral blood progenitor cell products (HPC-A)				
b. Bone marrow products (HPC-M)				
a. Cord blood products (HPC-C)*				
d. Donor Lymphocyte infusion (or unmanipulated non-mobilized peripheral blood mononuclear cells)				
e. Hematopoietic stem/progenitor cells, expanded				
f. Immunotherapies (natural killer cells, dendritic cells, T cells, other)				
g. Nonhematopoietic stem cells (mesenchymal stem cells (or multipotent stromal cells per ISCT recommendations) other)				
h. Other Products				

P. Cellular Therapy Products - Characterization of Reporting Facilities:

- Data will provide comparisons so that trends can be identified
- Questions characterize responders.

- Many centers are exploring these applications (under IND) and sometimes they are performed as part of cardiology and may not be within processing lab (such as was historically the case with tissues in ortho, opthamology, etc in years past). Helps identify future uses of products and determine scope of this practice.
- These questions assist with interpretation of data; define business model (ie: collection only, contract manufacturer, etc); provides context for responses.
- Questions help in understanding data; especially when a CB bank processes more than it collects such as was the case in the past. For example, >1/3 publicly donated cord blood products are discarded due to inadequate parameters for processing yet some report processing more than they collect). It also facilitates comparing data from year to year.

1. Which of the following best describes your program? Is your program a:
    a. Blood Center performing HPC collections only
    b. Blood center.....collecting and processing and/or storing of HPCs
    c. HPC collection facility within hospital
    d. Cord Blood collection facility only
    e. Other, please describe _____
    f. Cord Blood processing/storage facility only
    g. HPC processing/storage facility within hospital

2. Are any CT products at your facility used for cardiology applications?

3. Does your program collect cord blood?

4. Is your cord blood collected by:
    a. A nurse midwife/obstetrician
    b. Dedicated cord blood bank collector

Q. Human Tissue – Collections, Processing & Storage:

- Expanded use of human tissues brings new safety concerns and need for new regulations
- Collect quantitative data on tissue collection, processing and storage and adverse reactions to guide policy and strengthen regulations in the future
- In past year, responsibility for tissue has been extended in many hospitals to the hospital blood bank. Questions from this survey are designed to better understand how that responsibility has been structured and managed

1. Does your institution maintain an inventory of or use human tissue for transplantation?

2. What department(s) is responsible for any operational aspect of handling Human Tissue (i.e. ordering, receiving, storage, tracking, and/or issuance)?

3. What single department has the most responsibility for Human Tissue (i.e. ordering, receiving, storage, tracking, and/or issuance)?

4. What is the total number of human tissue implants/grafts that your facility:
   a. Used/implanted?
   b. Discarded?
   c. Returned?

R. Biovigilance:

- One of the objectives of this contract is the expansion of the survey into the area of Biovigilance, the monitoring of adverse outcomes of transfusion and transplantation
- The questions will gather baseline data from 2006 in areas which are intended to be used in the pilot national Hemovigilance system which is under development
- These categories of data (e.g. TRALI, severe allergic reactions, etc.) are commonly used in hemovigilance systems worldwide, and will allow the United States some preliminary comparative data for an assessment of the scope of its hemovigilance needs

1. How many severe donor adverse events did you have in 2006?

2. How many transfusion-related adverse reactions were reported to the transfusion service in 2006?

3. If any events reported, complete the table below indicating how many of these were:

   a. Life threatening, requiring major medical intervention following the transfusion, e.g. vasopressors, blood pressure support, intubation or transfer to the intensive care unit?
   b. Transfusion Related Acute Lung Injury (TRALI)?
   c. ABO incompatible?
   d. Transfusion Associated Circulatory Overload (TACO)?
   e. Acute Hemolysis?
   f. Delayed Hemolysis?
   g. Post transfusion sepsis
   h. Severe Allergic Reactions?

4. Do you have an electronic system for tracking events (i.e. unplanned, unexpected, and undesired occurrences)?

5. In 2006 how many adverse events have been associated with human tissue implants/grafts?

6. How many adverse events were related to viral transmission?

7. How many adverse events were related to bacterial infection?

8. How many adverse events were related to structural failure?

S. General Information:

- For data accuracy
- To avoid double reporting
- Characterize business practices in the blood collection, transfusion medicine, and cellular therapy community

1. Please provide the name, title, telephone number, and e-mail address of each person completing this survey:

2. List the official name, city, state, and zip code of every institution for which data are reported on this questionnaire.

3. Is your institution:

A local or regional blood center (non-hospital) that collects blood from donors and supplies blood and components to other facilities?

A hospital-based blood bank and transfusion service that collects blood from donors (may be only autologous or directed) and provides blood and components for transfusion primarily to your own facility?

A transfusion service that provides blood and components for transfusion, but does not collect blood from donors?

A local or regional blood center that collects blood from donors and supplies blood, components, and crossmatched blood products to participating facilities (such as a centralized transfusion service)? In this category, the service is not limited to reference laboratory work, but includes routine transfusion service.

An independent facility that collects, processes, manufactures, stores, or distributes **cellular therapy** products?

For Institutions 1-4 above:

Does your institution collect, process, manufacture, store, and/or distribute cellular therapy products?

Does your institution collect, process, manufacture, store, and/or distribute human tissue for transplantation?

4. Does your institution serve as a transfusion service for other institutions?

5. Which other institutions are served? Please provide the official name, city, state of every such facility, if different from your institution.