Appendix A: NCTTRAC Prehospital Transfusion Program – Standard Operating Guidelines

1. Purpose

To establish procedures for the application and management of the NCTTRAC Prehospital Transfusion Program (PTP).

2. Mission

To reduce morbidity and mortality related to traumatic injury, acute hemorrhagic conditions, and disaster events by implementing a Regional Prehospital Transfusion Program using evidence-based guidelines and practices.

3. Goals

3.1. Identify and research the need and effectiveness of a Regional Prehospital Transfusion Program

3.2. Identify and initiate partnerships with regional stakeholders to lend their input, support, and expertise.

3.3. Develop a framework for a Regional Prehospital Transfusion Program to:

3.3.1. Identify Initial agencies/locations to serve as prehospital transfusion providers.

3.3.2. Establish ground EMS and Air Medical blood product administration for routine and disaster use.

3.3.3. Identify hospital blood product usage for routine and disaster use.

3.3.4. Establish a regional cache of blood products for disaster use that includes a mechanism for the integration and sharing of blood products from Ground EMS and Air Medical.

3.3.5. Establish the storage, monitoring, maintenance, and administration of blood products, and standardization of the applicable equipment.

3.3.6. Develop state-wide disaster support through State Mission Assignment and fixed wing availability.

3.4. Measure program effectiveness through the submission and review of key data elements provided by prehospital and hospital transfusion providers.

3.5. Establish a donor support program to expand and replenish the blood supply in the region.

4. Structure and Representation

4.1. The NCTTRAC Regional PTP Workgroup will reside within the Trauma Committee. Program details and guidance developed by this Workgroup will be deemed recommendations unless approved by respective service line

committees and the NCTTRAC Board of Directors (BoD).

4.2. Workgroup Leadership: The NCTTRAC PTP is a workgroup within the Trauma Committee and will be led by representatives from within the workgroup.

4.3. Workgroup Structure – (see Annex A):

4.3.1. Will at a minimum include representation from the following:

4.3.1.1. Trauma Committee

4.3.1.2. Air Medical Committee

4.3.1.3. EMS Committee

4.3.1.4. EMS Medical Directors Committee

4.3.1.5. ED Ops Committee

4.3.1.6. Pediatrics

4.3.1.7. Perinatal

4.3.2. May include, either routinely or as needed, representation from the following:

4.3.2.1. Blood Bankers

4.3.2.2. MCI Taskforce

4.3.2.3. Any other NCTTRAC Committees/Workgroups/Task Forces

4.3.2.4. NCTTRAC member agencies, not representing one of the above committees.

4.4. Voting: Once approved by the Workgroup, actions will need to be presented at the Air Medical, ED Ops, EMS, EMS Medical Directors, Finance, Pediatric and Perinatal and Trauma committees for endorsement. Final approval rests with the NCTTRAC Board of Directors.

4.5. Meetings: Unless amended, the Workgroup will meet once a month and sub-groups may meet on an as needed basis.

5. Procedures

5.1. Applicants must meet program eligibility requirements and submit an application in accordance with the PTP requirements located on the NCTTRAC website. Questions concerning the application, should be emailed to NCTTRAC Staff at prehospitaltransfusion@ncttrac.org.

5.2. The PTP Workgroup will meet at a specified time to review all applications and submissions. The workgroup lead will work with NCTTRAC Staff to facilitate the meeting and review process.

5.3. Applications and submission will be reviewed and evaluated using the specified scoring rubric by a five (5) to seven (7) member group established from within the larger PTP Workgroup. At least one NCTTRAC Staff member will be in attendance to provide administrative support as needed. The Workgroup may request additional information and/or data from applicants and other sources as needed to support the recommendation-making process.

5.4. Once reviewed, the applications will be scored and prioritized accordingly with recommendation to the Trauma, Air Medical, ED Ops, EMS, EMS Medical Directors, Pediatric, and Perinatal Committees with final approval/disapproval from the NCTTRAC Board of Directors.

5.5. Upon Board of Directors approval, NCTTRAC will purchase and provide an initial cache of prehospital transfusion equipment for use by the approved Prehospital Provider to establish a prehospital transfusion site.

5.6. Equipment will be purchased from an approved equipment list. While other equipment may be purchased by the provider to support the program, all equipment shall be approved in advance by NCTTRAC and the Blood Supplier to promote highest standards and regional interoperability – (See Annex B)

5.7. Each Prehospital Transfusion Provider applicant must submit for review a prehospital transfusion inclusion criteria and protocol approved by their EMS Medical Director. While NCTTRAC neither develops nor endorses emergency medical protocols, an EXAMPLE protocol is provided within this document to assist EMS Medical Directors in development – (See Annex C)

5.8. The Prehospital Transfusion Workgroup will periodically evaluate the effectiveness of the program and may from time to time recruit other agencies to participate in the program and/or recommend the reallocation of equipment to other willing Prehospital Providers as needed to ensure the most appropriate utilization and administration of blood products within the region.

6. General Program Requirements

6.1. All costs associated with the Prehospital Transfusion program shall be reviewed and approved by the Board of Directors.

6.2. This document shall be referenced within the NCTTRAC Trauma Committee SOP and shall be reviewed annually and/or as necessary to determine if modifications are needed. Any modification to this document must be mutually agreed upon by the NCTTRAC Trauma Committee, representative committees comprising the NCTTRAC PTP Workgroup, and the NCTTRAC BoD before becoming effective.

7. Prehospital Transfusion Provider Application Process

7.1. Phases of the application process are outlined below with assigned responsibilities – (See Annex D)

Phase I – Application Submission (Prehospital Transfusion Provider Candidate):

- ☐ Submit intent to apply through the NCTTRAC website
- ☐ Complete and submit a Prehospital Transfusion Provider Application Review Tool along with all associated documentation and attachments – (See Annex E).

Phase II – Application Review (PTP Workgroup):

- ☐ Review application to determine whether EMS agency is eligible for program
  - approve/deny.
- ☐ Send to Trauma, Air Medical, EMS, ED Operations, and EMS Medical Directors committees for endorsement.
- ☐ Submit recommendation/endorsement to NCTTRAC Board of Directors for final approval.

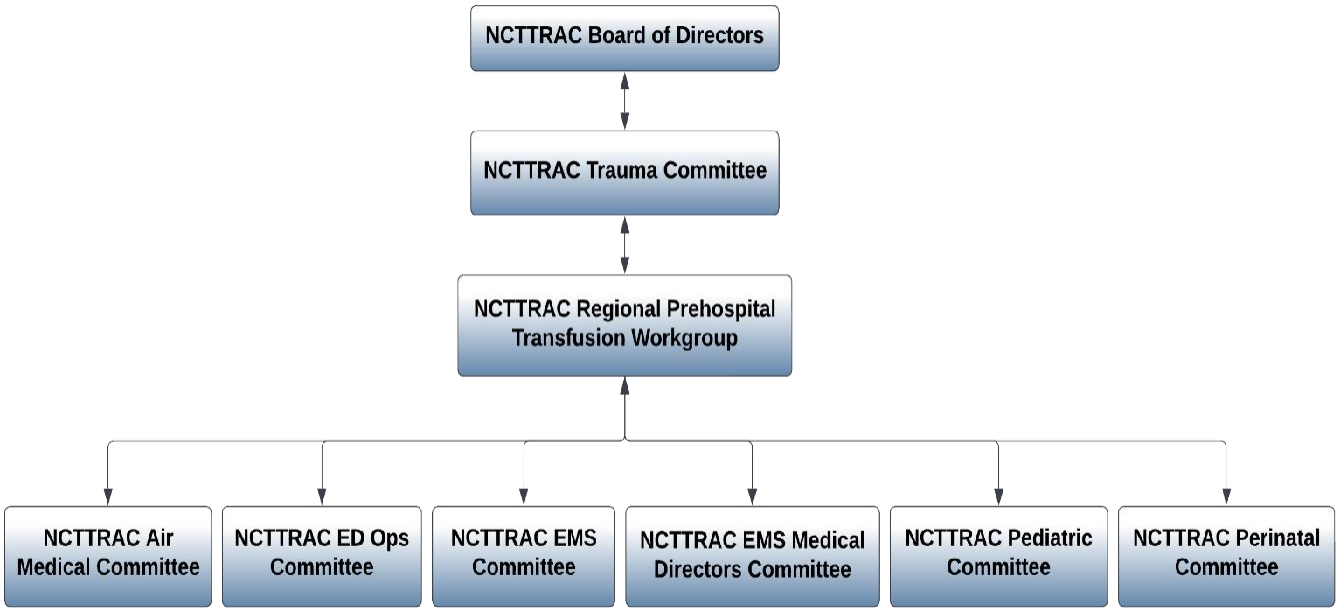
Phase III – Equipment Purchase & Distribution (NCTTRAC Staff):

- ☐ Send application approval/denial to Prehospital Transfusion Provider candidate.
- ☐ Ensure all agreements have been properly executed prior to equipment purchase – NCTTRAC MOU, Blood Service Agreement, RPPA/BAA, Amendments, etc.
- ☐ Purchase equipment from approved equipment list
- ☐ Coordinate equipment distribution to approved Prehospital Transfusion Provider

Phase IV – Program Implementation – on-going (Prehospital Transfusion Provider):

- ☐ Complete necessary training to place equipment in service.
- ☐ Establish and announce prehospital transfusion program start date. Implement Prehospital Transfusion Program
- ☐ Update agency capabilities in EMResource for regional awareness
- ☐ Submit program data to NCTTRAC in a prescribed manner and frequency

Annex A- Organizational Structure



Annex B- Transfusion Program Equipment List

NCTTRAC Approved Equipment list

- The vision of the Regional Pre-hospital Transfusion Program is to keep the highest standards and promote interoperability within our region.
- All items are FDA approved. For program integrity, all equipment used must be FDA approved.

NCTTRAC will purchase and provide the following approved prehospital transfusion equipment:

1. Delta Ice 2L Fridge Freezer for blood storage
   a. DELTAICE 2L (911tacmed.com)
   b. Must buy 2 extra Thermal Insulated Cooler (TIC)

2. QuinFlow- Blood warmer
   a. http://qinflow.com/Products
   b. With back up battery
   c. Agency will need to purchase their own disposable tubing to go along with the blood warmer

3. Temp Stick- continuous monitoring device
   a. Temp Stick with NIST Certification – Temp Stick
   b. This device continuously monitors the temperature in the blood cooler and gives the agency a tool to validate that the temperature of the blood stayed within the required temperature for the blood bank. This is a Bluetooth version that can be linked to a smartphone, dispatch, and any other identified personnel who needs to be alerted if there is an issue with the temperature.

4. Freezer
   a. Amazon.com: Midea WHS-109FW1 Upright Freezer, 3.0 Cubic Feet, White & Camco 42114 Thermometer - Refrigerator/Freezer/Dry Storage : Appliances
   b. Permanent storage solution to keep the blood frozen when not in transit.

Please note: While other prehospital transfusion equipment may be purchased and used to support this program, all equipment shall be approved in advance by NCTTRAC and the Blood Supplier to promote highest standards, FDA compliance, and regional interoperability.

Annex C -Regional PTP Example Criteria

Inclusion criteria

In the setting of hemorrhagic shock with suspected need for massive blood transfusion due to marked internal or external blood loss:

- ≥ 14 years old and SBP ≤ 70 mmHg **OR**
- ≥ 14 years old and SBP ≤ 90 mmHg **AND** HR ≥ 110 beats/min **OR**
- ≥ 65 years old and SBP ≤ 110 **AND** HR ≥ 100 beats/min **OR**
- < 14 years old and SBP < 70 + 2x age **OR**
- ETCO2 < 25

Contraindications

- Known objection to receiving blood products

Special Consideration

- Risks versus benefits should always be weighed when giving blood to a woman of childbearing age especially if Rh status unknown or known to be Rh-

Adverse Events (Monitor for, treat and report)

- Anaphylaxis
- Hemolytic reaction
- DIC
- Transfusion Reaction
- Infection

Potential signs/symptoms of an adverse event

- Body temp of 2 degrees F or more above baseline temp
- Anaphylaxis
- Hives, itching, or skin symptoms
- Nausea/vomiting
- Swelling, soreness, or hematoma at the venous site
- Blood in urine
- Flank pain/back pain
- Tachycardi
- Respiratory distress
- Hypotension
- Bleeding from various sites or previously clotted wounds

*If an adverse event is suspected immediately stop transfusion and treat per the Allergic Reaction protocol

Consent

- Patients who have decision-making capacity should receive informed consent:

"We believe the patient has a life-threatening hemorrhagic shock and the benefit of blood transfusion outweighs the risk. Risks include allergic reaction, transfusion reaction and transmission of disease such as HIV or Hepatitis. Risk of obtaining a disease is about 1 in 1 million. Do you consent to transfusion?"

- Patients who cannot make decisions for themselves and you believe the risks outweigh benefits, should be treated.

- Evaluate for religious exemptions (i.e. Jehovah Witness)

Procedure

- Gather and prepare appropriate equipment
  - LifeFlow Plus (if available)
  - QuinFlow blood/fluid warmer with disposable patient CDU
  - Blood tubing
  - Blood product(s)
- Obtain IV access—large bore IV or IO x 2
- Blood product verification
  - Verified by two paramedics
  - Ensure not expire

Administration of Blood Products

Adult (> 14):
-PRBC 1 unit IV/IO
-Liquid Plasma 1 unit IV/IO (TRAUMA OR WARFARIN ONLY)
-May repeat both once
-Give Calcium Gluconate 1 gram IV after first unit of PRBC
-Goal SBP ≥ 90

Pediatric (6-13):
-PRBC 1 unit IV/IO
-Liquid Plasma 1 unit IV/IO (TRAUMA ONLY)
-Give Calcium Gluconate 1 gram IV after first unit of PRBC
-Goal SBP ≥ 70 + 2x age

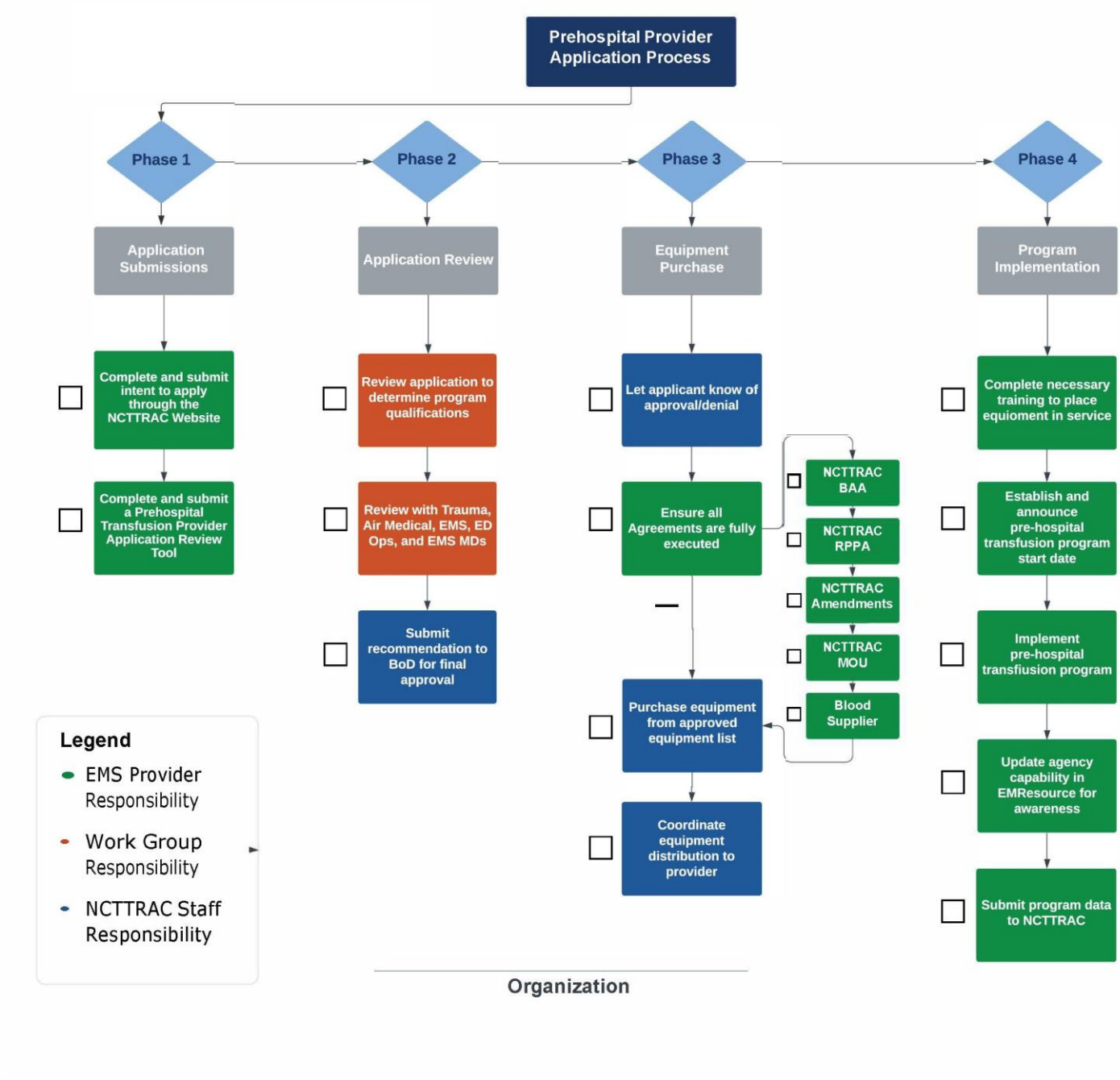
Pediatric (0-5):
-PRBC 10 ml/kg IV/IO
-Liquid Plasma 10 ml/kg IV/IO (TRAUMA ONLY)
-Give Calcium Gluconate 60 mg/kg IV (max 1 gram) after first unit of PRBC
-Goal SBP ≥ 70 + 2x age

Additional Information

- Trauma patients should be transported to a Level I or Level II trauma center
- Blood products supersede fluids and TXA
- If patient is on rate controlling medications and strong suspicion for hemorrhagic shock, call Medical Control
- May give TXA per protocol in addition to blood products if indicated
- Document blood product bag number, time of start, time infused (total ml's or complete) and the amount in the bag (ml's)

Disclaimer: NCTTRAC does not establish, develop or endorse EMS treatment protocols as a legal standard of care, but may from time to time provide examples and/or samples of EMS treatment protocols for EMS agencies to consider, adapt, and/or adopt at the sole discretion and approval of their EMS Medical Director.

Annex D - Prehospital Transfusion Program Application Process



Annex E- Regional PTP Review Tool

Prehospital Transfusion Program Application & Review Tool	
Agency Information	
A. Agency Name	B. Primary Contact Name
C. Agency Address	D. Primary Contact Phone
E. City, State, Zip	F. Primary Contact Email
G. Agency Phone	H. Alternate Contact Name
I. EMS Medical Director Name	J. Alternate Contact Phone
K. EMS Medical Director Phone	L. Alternate Contact Email
M. EMS Medical Director Email	N. Agency DSHS License No.
O. Organization Type (check one): □ EMS □ FRO	P. County/Counties served by Agency
Q. Service Type (check one): □ 911 Transport □ Inter-facility Transfer	R. Other relevant information:
***** The applicant information provided below must be as complete and accurate as possible. Applicant agency may attach additional information as needed or required *****	
I. Service Coverage Area	Agency Response/Comments:
A. List the county/counties that EMS agency services	
B. Provide the total population served by EMS agency	
C. List the EMS agency's receiving facilities	
D. List the EMS agency's receiving facilities using blood components or LTOWB	

(Table Continues)

E. Identify the closest Level I or II Trauma facility to the EMS agency's response area	
F. Provide the average transport time in minutes to a Level I or II Trauma facility	
G. Identify the primary EMS response unit in which the blood and transfusion equipment will be transported (SUV, Fire Apparatus, Ambulance, etc.)	
H. Provide total number of EMS responses annually	
I. Provide total number of EMS transports annually	
J. Provide total number of trauma transports in the past 24 months	
K. Provide total number of medical transports in the past 24 months	
L. Provide the total number or transports in the past 24 months that would have retrospectively met prehospital transfusion inclusion criteria for the following:	
1. Trauma	
2. Medical (GI, AAA, etc.)	
3. OB	
II. Agency Structure:	Agency Response / Comments
A. Identify the individual(s) in your agency who will be assigned to this project, their roles, and their location(s), with contact information.	
B. Identify who will be responsible for the overall project management and quality assurance.	
C. Identify any resources that your agency deems relevant in the management of this project.	

(Table Continues)

III. Response Capability / Plan	Agency Response/Comments:
A. Describe agency's response plan to fully staff response unit and respond to incidents	
B. Identify anticipated response time (from dispatch notification to "wheels roll") for response unit to deploy from designated primary housing location.	
C. Provide a copy of EMS agency's response plan and/or Standard Operating Procedure for Prehospital Transfusion Program implementation and maintenance	
D. Provide a map of the primary response unit's catchment area to include locations of Level I or II Trauma facilities	
E. Describe your agency's willingness to respond, share and/or pool blood product resources in support of a regional or state incident or event – include examples of participation in previous events.	
IV. Patient Care Guidelines / Inclusion Criteria	
A. Provide a copy of agency's current prehospital transfusion protocols/guidelines endorsed by agency's EMS Medical Director	
B. Provide a copy of any standard operating procedures/guidelines specific to the management of blood products – i.e., storage, transport, temperature control and management of blood components/products.	

(Table Continues)

V. Agency / Facility Support	Agency Response/Comments:
A. Provide a letter of support from agency's primary Level I or II Trauma Center destination receiving facility to include but not limited: 1. The facility's willingness and ability to support a prehospital transfusion program. 2. The facility's willingness to establish quarriable prehospital blood component fields within their internal registry to assist with future tracking and collecting of data. 3. The facility's willingness to submit program data to an outsourced third-party registry for the purpose of system development and performance improvement. 4. The facility's willingness to share and/or exchange data and/or information on a regular and on-going basis with agency regarding patient outcomes.	
B. Provide a statement of endorsement from the agency's EMS Medical Director describing how this program will improve patient care within the agency's response area	
VI. Data Submission / Quality Assurance	
A. Describe your agency's willingness to submit and/or share data to and/or with NCTTRAC or a prescribed outsourced third-party registry for system performance improvement – provide examples of previous participation	
B. Provide screenshots of agency's electronic patient care record (ePCR) showing evidence of a quarriable field(s) for blood component intervention	

(Table Continues)

C. Describe whether your agency is willing to coordinate with receiving facilities to receive, report, and share outcome data to NCTTRAC or a prescribed outsourced third-party registry for system performance improvement – provide examples of current or previous participation.	
D. Describe agency's QA/QI process as it applies to prehospital transfusion, provide a copy of any standard operating procedures/guidelines specific to this program including contact information for primary oversight (name, position, email and phone)	
VII. Program Sustainment	Agency Response/Comments:
A. Describe your agency's donation plan to replace or replenish blood products in accordance with the Blood Supplier's requirements.	
B. Describe how your agency plans to financially support the continuation of this program.	