

INFECTED BLOOD INQUIRY

BRENDON GRAY WITNESS STATEMENT

EXHIBIT WITN6984032

Our Ref MWT/svs

17th May 1983.

Dr. L.K. Fowler,
Department of Health & Social Security,
Market Towers,
1, Nine Elms Lane,
Vauxhall,
London,
SW8 5NQ.

Dear Dr. Fowler,

CUTTER - PLASMA COLLECTION

I enclose for your information some documents issued by Cutter Laboratories concerning the procedure for collection of plasma at their centres in the U.S.A., notices which are displayed at the centres and literature relating to AIDS.

These documents will be presented to regulatory authorities in response to any queries and we thought you may find them useful.

Yours sincerely,

Marie W. Tatt,
Registration Manager.

CUTTER LABORATORIES QUALITY ASSURANCE DOCUMENT		Sheet 1 of 3 : Document No.: : Rev.: : CSCP 401 : 1 : Date: FEB 01 1983
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	: Prepared by: GRO-C
Subject:	DONOR CARD - FORM NO. 81-9723	: Approved by: GRO-C
		: Approved by: GRO-C

Responsibility: Receptionist

1. Donor Name:

Males - last, first, middle.
Females - if single - last, first, middle.
Females - if married - last, first, maiden.

When a donor undergoes a name change, eg: due to a change in marital status, note change on all current forms retained in donor chart.

2. Address: Permanent street address and town.

3. Identification: Number for identification purposes. Note source of number as well, eg: Driver's License (also note State), I.D. cards (military, student, State, Welfare), Social Security, etc.

4. Donor Number: Consists of a one or two letter alphabetic Center Code assigned by Cutter Laboratories and a five digit number. Use zeros in front of lower numbers to fill all spaces (eg: AT 00057). Must correspond to permanent Donor Number assigned to donor and recorded in Donor Log Book (CSOP 201).

5. Plasma Type: N for normal (with black Control Number label), T for Tetanus (with red Control Number label), etc. Use space to left first. Use other spaces as Plasma Type changes.

6. Card No.: First Donor Card used will be 1, second Donor Card on same donor will be 2, etc.

7. Code: Donor Code.

8. Age: Consider both month and year. Example: If a donor was born on 11-14-35 and is applying to be a donor on 3-8-83 the age is 47 NOT 48. This is particularly important on donors who are near minimum age. Inattention in this area could result in taking a donor who is not yet of legal age.

9. Height: Feet and Inches.

10. Date: Place date donor comes to Center in next available space. Date must be entered even if donor does not complete donation. In this event make appropriate comment in Comments space.

QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
Document Type:	: CSOP 401	: 1
UTTER SYSTEM OF PLASMAPHERESIS	: Date:	: FEB 01 1983

Responsibility: Receptionist or Prep Technician

11. Control No. (bleed number): Place Control Number label in space provided adjacent to date.
12. Weight: In pounds, from actually weighing donor without overcoats, jackets, galoshes, etc. Center personnel must read scale. Minimum 110 pounds. Record in space provided. Refer to physician for evaluation in cases of recent marked weight loss, i.e.: greater than 5 pounds in two weeks or 10 pounds in one month.

Responsibility: Prep Technician

13. Blood Pressure: Systolic 100-150, Diastolic 50-100. Donation can be given with blood pressure outside these limits if approved by physician.
14. Pulse: Determine for at least 30 seconds. Acceptable limits: 50-100. Physician must approve for donation if over 100 or under 50.
15. Temperature: Lower limit is 97.6°F. Upper limit is 99.6°F. Record in space provided.
16. Initials: Initials of person determining blood pressure, pulse and temperature. (
17. Hct: Hematocrit, minimum 38%. Record in space provided.
18. T.P: Total Protein, done on capillary blood only. Minimum 6.0 gm%. Record in space provided.
19. Initials: Initials of person determining hematocrit and total protein.
20. Comments: Comments used for various purposes (CSOP 150, 201, 202, 203, 204, 238, 242, 243, 244, 253, 301, 302, 303, 307). Use next donation space for completeness of record if necessary.
- 20.1 Record DTH reaction: Donor transient hypotension is to be graded by physician according to degree of reaction.
 - 1+ Slight or mild degree of signs and symptoms of DTH (e.g.: pallor, restlessness, cold skin, nausea, sweating, dizziness, slow pulse); systolic blood pressure tends to be in 90-100 range.
 - 2+ More marked degree of signs and symptoms as above; systolic blood pressure tends to be less than 90-100 range.
 - 3+ Actual unconsciousness (fainting or grand mal seizure).
 - 4+ Hospital observation carried out.
 - 5+ Hypotensive sequelae (coronary, CVA, etc.).

QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
Document Type:	: CSCP 401	: 1
CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 01 1993

20.2 Note failure to donate (and give reason), loss of red blood cells, incomplete donation, temporary rejection due to bright finger staining indicating which finger was brightly stained. If appropriate, note also when donor may again be accepted for donation.

21. Appendix

21.1 Form 81-9723 - Donor Card

CUTTER LABORATORIES QUALITY ASSURANCE DOCUMENT		Document No.: CSOP 402	Rev.: 1
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	Date:	FEB 01 1983
Subject:	PREDONATION HISTORY - FORM 81-9711	Prepared by:	GRO-C
		Approved by:	GRO-C
		Reviewed by:	GRO-C

Responsibility: Receptionist or Prep Technician and Center Physician

1. Complete Donor Name and Donor No. as on Donor Card (CSOP 401) on first donation.
2. Write date (month, day, year) donor is next due for a physical examination by physician in space labeled MD Exam Due.
3. On day of each donation, except those on which donor has physical examination by physician, write date in space provided and ask donor following questions, giving donor adequate time for response before marking each space yes (+) or no (0). A yes (+) answer to any medical history question may prevent donor from donating. Refer questionable donors to physician for final determination.
 - 3.1 Identification: Can donor be positively identified as person described from information in chart? Involves visual recognition from photograph and comparison of donor's signature on photograph.
 - 3.2 Respiratory Disease: Does donor have presently an acute disease, eg: cold, dry cough, sore throat, influenza, bronchitis, tonsillitis, asthma, hayfever, tuberculosis? Donor must not be accepted until one week after complete recovery from upper respiratory problems and ten years following tuberculosis.
 - 3.3 Infectious Skin Disease: Does donor have any evidence of skin disease eg: redness, swelling, flaking, scaling, eruptions, on arms, particularly in ante cubital fossa? Does donor have boils, furuncles, carbuncles, psoriasis, erysipelas anywhere on body? Has donor recently developed brownish, reddish or purplish lesions, modular or flat, anywhere on body?
 - 3.4 Disease Carried by Blood: Donors who have had brucellosis or undulant fever are not acceptable until two years after recovery. Donors who have had dental surgery or tooth extractions are not acceptable for 72 hours following procedure.
 - 3.5 Recent Illness: Has donor been hospitalized, had any treatment for illness, visited a doctor, had any inoculations or vaccinations or taken any medicine since last donation? May require evaluation by physician. Has donor had persistent diarrhea (>seven days duration), swollen glands, or night sweats? Will require evaluation by physician.
 - 3.6 History of Viral hepatitis: Has donor ever had hepatitis or jaundice? Has donor ever been told he was HBsAg (Australia antigen, HAA) positive? If yes, permanently reject and update permanent reject file.

QUALITY ASSURANCE DOCUMENT : Document No.: : Rev.:
Document Type: : CSCP 402 : 1
CUTTER SYSTEM OF PLASMAPHERESIS : Date: FEB 01 1983

- 3.7 Hepatitis Contact: Has donor had contact with any person who had hepatitis in last x months? Contact means cohabitation or using same eating and sanitary facilities. Has donor been tattooed or had ears pierced since last donation? If affirmative, donor is rejected until six months without evidence of hepatitis has elapsed.
- 3.8 Blood/Plasma Received: Has donor received a blood transfusion (whole blood, packed red cells, platelet concentrate, fresh, frozen or single donor plasma cryoprecipitates, fibrinogen, blood coagulation factors (AHF, Factor IX), since last donation? If so, donation must be deferred for six months without any signs or symptoms of hepatitis. Donation need not be deferred following administration of albumin, plasma protein fraction or immune serum globulin provided receipt of these items does not point to some underlying disease or recent contact with hepatitis.
- 3.9 Arm Skinuncture Scars: Has donor given blood within the past 8 weeks or plasma within past 48 hours? Examination of both exposed arms and hands must show absence of unexplained needle marks or scars possibly suggesting use of drugs. If donor has given whole blood or lost a unit of red cells during a plasmapheresis procedure, donor will not be permitted to participate in plasmapheresis for a period eight weeks from date of blood loss.
- 3.10 Drug or Alcohol Influence: Donor must not be under influence of drugs or alcohol on day of donation. Refer to physician for final determination if (
- 3.11 Interviewer Initials: Initials of person conducting interview.
4. Comments Donor Acceptability:
- 4.1 Use for lack of donor acceptability for any reason not covered in the above questions.
- 4.2 On female donors only, use space for answering questions: 1) Are you menstruating today? 2) When did you stop your last menstrual period? 3) To the best of your knowledge, are you pregnant? Need not be done if donor is post menopausal or if hysterectomy has been performed. Documentation of either of these situations must be clear on Form No. 81-9731 (Medical History and Physical Examination).
- 4.3 Physician uses for recording results of Review of Donor Chart (CSOP 222).
- 4.3.1 During initial physical examination and each Review of Donor Chart, physician writes date (Month and year) of next review in spaces provided.
- 4.4 If donor is not acceptable, clearly document reason for lack of acceptability, whether permanent or temporary and, if temporary, date on which donor may again be considered.
- 4.5 Appendix
- 4.5.1 Form 81-9711 - Predonation History

CUTTER LABORATORIES QUALITY ASSURANCE DOCUMENT		Sheet 1 of 7 : Document No.: : Rev.: : CSQP 403 : 2 : Date: FEB 14 1983 : Prepared By: GRO-C : Approved By: GRO-C : : GRO-C
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	
Subject:	MEDICAL HISTORY AND PHYSICAL EXAMINATION - FORM NO. 81-9731	

Responsibility: Center Physician

1. General

- 1.1 Donor name, Donor Number, sex, race and birthdate are completed by receptionist. All other entries are made by (or under the direct supervision of) physician.
- 1.2 Specific explanations given below are to be considered as guidelines. In many cases your own medical judgement must prevail.
- 1.3 Note that many items are asked more than once allowing different approaches to be used in eliciting information. The form has been specifically designed to contain this feature at the request of several physicians.

2. Donor Identification.

- 2.1 Name: last name first, comma, first name and middle initial.
- 2.2 Donor Number: consists of 7 figures, a one or two place alphabetic Center Code and a 5 digit number. Use zeros in front of the lower numbers to fill the five spaces (e.g.: AT 00057).
- 2.3 Ideally, donor name and number should be applied with imprinting card. If not possible, use clean, neat printing with block letters.
- 2.4 Sex: circle M or F as appropriate.
- 2.5 Race: circle appropriate symbol C - Caucasian, N - Negro, I - Indian, O - Oriental, L - Latin.
- 2.6 Birthdate: month, day, year.

3. DONOR HISTORY - This section provides opportunity to elicit general information from donor which may be more fully covered later in examination.

- 3.1 Date - write month, day, year in the appropriate column space. Each column is to be used for one examination only.
- 3.2 Occupation - write in occupation. This may give clues to specific areas to be covered in greater detail, e.g.: coal miners - black lung disease; farmers - diseases associated with animals; chemical plant worker - liver damage from industrial solvents, etc. This is also an opportunity to warn those in hazardous occupations (e.g.: operators of power machinery, cranes, drivers of buses, trains, cabs, workers on ladders or scaffolding, airplane

		Sheet 2 of 7	
Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
		: CSOP 403	: 2
	CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983

- crews, etc.) not to engage in their occupation for 12 hours after donation or longer if a unit of red blood cells is not returned to them.
- 3.3 Military Service - give dates, was person overseas and ever receive any medical treatment?
 - 3.4 Illnesses and Injuries (Past and Recent) - Is donor currently under a doctor's care? Some specific items are: no donation for 72 hours after dental surgery, two weeks if dental surgery involved infection; no donation for 2 years following recovery from brucellosis (undulant fever), relapsing fever; no donation for 1 year following recovery from infectious mononucleosis; no donation until complete recovery from flu, cold, sore throat, sinusitis or other upper respiratory infections for 1 week.
 - 3.5 Hospitalization - No donation until at least 6 months after major surgery (may have been given transfusion with risk of hepatitis) or until wound from minor surgery has completely healed. Hospitalization for diagnostic procedures or minor treatment usually will not delay donation but may suggest other areas for investigation.
 - 3.6 Medication, Drugs, Alcohol - Medication such as insulin, digitals, quinidine, nitroglycerin, antihypertensives, anticoagulants, dilantin, thorazine or heavy doses of tranquilizers suggest a donor not be accepted or retained on the program. Recent narcotic addiction, usage of hallucinogens will prevent donor from being accepted. If donor has been six months without drug use and no evidence of hepatitis during that time, donor is acceptable. Recent participation in drug testing programs may suggest a donor not be bled for some period of time. Donation should be deferred until 30 days after cessation of antibiotic therapy. Alcohol habituation may suggest donor not be accepted. Use of drugs such as oral contraceptives, hormones, vitamins, occasional analgesics or low doses of tranquilizers usually will not prevent acceptance into the program. In short, any use of a drug by a potential donor at the time of being examined is reason of non-acceptance of donor for plasmapheresis for that visit.
 - 3.7 Transfusions or Blood Fractions - Following transfusion of whole blood, packed red cells, platelet concentrates, fresh frozen or single donor plasma, cryoprecipitates, fibrinogen, blood coagulation factors (AHF, Factor IX), donation must be deferred for 6 months without any signs or symptoms of hepatitis. Donation need not be deferred following administration of albumin, plasma protein fraction or immune globulin provided use of these items does not point to some underlying chronic disease or recent contact with hepatitis.
 - 3.8 Hepatitis (Disease or Contact) - Any history of hepatitis will prevent donor from entering program. Clinical jaundice from an unproven cause is to be considered as indicative of a positive history of hepatitis. Contact with person who has hepatitis will cause donation to be deferred for 6 months without symptoms of hepatitis. Contact means cohabitation, routine use of the same eating and sanitary facilities.

Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
		: CSOP 403	: 2
	CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983

- 3.9 Malaria - Donor must be symptom free and not under current drug therapy for the disease. Donor may be accepted with a past history of malaria (at least 6 months must have elapsed since last drug therapy has been taken) or malaria suppressive therapy or travel in an endemic malaria area.
- 3.10 Convulsions, Coma, Fainting, Epilepsy - All may be causes for non-entrance into program if occurring past infancy. Convulsions in infancy are no barrier to donation.
- 3.11 Immunizations - Any donor with a history of immunization with red blood cells or blood group specific substances will not be accepted in the program. Donations are to be deferred until 2 weeks following smallpox or yellow fever immunizations, 24 hours or until any local reaction subsides following immunization with Salk polio, plague, flu, typhoid, measles, typhus, Rocky Mountain Spotted Fever, cholera, diphtheria or administration of therapeutic animal serums (e.g.: horse tetanus antitoxin).
- 3.12 Tattoos and ears pierced - Donation deferred until 6 months after tattooing and ear piercing with no symptoms of hepatitis.
- 3.13 Blood, Plasma donor (difficulties) - Any adverse reaction (e.g.: DTH or other) may be reason for non-acceptance into the program.
- 3.14 Comments, Pertinent Family History - This space is provided for explanation of any of above items and for comments on such items as recent direct contact with family member who has a communicable disease, any family history of inheritable disease such as bleeding tendencies (hemophilia), etc.

4. REVIEW OF SYSTEMS

This section is a continuation of donor history and provides an opportunity to explore further any areas uncovered in the more general review above. It also provides for an orderly review of donor's past health status.

- 4.1 Allergies - Chronic asthma under current drug therapy is a cause for rejection. Seasonal hayfever, food allergies, drug sensitivities are acceptable if not active at present time and donor is not currently taking antihistamines plus if recovery has been of at least 1 week's duration.
- 4.2 Skin - Unexplained jaundice provides another clue to hepatitis. Recent appearance of brownish, reddish, or purplish lesions, nodular or flat, anywhere on entire body surface could be indicative of AIDS. Chronic eczema, chronic dermatitis, recurring boils may be cause for rejection.
- 4.3 EENT - Dental surgery, chronic tonsillitis or other underlying infections may be cause for deferring donation for a short period. Difficulty with eyes or ears may signify partial sight or hearing.

Document Type: QUALITY ASSURANCE DOCUMENT	: Document No.: : Rev.:
CUTTER SYSTEM OF PLASMAPHERESIS	: CSOP 403 : 2
	: Date: FEB 14 1983

- 4.4 Cardiovascular - Rheumatic fever in last year, heart disease, chest pain, shortness of breath, hypertension, hypotension, chronic phlebitis, palpitation, irregular pulse, shifting of apex beat, syncope, may be causes for rejection. Past short episodes of rheumatic fever, pericarditis, heart murmur or thrill, repair of congenital heart defect usually are not causes for rejection.
- 4.5 Pulmonary - Active tuberculosis within past 10 years, shortness of breath especially on exertion may be reasons for rejection. Recovery from any upper respiratory disease should be of at least one week's duration prior to donation.
- 4.6 Gastrointestinal: Jaundice, liver trouble, cirrhosis, ulcers, ulcerative colitis, especially accompanied by recent episodes of gastrointestinal bleeding or black stool, may be cause for rejection.
- 4.7 Genitourinary - Chronic kidney diseases, red blood cells, pus cells or protein in urine may be cause for rejection.
- 4.7.1 Menstrual cycle - should be regular and uncomplicated, frequent excessive bleeding may be cause for rejection.
- 4.7.2 Last menstrual period - month, day, year. Abnormal or excessive bleeding may be reason for rejection. Provides beginning point for question of pregnancy.
- 4.7.3 Pregnancy GPAM - G - gravida, P - para, A - abortion, M - miscarriage. Insert numbers where appropriate. Prospective donor must not be pregnant now and must be 8 weeks after pregnancy no matter how terminated.
- 4.8 Neuromuscular - Seizures, fainting epilepsy, collagen diseases, myasthenia gravis, arthritis if associated with anemia may be cause for rejection.
- 4.9 Skeletal - Recent fractures particularly with open reduction and/or complications, osteomyelitis may be cause for rejection.
- 4.10 Blood diseases - Bleeding tendencies, slow clotting, easy bruising, frequent nose bleeds, chronic anemia, polycythemia, leukemia are cause for rejection.
- 4.11 Comments: This space is provided for explanation of, or further comment on, any of above items.

5. LABORATORY

Results of these tests are available on Donation Record which should accompany donor to physical examination area..

- 5.1 Hematocrit (%) - minimum 38%.

QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
Document Type:	: CSOP 403	: 2
CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983

5.2 Total Protein (g%) - Minimum 6.0 g%.

5.3 Urine - Negative for protein and sugar.

NOTE: traces of sugar and protein such as from dietary or hydration variability are acceptable.

5.4 Other - Results of any other tests done should be entered here.

5.5 Comments: This space is provided for explanation of or further comment on any of the above items.

6. PHYSICAL EXAMINATION

This section is provided for results of actual observation of donor.

6.1 Date - Write month, day, year in appropriate column space. Each column is to be used for one examination only.

6.2 Vital signs - Results of these observations are available on Donation Record which should accompany donor to examination area. Physician will determine blood pressure. However, if physician repeats the other observations it will provide an excellent opportunity to maintain a continuous check on capabilities of Prep Technicians by comparing physician's findings to those on Donation Record.

6.2.1 Temperature - Minimum 97.6°F., maximum 99.6°F.

6.2.2 Pulse - Must be regular, Minimum 50, Maximum 100.

6.2.3 Respiration - Must be regular, not labored.

6.2.4 Blood Pressure - Systolic 100-150, Diastolic 50-100. Donation can be given with systolic blood pressure up to 200 if approved by physician.

6.2.5 Weight - Minimum 110 lbs. No maximum has been established. Donors of excessive weight should be carefully evaluated for other medical problems and for difficulties in performing venipuncture. Physician should also evaluate recent marked weight loss. If unexplained (e.g.: dieting), may be indicative of some inapparent disease state.

6.2.6 Height - If recorded here does provide a way to examine the height to weight-ratio.

6.3 General Appearance and Nutrition - In addition to the usual meaning of this section, physician should be aware of mental or emotional difficulties presented by donor. Does donor present adequate mental capabilities to understand and to participate in identification of red blood cells? Does donor have sufficient emotional stability to not present a problem in the donor room?

QUALITY ASSURANCE DOCUMENT		Document No.:	Rev.:
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	CSOP 403	2
		Date:	FEB 14 1983

- 6.4 Skin - Note: Jaundice, chronic exzema, chronic dermatitis, boils. Look for unexplained needle marks on both arms or other areas where narcotic administration might be practiced. Examine skin for signs of AIDS.
- 6.5 Head and Neck - Scars indicative of severe head injury.
- 6.5.1 Eyes - Jaundice; narcotic influence; does donor have sufficient vision to participate in identification of red blood cells? If not Donor Donor Card (Form 81-9723) must be conspicuously marked that assistance must be provided. Similar notation must be made in "Comment" section of Form 81-9731. Should donor be required to wear glasses (contact lenses) while participating in identification of red cells?
- 6.5.2 ENT - Note: current infections. Does donor have sufficient hearing to be able to participate in identification of red blood cells?
- 6.5.3 Teeth - Infections or abscesses; does donor have sufficient teeth to be able to obtain a normal diet?
- 6.6 Cardiovascular System - Note: Irregular pulse, engorged neck veins, presence, absence or diminution peripheral arterial pulse; deformities of chest, visible cardiac impulses. apex beat and thrill; precordial bulging, auscultation of heart sounds; rhythm, force and quality of sounds; any friction rub or gallop; heart murmur, rate, location, position in cycle, intensity, pitch, effect of change of position and transmission.
- 6.7 Pulmonary System - Note: Any deformities of chest, type of breathing, dyspnea, prolongation of expiration, unequal or diminished movement of either or both sides of chest; cough, stridors or wheezes; vocal fremitus, any dullness to percussion; auscultation of breath sounds, rhonchi, rales, crepitation, friction rub, wheezing or diminished air entry.
- 6.8 Abdomen - Note: size and contour, visible peristalsis, respiratory movement, distended veins, tenderness and rigidity, shifting dullness, tympany, rebound tenderness and fluid waves; palpable organs (to be performed with donor lying down), liver, spleen, kidneys or masses, abdominal bruit, bowel sounds.
- 6.9 Genitourinary - Exclude chronic kidney disease or kidney enlargement detected by abdominal palpation. Female donors: Examine for engorged or lactating breast, change of color of areola, uterus enlargement etc., which may point to pregnancy or recent period of post-partum.
- 6.10 Neuromuscular - Note: Cerebral function, general behavior, level of consciousness, emotional status, orientation, ability to understand and follow instructions; cranial nerve function; motor system function, reflexes. Some test for neuromuscular function other than eye response to light must be performed.

Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
		: CSOP 403	: 2
	CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983

- 6.11 Skeletal - Note: casts, scars due to open reduction of fractures.
- 6.12 Lymphatic System: Enlarged or tender cervical, axillary, supratrochlear or inguinal lymph nodes could be indicative of AIDS. —
- 6.13 Comments: This space is provided for explanation of or further comment on any of the above items.

7. ACCEPTANCE

- 7.1 Plasmapheresis Donor - Write yes or no. DO NOT use checks, pluses, dashes, minuses or other symbols. Symbol O.K. is acceptable.
- 7.2 Reason if rejected - If the answer is no, a short simple statement of the reason should be given here.
- 7.3 For Hyperimmunization - List the types of toxoids or vaccines which the donor is eligible to receive. This can be done most easily by giving the plasma type, e.g.: T.P. etc.
- 7.4 Rejected for Hyperimmunization - List the types of toxoids or vaccines which the donor is NOT eligible to receive. This can be done most easily by giving the plasma type, e.g.: T.P. etc.
- 7.5 Comments: This space is provided for explanation of or further comment on any of above items.
- 7.6 M.D. - This space is provided for the signature of the physician performing the Medical History and Physical Examination. No rubber stamps are permissible for signatures or initials.

8. Appendix

- 8.1 Form 81-9731 - Medical History and Physical Examination

NAME

ROOM NUMBER

SEX M F
RACE C N I O L
BIRTHDATE

MEDICAL AND PHYSICAL EXAMINATION

DONOR HISTORY

	DATE				
Occupation					
Military Service					
Illnesses and Injuries (Past and Recent)					
Hospitalizations					
Medications, Drugs, Alcohol					
Transfusions or Blood Fractions					
Hepatitis (Disease or Contact)					
Mal					
ions, Coma, Fainting, Epilepsy					
Immunizations					
Tattoos					
Blood, Plasma Donor (Difficulties)					
COMMENTS, Pertinent Family History:					

REVIEW OF SYSTEMS:

Allergies					
Skin					
EENT					
Cardiovascular					
Pulm					
Gastrointestinal					
Genitourinary					
a. Menstrual Cycle					
b. Last Menstrual Period					
c. Pregnancy G P A M					
Neuromuscular					
Skeletal					
Blood Diseases					
COMMENTS:					

LABORATORY

Hematocrit (%)					
Total Protein (gm. %)					
Urine					
Other					
COMMENTS:					

PHYSICAL EXAMINATION

Vital Signs	DATE				
a. Temperature					
b. Pulse					
c. Respiration					
d. Blood Pressure					
e. Weight					
f. Height					
General Appearance & Nutrition					
Skin					
Head and Neck					
a. Eyes					
b. ENT					
c. Teeth					
Cardiovascular System					
Respiratory System					
Abdomen					
Genitourinary					
Neuromuscular					
Skeletal					

COMMENTS:

Lymphatic System (rubber stamp on form)

ACCEPTANCE

Plasmapheresis Donor					
Reason if Rejected					
For Hyperimmunization					
Rejected for Hyperimmunization					
COMMENTS:					

Our Ref MWT/svs

17th May 1983.

Dr. L.K. Fowler,
Department of Health & Social Security,
Market Towers,
1, Nine Elms Lane,
Vauxhall,
London,
SW8 5NQ.

Dear Dr. Fowler,

CUTTER - PLASMA COLLECTION

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These documents will be presented to regulatory authorities in response to any queries and we thought you may find them useful.

Yours sincerely,

Marie W. Tatt,
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Responsibility: Receptionist

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 Females - if married - last, first, maiden.

When a donor undergoes a name change, eg: due to a change in marital status, note change on all current forms retained in donor chart.
2. Address: Permanent street address and town.
3. Identification: Number for identification purposes. Note source of number as well, eg: Driver's License (also note State), I.D. cards (military, student, State, Welfare), Social Security, etc.
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7. Code: Donor Code.
8. Age: Consider both month and year. Example: If a donor was born on 11-14-35 and is applying to be a donor on 3-8-83 the age is 47 NOT 48. This is particularly important on donors who are near minimum age. Inattention in this area could result in taking a donor who is not yet of legal age.
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12. Weight: In pounds, from actually weighing donor without overcoats, jackets, galoshes, etc. Center personnel must read scale. Minimum 110 pounds. Record in space provided. Refer to physician for evaluation in cases of recent marked weight loss, i.e.: greater than 5 pounds in two weeks or 10 pounds in one month.

Responsibility: Prep Technician

13. Blood Pressure: Systolic 100-150, Diastolic 50-100. Donation can be given with blood pressure outside these limits if approved by physician.
14. Pulse: Determine for at least 30 seconds. Acceptable limits: 50-100. Physician must approve for donation if over 100 or under 50.
15. Temperature: Lower limit is 97.6°F. Upper limit is 99.6°F. Record in space provided.
16. Initials: Initials of person determining blood pressure, pulse and temperature. (
17. Hct: Hematocrit, minimum 38%. Record in space provided.
18. T.P: Total Protein, done on capillary blood only. Minimum 6.0 gm%. Record in space provided.
19. Initials: Initials of person determining hematocrit and total protein.
20. Comments: Comments used for various purposes (CSOP 150, 201, 202, 203, 204, 238, 242, 243, 244, 253, 301, 302, 303, 307). Use next donation space for completeness of record if necessary.
- 20.1 Record DTH reaction: Donor transient hypotension is to be graded by physician according to degree of reaction.
 - 1+ Slight or mild degree of signs and symptoms of DTH (e.g.: pallor, restlessness, cold skin, nausea, sweating, dizziness, slow pulse); systolic blood pressure tends to be in 90-100 range.
 - 2+ More marked degree of signs and symptoms as above; systolic blood pressure tends to be less than 90-100 range.
 - 3+ Actual unconsciousness (fainting or grand mal seizure).
 - 4+ Hospital observation carried out.
 - 5+ Hypotensive sequelae (coronary, CVA, etc.).

		Sheet 3 of 3	
QUALITY ASSURANCE DOCUMENT		: Document No.:	: Rev.:
Document Type:		: CSOP 401	: 1
CUTTER SYSTEM OF PLASMAPHERESIS		: Date:	FEB 01 1993

20.2 Note failure to donate (and give reason), loss of red blood cells, incomplete donation, temporary rejection due to bright finger staining indicating which finger was brightly stained. If appropriate, note also when donor may again be accepted for donation.

21. Appendix

21.1 Form 81-9723 - Donor Card

CUTTER LABORATORIES QUALITY ASSURANCE DOCUMENT		Document No.: CSCP 402	Rev.: 1
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	Date:	FEB 01 1983
Subject:	PREDONATION HISTORY - FORM 81-9711	Prepared:	GRO-C
		Approved:	GRO-C
		Approved:	GRO-C

Responsibility: Receptionist or Prep Technician and Center Physician

1. Complete Donor Name and Donor No. as on Donor Card (CSCP 401) on first donation.
2. Write date (month, day, year) donor is next due for a physical examination by physician in space labeled MD Exam Due.
3. On day of each donation, except those on which donor has physical examination by physician, write date in space provided and ask donor following questions, giving donor adequate time for response before marking each space yes (+) or no (-). A yes (+) answer to any medical history question may prevent donor from donating. Refer questionable donors to physician for final determination.
 - 3.1 Identification: Can donor be positively identified as person described from information in chart? Involves visual recognition from photograph and comparison of donor's signature on photograph.
 - 3.2 Respiratory Disease: Does donor have presently an acute disease, eg: cold, dry cough, sore throat, influenza, bronchitis, tonsillitis, asthma, hayfever, tuberculosis? Donor must not be accepted until one week after complete recovery from upper respiratory problems and ten years following tuberculosis.
 - 3.3 Infectious Skin Disease: Does donor have any evidence of skin disease eg: redness, swelling, flaking, scaling, eruptions, on arms, particularly in ante cubital fossa? Does donor have boils, furuncles, carbuncles, psoriasis, erysipelas anywhere on body? Has donor recently developed brownish, reddish or purplish lesions, nodular or flat, anywhere on body?
 - 3.4 Disease Carried by blood: Donors who have had brucellosis or undulant fever are not acceptable until two years after recovery. Donors who have had dental surgery or tooth extractions are not acceptable for 72 hours following procedure.
 - 3.5 Recent Illness: Has donor been hospitalized, had any treatment for illness, visited a doctor, had any inoculations or vaccinations or taken any medicine since last donation? May require evaluation by physician. Has donor had persistent diarrhea (> seven days duration), swollen glands, or night sweats? Will require evaluation by physician.
 - 3.6 History of Viral hepatitis: Has donor ever had hepatitis or jaundice? Has donor ever been told he was HBAg (Australia antigen, HAA) positive? If yes, permanently reject and update permanent reject file.

QUALITY ASSURANCE DOCUMENT : Document No.: : Rev.:
 Document Type: : CSCP 402 : 1
 CUTTER SYSTEM OF PLASMAPHERESIS : Date: FEB 01 1983

- 3.7 Hepatitis Contact: Has donor had contact with any person who had hepatitis in last six months? Contact means cohabitation or using same eating and sanitary facilities. Has donor been tattooed or had ears pierced since last donation? If affirmative, donor is rejected until six months without evidence of hepatitis has elapsed.
- 3.8 Blood/Plasma Received: Has donor received a blood transfusion (whole blood, packed red cells, platelet concentrate, fresh, frozen or single donor plasma cryoprecipitates; fibrinogen, blood coagulation factors (AHF, Factor IX), since last donation? If so, donation must be deferred for six months without any signs or symptoms of hepatitis. Donation need not be deferred following administration of albumin, plasma protein fraction or immune serum globulin provided receipt of these items does not point to some underlying disease or recent contact with hepatitis.
- 3.9 Arm Skin Puncture Scars: Has donor given blood within the past 8 weeks or plasma within past 48 hours? Examination of both exposed arms and hands must show absence of unexplained needle marks or scars possibly suggesting use of drugs. If donor has given whole blood or lost a unit of red cells during a plasmapheresis procedure, donor will not be permitted to participate in plasmapheresis for a period eight weeks from date of blood loss.
- 3.10 Drug or Alcohol Influence: Donor must not be under influence of drugs or alcohol on day of donation. Refer to physician for final determination if (
- 3.11 Interviewer Initials: Initials of person conducting interview.
4. Comments Donor Acceptability:
 - 4.1 Use for lack of donor acceptability for any reason not covered in the above questions.
 - 4.2 On female donors only, use space for answering questions: 1) Are you menstruating today? 2) When did you stop your last menstrual period? 3) To the best of your knowledge, are you pregnant? Need not be done if donor is post menopausal or if hysterectomy has been performed. Documentation of either of these situations must be clear on Form No. 81-9731 (Medical History and Physical Examination).
 - 4.3 Physician uses for recording results of Review of Donor Chart (CSOP 222).
 - 4.3.1 During initial physical examination and each Review of Donor Chart, physician writes date (Month and year) of next review in spaces provided.
 - 4.4 If donor is not acceptable, clearly document reason for lack of acceptability, whether permanent or temporary and, if temporary, date on which donor may again be considered.
 - 4.5 Appendix
 - 4.5.1 Form 81-9711 - Predonation History

CUTTER LABORATORIES QUALITY ASSURANCE DOCUMENT		Document No.: CSOP 403	Rev.: 2
Date: FEB 14 1983			
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	Prepared By:	GRO-C
Subject:	MEDICAL HISTORY AND PHYSICAL EXAMINATION - FORM NO. 81-9731	Approved By:	GRO-C
		Approved By:	GRO-C

Responsibility: Center Physician

1. General

- 1.1 Donor name, Donor Number, sex, race and birthdate are completed by receptionist. All other entries are made by (or under the direct supervision of) physician.
- 1.2 Specific explanations given below are to be considered as guidelines. In many cases your own medical judgement must prevail.
- 1.3 Note that many items are asked more than once allowing different approaches to be used in eliciting information. The form has been specifically designed to contain this feature at the request of several physicians.

2. Donor Identification.

- 2.1 Name: last name first, comma, first name and middle initial.
- 2.2 Donor Number: consists of 7 figures, a one or two place alphabetic Center Code and a 5 digit number. Use zeros in front of the lower numbers to fill the five spaces (e.g.: AT 00057).
- 2.3 Ideally, donor name and number should be applied with imprinting card. If not possible, use clean, neat printing with block letters.
- 2.4 Sex: circle M or F as appropriate.
- 2.5 Race: circle appropriate symbol C - Caucasian, N - Negro, I - Indian, O - Oriental, L - Latin.
- 2.6 Birthdate: month, day, year.

3. DONOR HISTORY - This section provides opportunity to elicit general information from donor which may be more fully covered later in examination.

- 3.1 Date - write month, day, year in the appropriate column space. Each column is to be used for one examination only.
- 3.2 Occupation - write in occupation. This may give clues to specific areas to be covered in greater detail, e.g.: coal miners - black lung disease; farmers - diseases associated with animals; chemical plant worker - liver damage from industrial solvents, etc. This is also an opportunity to warn those in hazardous occupations (e.g.: operators of power machinery, cranes, drivers of buses, trains, cabs, workers on ladders or scaffolding, airplane

		Sheet 2 of 7	
QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:	
Document Type:	: CSOP 403	: 2	
CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983	

- crews, etc.) not to engage in their occupation for 12 hours after donation or longer if a unit of red blood cells is not returned to them.
- 3.3 Military Service - give dates, was person overseas and ever receive any medical treatment?
 - 3.4 Illnesses and Injuries (Past and Recent) - Is donor currently under a doctor's care? Some specific items are: no donation for 72 hours after dental surgery, two weeks if dental surgery involved infection; no donation for 2 years following recovery from brucellosis (undulant fever), relapsing fever; no donation for 1 year following recovery from infectious mononucleosis; no donation until complete recovery from flu, cold, sore throat, sinusitis or other upper respiratory infections for 1 week.
 - 3.5 Hospitalization - No donation until at least 6 months after major surgery (may have been given transfusion with risk of hepatitis) or until wound from minor surgery has completely healed. Hospitalization for diagnostic procedures or minor treatment usually will not delay donation but may suggest other areas for investigation.
 - 3.6 Medication, Drugs, Alcohol - Medication such as insulin, digitalis, quinidine, nitroglycerin, antihypertensives, anticoagulants, dilantin, thorazine or heavy doses of tranquilizers suggest a donor not be accepted or retained on the program. Recent narcotic addiction, usage of hallucinogens will prevent donor from being accepted. If donor has been six months without drug use and no evidence of hepatitis during that time, donor is acceptable. Recent participation in drug testing programs may suggest a donor not be bled for some period of time. Donation should be deferred until 30 days after cessation of antibiotic therapy. Alcohol habituation may suggest donor not be accepted. Use of drugs such as oral contraceptives, hormones, vitamins, occasional analgesics or low doses of tranquilizers usually will not prevent acceptance into the program. In short, any use of a drug by a potential donor at the time of being examined is reason of non-acceptance of donor for plasmapheresis for that visit.
 - 3.7 Transfusions or Blood Fractions - Following transfusion of whole blood, packed red cells, platelet concentrates, fresh frozen or single donor plasma, cryoprecipitates, fibrinogen, blood coagulation factors (AHF, Factor IX), donation must be deferred for 6 months without any signs or symptoms of hepatitis. Donation need not be deferred following administration of albumin, plasma protein fraction or immune globulin provided use of these items does not point to some underlying chronic disease or recent contact with hepatitis.
 - 3.8 Hepatitis (Disease or Contact) - Any history of hepatitis will prevent donor from entering program. Clinical jaundice from an unproven cause is to be considered as indicative of a positive history of hepatitis. Contact with person who has hepatitis will cause donation to be deferred for 6 months without symptoms of hepatitis. Contact means cohabitation, routine use of the same eating and sanitary facilities.

Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
		: CSOP 403	: 2
	CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	FEB 14 1983

- 3.9 Malaria - Donor must be symptom free and not under current drug therapy for the disease. Donor may be accepted with a past history of malaria (at least 6 months must have elapsed since last drug therapy has been taken) or malaria suppressive therapy or travel in an endemic malaria area.
- 3.10 Convulsions, Coma, Fainting, Epilepsy - All may be causes for non-entrance into program if occurring past infancy. Convulsions in infancy are no barrier to donation.
- 3.11 Immunizations - Any donor with a history of immunization with red blood cells or blood group specific substances will not be accepted in the program. Donations are to be deferred until 2 weeks following smallpox or yellow fever immunizations, 24 hours or until any local reaction subsides following immunization with Salk polio, plague, flu, typhoid, measles, typhus, Rocky Mountain Spotted Fever, cholera, diphtheria or administration of therapeutic animal serums (e.g.: horse tetanus antitoxin).
- 3.12 Tattoos and ears pierced - Donation deferred until 6 months after tattooing and ear piercing with no symptoms of hepatitis.
- 3.13 Blood, Plasma donor (difficulties) - Any adverse reaction (e.g.: DTH or other) may be reason for non-acceptance into the program.
- 3.14 Comments, Pertinent Family History - This space is provided for explanation of any of above items and for comments on such items as recent direct contact with family member who has a communicable disease, any family history of inheritable disease such as bleeding tendencies (hemophilia), etc.

4. REVIEW OF SYSTEMS

This section is a continuation of donor history and provides an opportunity to explore further any areas uncovered in the more general review above. It also provides for an orderly review of donor's past health status.

- 4.1 Allergies - Chronic asthma under current drug therapy is a cause for rejection. Seasonal hayfever, food allergies, drug sensitivities are acceptable if not active at present time and donor is not currently taking antihistamines plus if recovery has been of at least 1 week's duration.
- 4.2 Skin - Unexplained jaundice provides another clue to hepatitis. Recent appearance of brownish, reddish, or purplish lesions, nodular or flat, anywhere on entire body surface could be indicative of AIDS. Chronic eczema, chronic dermatitis, recurring boils may be cause for rejection.
- 4.3 EENT - Dental surgery, chronic tonsillitis or other underlying infections may be cause for deferring donation for a short period. Difficulty with eyes or ears may signify partial sight or hearing.

Document Type: QUALITY ASSURANCE DOCUMENT
CUTTER SYSTEM OF PLASMAPHERESIS

: Document No.: : Rev.:
: CSOP 403 : 2
: Date: FEB 14 1983

- 4.4 Cardiovascular - Rheumatic fever in last year, heart disease, chest pain, shortness of breath, hypertension, hypotension, chronic phlebitis, palpitation, irregular pulse, shifting of apex beat, syncope, may be causes for rejection. Past short episodes of rheumatic fever, pericarditis, heart murmur or thrill, repair of congenital heart defect usually are not causes for rejection.
- 4.5 Pulmonary - Active tuberculosis within past 10 years, shortness of breath especially on exertion may be reasons for rejection. Recovery from any upper respiratory disease should be of at least one week's duration prior to donation.
- 4.6 Gastrointestinal: Jaundice, liver trouble, cirrhosis, ulcers, ulcerative colitis, especially accompanied by recent episodes of gastrointestinal bleeding or black stool, may be cause for rejection.
- 4.7 Genitourinary - Chronic kidney diseases, red blood cells, pus cells or protein in urine may be cause for rejection.
- 4.7.1 Menstrual cycle - should be regular and uncomplicated, frequent excessive bleeding may be cause for rejection.
- 4.7.2 Last menstrual period - month, day, year. Abnormal or excessive bleeding may be reason for rejection. Provides beginning point for question of pregnancy.
- 4.7.3 Pregnancy GPAM - G - gravida, P - para, A - abortion, M - miscarriage. Insert numbers where appropriate. Prospective donor must not be pregnant now and must be 8 weeks after pregnancy no matter how terminated.
- 4.8 Neuromuscular - Seizures, fainting epilepsy, collagen diseases, myasthenia gravis, arthritis if associated with anemia may be cause for rejection.
- 4.9 Skeletal - Recent fractures particularly with open reduction and/or complications, osteomyelitis may be cause for rejection.
- 4.10 Blood diseases - Bleeding tendencies, slow clotting, easy bruising, frequent nose bleeds, chronic anemia, polycythemia, leukemia are cause for rejection.
- 4.11 Comments: This space is provided for explanation of, or further comment on, any of above items.

5. LABORATORY

Results of these tests are available on Donation Record which should accompany donor to physical examination area..

- 5.1 Hematocrit (%) - minimum 38%.

Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
	CUTTER SYSTEM OF PLASMAPHERESIS	: CSOP 403	: 2
		: Date:	FEB 14 1983

5.2 Total Protein (g%) - Minimum 6.0 g%.

5.3 Urine - Negative for protein and sugar.

NOTE: traces of sugar and protein such as from dietary or hydration variability are acceptable.

5.4 Other - Results of any other tests done should be entered here.

5.5 Comments: This space is provided for explanation of or further comment on any of the above items.

6. PHYSICAL EXAMINATION

This section is provided for results of actual observation of donor.

6.1 Date - Write month, day, year in appropriate column space. Each column is to be used for one examination only.

6.2 Vital signs - Results of these observations are available on Donation Record which should accompany donor to examination area. Physician will determine blood pressure. However, if physician repeats the other observations it will provide an excellent opportunity to maintain a continuous check on capabilities of Prep Technicians by comparing physician's findings to those on Donation Record.

6.2.1 Temperature - Minimum 97.6°F., maximum 99.6°F.

6.2.2 Pulse - Must be regular, Minimum 50, Maximum 100.

6.2.3 Respiration - Must be regular, not labored.

6.2.4 Blood Pressure - Systolic 100-150, Diastolic 50-100. Donation can be given with systolic blood pressure up to 200 if approved by physician.

6.2.5 Weight - Minimum 110 lbs. No maximum has been established. Donors of excessive weight should be carefully evaluated for other medical problems and for difficulties in performing venipuncture. Physician should also evaluate recent marked weight loss. If unexplained (e.g.: dieting), may be indicative of some inapparent disease state.

6.2.6 Height - If recorded here does provide a way to examine the height to weight-ratio.

6.3 General Appearance and Nutrition - In addition to the usual meaning of this section, physician should be aware of mental or emotional difficulties presented by donor. Does donor present adequate mental capabilities to understand and to participate in identification of red blood cells? Does donor have sufficient emotional stability to not present a problem in the donor room?

QUALITY ASSURANCE DOCUMENT		: Document No.:	: Rev.:
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	: CSOP 403	: 2
		: Date:	FEB 14 1983

- 6.4 Skin - Note: Jaundice, chronic exzema, chronic dermatitis, boils. Look for unexplained needle marks on both arms or other areas where narcotic administration might be practiced. Examine skin for signs of AIDS.
- 6.5 Head and Neck - Scars indicative of severe head injury.
- 6.5.1 Eyes - Jaundice; narcotic influence; does donor have sufficient vision to participate in identification of red blood cells? If not Donor Donor Card (Form 81-9723) must be conspicuously marked that assistance must be provided. Similar notation must be made in "Comment" section of Form 81-9731. Should donor be required to wear glasses (contact lenses) while participating in identification of red cells?
- 6.5.2 ENT - Note: current infections. Does donor have sufficient hearing to be able to participate in identification of red blood cells?
- 6.5.3 Teeth - Infections or abscesses; does donor have sufficient teeth to be able to obtain a normal diet?
- 6.6 Cardiovascular System - Note: irregular pulse, engorged neck veins, presence, absence or diminution peripheral arterial pulse; deformities of chest, visible cardiac impulses. apex beat and thrill; precordial bulging, auscultation of heart sounds; rhythm, force and quality of sounds; any friction rub or gallop; heart murmur, rate, location, position in cycle, intensity, pitch, effect of change of position and transmission.
- 6.7 Pulmonary System - Note: Any deformities of chest, type of breathing, dyspnea, prolongation of expiration, unequal or diminished movement of either or both sides of chest; cough, stridors or wheezes; vocal fremitus, any dullness to percussion; auscultation of breath sounds, rhonchi, rales, crepitation, friction rub, wheezing or diminished air entry.
- 6.8 Abdomen - Note: size and contour, visible peristalsis, respiratory movement, distended veins, tenderness and rigidity, shifting dullness, tympany, rebound tenderness and fluid waves; palpable organs (to be performed with donor lying down), liver, spleen, kidneys or masses, abdominal bruit, bowel sounds.
- 6.9 Genitourinary - Exclude chronic kidney disease or kidney enlargement detected by abdominal palpation. Female donors: Examine for engorged or lactating breast, change of color of areola, uterus enlargement etc., which may point to pregnancy or recent period of post-partum.
- 6.10 Neuromuscular - Note: Cerebral function, general behavior, level of consciousness, emotional status, orientation, ability to understand and follow instructions; cranial nerve function; motor system function, reflexes. Some test for neuromuscular function other than eye response to light must be performed.

Document Type:	QUALITY ASSURANCE DOCUMENT	: Document No.:	: Rev.:
		: CSOP 403	: 2
	CUTTER SYSTEM OF PLASMAPHERESIS	: Date:	: FEB 14 1993

- 6.11 Skeletal - Note: casts, scars due to open reduction of fractures.
- 6.12 Lymphatic System: Enlarged or tender cervical, axillary, supratrochlear or inguinal lymph nodes could be indicative of AIDS.
- 6.13 Comments: This space is provided for explanation of or further comment on any of the above items.

7. ACCEPTANCE

- 7.1 Plasmapheresis Donor - Write yes or no. DO NOT use checks, pluses, dashes, minuses or other symbols. Symbol O.K. is acceptable.
- 7.2 Reason if rejected - If the answer is no, a short simple statement of the reason should be given here.
- 7.3 For Hyperimmunization - List the types of toxoids or vaccines which the donor is eligible to receive. This can be done most easily by giving the plasma type, e.g.: T.P. etc.
- 7.4 Rejected for Hyperimmunization - List the types of toxoids or vaccines which the donor is NOT eligible to receive. This can be done most easily by giving the plasma type, e.g.: T.P. etc.
- 7.5 Comments: This space is provided for explanation of or further comment on any of above items.
- 7.6 M.D. - This space is provided for the signature of the physician performing the Medical History and Physical Examination. No rubber stamps are permissible for signatures or initials.

8. Appendix

- 8.1 Form 81-9731 - Medical History and Physical Examination

NAME:

ID NUMBER:

SEX M F

RACE C N I O L

BIRTHDATE

MEDICAL AND PHYSICAL EXAMINATION

DONOR HISTORY

	DATE				
Occupation					
Military Service					
Illnesses and Injuries (Past and Recent)					
Hospitalizations					
Medications, Drugs, Alcohol					
Transfusions or Blood Fractions					
Hepatitis (Disease or Contact)					
Mal					
Concussions, Coma, Fainting, Epilepsy					
Immunizations					
Tattoos					
Blood, Plasma Donor (Difficulties)					
COMMENTS, Pertinent Family History:					

REVIEW OF SYSTEMS:

Allergies					
Skin					
EENT					
Cardiovascular					
Pulm					
Gastrointestinal					
Genitourinary					
1. Menstrual Cycle					
2. Last Menstrual Period					
3. Pregnancy G P A M					
Neuromuscular					
Skeletal					
Blood Diseases					
COMMENTS:					

LABORATORY

Hematocrit (%)					
Total Protein (gm. %)					
Urine					
Other					
COMMENTS:					

PHYSICAL EXAMINATION

Vital Signs	DATE				
a. Temperature					
b. Pulse					
c. Respiration					
d. Blood Pressure					
e. Weight					
f. Height					
General Appearance & Nutrition					
Skin					
Head and Neck					
a. Eyes					
b. ENT					
c. Teeth					
Cardiovascular System					
Pulmonary System					
Abdomen					
Genitourinary					
Neuromuscular					
Skeletal					

COMMENTS:

Lymphatic System (rubber stamp on form)

ACCEPTANCE

Plasmapheresis Donor					
Reason if Rejected					
For Hyperimmunization					
Rejected for Hyperimmunization					
COMMENTS:					

