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CUTTER LABORATORIES, INC. QUALITY ASSURANCE DOCUMENT		Sheet 1 of 7
Document Type:	CUTTER SYSTEM OF PLASMAPHERESIS	: Document No.: : Rev.: : CSOP 403 : N/C : Date: DEC 05 1981
Subject:	MEDICAL HISTORY AND PHYSICAL EXAMINATION - FORM NO. 81-9731	: Prepared By: GRO-C : Approved By: GRO-C : Approved By: GRO-C

Responsibility: Center Physician

HISTORY

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

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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, diltatin, 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.

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- 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. 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.
- 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.

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- 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 6 months 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%.
- 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.

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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?
- 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.

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- 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.
- 6.11 Skeletal - Note: casts, scars due to open reduction of fractures.
- 6.12 Comments: This space is provided for explanation of or further comment on any of the above items.

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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

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