Treasury in 1968 for volunteers who were being immunised to provide anti-D immunoglobulin, and was subsequently approved for application to the proposed bone-marrow donor panel. BTS Directors regard the existence of the scheme as a great asset in reassuring prospective donors hesitant about the domestic financial consequences of an accident; and it is fair to say that as a Department we would be bound to have reservations about exposing the NHS volunteers to the more risky procedures without a financial safety net for them and their families. The Pearson Commission will doubtless have some relevant recommendations, but we do not wish to delay issue of the code of practice while Pearson is digested; the compensation scheme could be amended at a later date if necessary.

4. We propose that consultation on the HN and report should be primarily with professional bodies. Our draft list consists of:

Royal College of Physicians
Royal College of Pathologists
Joint Consultants Committee
Medical Defence Societies
British Society of Haematology
Royal College of Nursing
Staff Side of the General Whitley Council

Perhaps RL5 would advise whether or not the draft HN should be subjected to the consultation process with health authorities. The report and code of practice will also be shown to SMAC and SNMAC for their endorsement.

5. I would welcome any comments you may have on this proposed course of action by /3 weeks' time/. Although we would prefer to keep the HN brief, we will gladly consider the inclusion of any additional points which a reading of the report and code suggests to you. You will have a particular interest in:

HN paras Report paras Code paras

To avoid duplication, this minute is being sent to administrative branches only, and I would be glad if your reply could therefore take account of the views of professional colleagues where appropriate.

JW

(87)

DRAFT [22.12.77]

HEALTH NOTICE HN(78)CS

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

TO: Area Health Authorities) for action
Boards of Governors)

Regional Health Authorities) for information
Community Health Councils)

[December 1977]

HEALTH SERVICES MANAGEMENT

THE CLINICAL USE OF BLOOD CELL SEPARATORS

SUMMARY

This notice anounces the publication of a code of practice for the clinical use of blood cell separators.

INTRODUCTION

1. The enclosed booklet contains the report of an expert working party established by the Department to prepare a code of practice for the clinical use of blood cell separators. The code of practice, which has been endorsed by the Standing Medical Advisory Committee and the Standing Nursing and Midwifery Advisory Committee, is appended to the report.

EXPENSES OF DONORS

2. The Department agrees with the recommendation, in paragraph 6 of the report, that cell separator donors should not suffer financial loss. Authorities are therefore free to adopt the recommendations in sub-paragraphs 6a - c of the report, with the proviso that any payments in respect of travelling expenses or loss of earnings should not exceed the levels authorised for members of health authorities.

CLAIMS FOR COMPENSATION

3. In the event of a claim being received from a donor (or a donor's relatives) for compensation from public funds for any injury or loss allegedly suffered as a result of donation by cell separator (sub-paragraph 6 d of the report), authorities should be guided by the procedure set out in the annex to this notice.

ACTION

4. Authorities are asked to draw the attention of staff currently working with cell separators to the report and code of practice: additional copies of the booklet are available from Room 1217, Hannibal House.

From:

Health Services Division 2A

Hannibal House

Elephant and Castle

LONDON SE1 6TE

Tel: 01-703 6380 Ext (3411)

H1/B17/3

ANNEX TO HN(78)CS

COMPENSATION FOR CELL SEPARATOR DONORS (PARAGRAPH 3 OF HN (78)CS)

1. Where the claim arises from an incident involving negligence on the part of the authority's staff, the general rules for handling such cases will apply. These are set out in HM(55)66 and DS200/75, to be read in conjunction with RHB(49)128 and HM(54)32.

2. In cases where negligence is not proven, an ex gratia payment will often be appropriate. Although authorities have discretion to make ex gratia payments of up to £1,000 without reference to the Department, this arrangement does not apply in cases involving personal injury. Accordingly, any claims for compensation from a cell separator donor, or from the donor's family, where an ex gratia payment appears to be appropriate should be referred promptly to the Department. In these circumstances the Department will appoint a panel of assessors - a lawyer from the Department's Solicitor's Office, a Regional Transfusion Director (other than the Director for the Region in which the claim arose), and a doctor from the Civil Service Department Medical Service - to advise on the claim.

X40

A CODE OF PRACTICE FOR THE CLINICAL USE OF BLOOD CELL SEPARATORS

REPORT OF THE WORKING PARTY

1. The Working Party was set up in December 1975 by the Department of Health and Social Security, in collaboration with the Scottish Home and Health Department and the Welsh Office. Its terms of reference were:

> "To prepare a code of practice for the use of blood cell separators with particular reference to the interests of donors".

The Working Party met on 4 occasions, and its membership was as follows:

Dr W d'A Maycock CBE MVO MD FRCP FRCPath (Chairman)
Dr I W Delamore PhD MB ChB FRCPE FRCPath
Dr J M Ford MB BS MRCP
Dr J M Goldman BM BCh MRCP
Dr A B Kay PhD MB ChB MRCP FRCPE
Dr H E M Kay MD FRCP FRCPath
Dr R Powles BSc MB BS MRCP
Dr Barbara C Roberts BSc MB BCh FFARCS
Miss M C Schurr SRN NAdmin Cert RCN
Dr F Stratton DSc MD FRCP FRCPath
Dr W Wagstaff MB ChB MRCPath
Dr M L N Willoughby MA MD FRCPath
Mr R P Cleasby) (Joint Secretaries, Department of Health and Social
Dr Alison Smithies) Security)

This report briefly reviews the background to the need for a code of practice and makes certain recommendations to the Health Departments.

2. The support of patients with aplastic anaemia and certain neoplastic disorders involves the transfusion of platelets and sometimes also of leucocytes. Over the last 20 years, the cell separating centrifuge (cell separator), necessary to collect platelets and leucocytes in sufficient numbers for effective transfusions, has been developed and is now being increasingly used in clinical practice. The equipment is based upon centrifugal separation of blood into plasma, buffy coat and packed red cells and can also be employed to perform plasmapheresis or plasma exchange.

The value of platelet suspensions for supportive therapy in thrombocytopenic patients, and the advantages of lowering plasma viscosity and of collecting special plasma are well-established; on the other hand the value of transfusion of white cells and of plasma exchange and the possible complications which may occur in patients so treated clearly need critical assessment before this equipment is widely applied. Because of the growing use of this equipment to obtain various components of blood from normal blood donors and because of the hazards, although apparently infrequent, associated with this technique, a working party set up to advise on the formation of a Bone-marrow Donor Panel recommended that the Health Departments should arrange for the preparation of a code of practice on the use of cell separators.

3. Because there were insufficient data available to the Working Party, it has concluded it should not make specific recommendations about using cell separators for plasmapheresis of the normal donor. There is therefore no reference to the use of the apparatus for this purpose in the Code. However, if it is decided to use the cell separator for this purpose, the recommendations in the Code should be observed and the volume of plasma removed by the manual technique (ie up to a total volume of 15 litres of plasma per annum and not more than 600 ml at each session) should not be exceeded.

4. The Working Party recommends that a cell separator should not be brought into use unless it has been ascertained that the means of carrying out all the recommendations contained in the code of practice (ie staff, accommodation, revenue expenditure, and transfusion supplies) are available. "Short cuts" in the operation of a unit put donors at risk.

5. The Working Party has not thought it appropriate that the Code of Practice should contain guidance on staff training in any greater detail than that included in Section 11, but the possibility of devising standard courses of formal training might usefully be considered by those responsible in conjunction with suitable educational bodies.

6. Cell separator donors should not suffer financial loss. The Working Party therefore recommends that the Health Departments should authorise health authorities to:

a. provide transport for donors between their homes and the unit where the cell separator is sited;

b. reimburse reasonable travelling expenses of donors, when transport is not provided;

c. reimburse any loss of earnings, if the donor's employer is unwilling to continue remuneration during any period of absence for attendance at the cell separator unit;

d. consider sympathetically and decide promptly any claim by a donor for compensation for any injury or loss allegedly attributable to having given blood (as one of the formed elements or as plasma) by cell separator and further, in considering any such claim, to use the procedure accepted by the Departments for dealing with claims arising from the deliberate immunisation of Rh negative male volunteers with Rh(D) antigen.

As a corollary to (d), it is recommended that (when the risks attaching to donation by cell separator have been defined) the Departments should if thought necessary approach the Association of Life Offices to seek an assurance that cell separator donors will not be placed under any disadvantage in respect of their current assurance policies or of any new policies they may propose.

7. The code of practice drawn up by the Working Party is attached.

December 1977

JKM

A CODE OF PRACTICE FOR THE CLINICAL USE OF BLOOD CELL SEPARATORS

INTRODUCTION

1. This code of practice provides guidance for using blood cell separators in NHS hospitals and other medical units. The code proposes a classification of donors, makes recommendations regarding their selection, medical examination and care and the procedure for obtaining informed consent. The code also contains information about the use and care of this equipment, the frequency of use necessary to maintain a high standard of proficiency, the hazards associated with its use, the numbers, grades and training of staff and the physical and special resuscitation facilities which must be present if it is decided to install and operate a cell separator. Many of the recommendations apply equally when cell separators are used in the course of treating patients.

PART I: SELECTION AND CARE OF DONORS

2. RECRUITMENT AND EXAMINATION

2.1 Group 1 Unrelated donors should be recruited from the National Blood Transfusion Service donor panels. To be admitted to the panel of donors for cell separators maintained at a Regional Transfusion Centre (RTC), these volunteers must satisfy the criteria with certain exceptions (see below) for the selection and medical examination of normal blood donors (see Appendix I). The donor should be aged between 18 and 60 years, should have given at least 3 donations and should weigh not less than 60 kg if an intermittent flow cell separator is used unless the small bowl is available. Requests for unrelated donors must be made to the Regional Transfusion Director.

Group 2 Unrelated specially motivated donors, such as friends or colleagues of the recipients; also in this group are persons who volunteer in response to a public appeal in a specific case. Persons who volunteer in this way usually do so direct to the hospital making the appeal. Such volunteers should be supervised by the director of the cell separator unit and should satisfy the same criteria as volunteers in Group 1. When their assistance is no longer required for the specific case for whom they volunteered, their names should be sent to the appropriate Regional Transfusion Centre, if they are interested in continuing as cell separator donors.

Group 3 Donors related to the recipient.

Group 4 The patient acting as a donor.

2.2 Before a volunteer in any of these groups is enrolled as a member of a cell separator donor panel his general practitioner should preferably be consulted.

2.3 The volunteer should be fully informed about the procedures he will undergo and the risks incurred when giving a donation by cell separator. A written statement of his informed consent should then be obtained, and a standard form for this purpose is at Appendix IV. If subsequently there is a delay before the volunteer is called upon, the explanation of the procedure should be repeated and the donor invited to give a further written statement of consent.

2.4 Immediately before donation by cell separator the donor should be examined by the director of the unit or by a deputy appointed by him. The following examinations should be carried out unless these have already been performed and repetition is considered unnecessary:

Blood grouping (ABO and Rh)) HLA typing (when indicated))	Normally previously carried out at the RTC

PC

HBsAg)
Syphilis test) Normally previously carried out at the RTC
Temperature, pulse, blood pressure
Red, white cell and platelet count
Prothrombin and partial thromboplastin tests
Total plasma proteins and immunoglobulins
Electrocardiogram (in donors over 40 years of age)
Chest X-ray (if steroids are to be given, and a film taken within the previous 2 years is not available)

2.5 It is recommended that the choice of drugs and other substances given to donors should be restricted and that normally only the following should be used. The agreement of the doctor who examined the donor (para 2.4) should be obtained.

Acid citrate dextrose
Heparin
Steroids
Dextran
Hydroxyethyl starch
Modified fluid gelatin

As experience grows this list may need modification. Although there is no evidence that small doses of corticosteroids over short periods are harmful, they nevertheless should be used with care. Records of cumulative dosage should be kept for each donor. When complications develop during the procedure, any other drugs (eg protamine) may be used at the discretion of the consultant in charge of the cell separator unit or his deputy.

2.6 Donors should not be asked to give donations of white cells or platelets by cell separator more often than 12 times per year. It is recommended that on no occasion should the platelet count be reduced below 100 x 10^9/l. When a cell separator is used for plasmapheresis the amount of plasma removed from the donor should not exceed 600 ml on any one occasion or 15 litres annually.

2.7 Extreme care should be taken to ensure that unrelated specially motivated donors (Group 2) are not placed in a position where it is difficult for them not to continue giving further donations although they wish to stop.

2.8 Donors should be seen by a doctor from the cell separator unit, before leaving after giving a donation, in order to ensure fitness to resume normal activities.

2.9 Donors who give the recommended maximum amounts of plasma or cells annually should be given a full medical examination (including appropriate laboratory tests) once a year by an independent clinician.

2.10 Related donors (Group 3) should normally be treated in the same way and with the same safeguards as unrelated donors. In certain circumstances however the director of a cell separator unit may consider that there are good reasons for modifying these criteria, eg the donor may suffer from a condition which would normally exclude him but because of extreme motivation and the clinical needs of the recipient the donor may be willing to accept the additional risks involved. In such circumstances the donor must be made fully aware of these additional risks and every effort should be made to reduce emotional pressure upon him. Highly motivated parents should be persuaded to recognise their

are related +

Still wrong! - even more wrong!

responsibility to their spouse and other healthy children. Although [related] donors under 18 years of age should not normally be considered, nevertheless, if they have the capacity to understand what is being asked of them, then it would be possible to consider their recruitment, but the doctor or doctors concerned should take legal advice in each instance.

2.11 When the donor is a patient who is unlikely to benefit from the removal of cells this fact must first be explained. The clinical and laboratory criteria required for normal donors will probably have to be modified for these patients, who should be made fully aware of the risks involved.

PART II: USE AND HAZARDS OF CELL SEPARATORS

3. CELL SEPARATORS

3.1 Two types of cell separator are available at present. Brief details of the 3 models are given in Appendix II. Two of the models operate on a continuous flow principle and the third on the intermittent flow principle, thus placing differing demands on the donor. The 2 types are designed to meet different needs.

3.2 A cell separator should only be purchased when the equipment is to be used regularly and frequently, ie at least twice a week, so that the staff concerned can reach and maintain a high standard of proficiency in the operation and the care of this equipment.

3.3 Prospective buyers should consult the Scientific and Technical Branch, Supply Division, Department of Health and Social Security, 14 Russell Square, London WC1B 5EP or (in Scotland) Supplies Division, Common Services Agency, Trinity Park House, South Trinity Road, Edinburgh EH5 3SH, about cell separators, particularly for information relating to electrical safety.

4. BOWLS, PORTS AND HARNESS

4.1 Continuous flow separators are fitted with a re-usable centrifuge bowl and seal. The bowl consists of an outer shell, an inner core, and a transparent cover made of polycarbonate. The seal consists of an alumina ceramic bottom seal seated on 4 concentric silastic O rings fitted to the bowl and a stainless steel top seal fitted to the cover which is held stationary when the bowl rotates, and to which the tubing sets are attached. After each procedure, the bowl and complete seal assembly should be cleaned according to the manufacturer's instructions and then sterilized. Both the cleaning and sterilization processes should be strictly controlled in order to achieve the maximum life of the polycarbonate components. These should be inspected after each run for signs of deterioration (eg scratches, cracks) and in particular for crazing, in which case the component must be replaced because effective sterilization is then impossible. Further guidance on sterilization procedures is given in Appendix III.

4.2 The bowl for the intermittent flow cell separator and the harness for all 3 models are disposable and must not be re-used.

4.3 Apart from those items which can be removed, for cleaning and sterilization or those which are disposable, the working surfaces of the separator must be cleaned after each procedure with a disinfectant, eg a phenolic compound, glutaraldehyde.

5. SERVICING

5.1 Separators should be serviced in accordance with the manufacturer's instructions. A planned maintenance scheme should be followed.

5.2 If servicing of the separator is to be undertaken by a member of the staff of the Medical Physics or other hospital Department, he should have been trained in the full servicing procedure under arrangements made with the manufacturer.

5.3 The telephone number of any person(s) who would need to be contacted in the event of a mechanical failure of the separator should be immediately available.

5.4 Staff using and servicing the separator should be acquainted with the manufacturer's instructions.

6. HAZARDS AND MONITORING

6.1 All staff working with cell separators must be aware of the complications which may arise during use of the separator so that rapid corrective or preventive action can be taken. Such hazards include: tachycardia, anoxia, cardiac failure and arrest, haemorrhage, haematoma and haemolysis, venous thrombosis, electrolyte imbalance, allergic reactions, air embolus, and electric shock. Delayed complications may also occur, such as septicaemia and hepatitis. In the event of a mechanical defect developing in the separator, the procedure must be stopped immediately.

6.2 The donor must be kept under constant observation to detect early indications of any adverse reaction. As a minimum the following measurements should be made during the procedure:

a. temperature:)
b. pulse:) to be taken regularly throughout the procedure;
c. blood pressure: at least before and after the procedure.

A continuous cardiac monitor is used in some units so that, should an adverse reaction occur, the apparatus is ready to monitor the condition of the donor.

6.3 A constant watch must be kept to ensure that the donor's veins do not become occluded, that all lines remain patent and free of air bubbles and that anticoagulant and lubricating fluid reservoir contents are maintained at a safe level.

6.4 The use of cell separators is still undergoing evaluation. It is therefore most important that complete records, particularly of adverse reactions in donors or mechanical incidents involving separators, should be kept.

7. ANTICOAGULANTS

7.1 Anticoagulants are necessary to maintain blood flow during the use of cell separators. Heparin and ACD solution are the 2 anticoagulants used at present. The intermittent flow separator is usually operated with ACD.

7.2 Protamine may occasionally be necessary to reverse the action of heparin. See paragraph 2.5

8. FILTRATION LEUCAPHERESIS

8.1 Granulocytes may be collected by filtration alone. A filtration kit may be used by attaching it to a circuit consisting of a pump, an occluded vein sensor and a bubble trap of any one of the machines. A more simple circuit in which only a pump is incorporated may also be used.

8.2 Granulocytes retain sufficient activity after elution from the filters to be effective in vivo. It is recommended that the volume of eluting plasma/ACD mixture should be limited to one litre and the granulocytes should be eluted without tapping the filters. The filter should not be reversed in the flow line in order to wash entrapped red cells back into the donor after collecting granulocytes.

8.3 Experimental evidence suggests that the nylon fibres of the filter may activate complement. The use of this method and its effect on donors must, therefore, be carefully monitored.

PART III: ACCOMMODATION AND STAFFING OF CELL SEPARATOR UNITS

9. ACCOMMODATION

9.1 CELL SEPARATORS MUST ONLY BE USED IN PLACES WHERE A CARDIAC ARREST TEAM IS IMMEDIATELY AVAILABLE SHOULD A DONOR COLLAPSE DURING DONATION. The most suitable site for a unit is considered to be an area which is part of or adjacent to a ward or an intensive therapy unit, but other sites which meet this requirement are acceptable.

9.2 A minimum area of 18 to 20 m^2 to accommodate the cell separator during use is recommended. In addition a changing area with washing facilities for staff, a changing area for donors and accommodation for their care during the recovery period are necessary. There should be arrangements for providing donors with meals and refreshments.

10. STAFFING OF UNITS

10.1 A consultant, fully experienced in the operation of cell separators, must be in charge of the unit and responsible for the health and welfare of donors and for the observance of this Code of Practice. He or a medical deputy appointed by him must be present at the beginning of each donation. A doctor must then remain within immediate direct call until the donation is complete and he should be present at the end of the procedure.

10.2 The donor should never be left in the room without the presence of a State Registered Nurse† or a doctor. The actual procedure should be carried out by a team of 2 trained personnel (see paragraph 11.1) one of whom should be a SRN. These 2 should normally be with the donor throughout a donation.

11. TRAINING OF STAFF

11.1 All members of the staff of the cell separator team must receive formal training either in their own or in another established unit. The director of each unit must be responsible for arranging, with those concerned (eg the head of the nursing services), the training of his staff.

11.2 The director of the unit must satisfy himself that the necessary training has been completed before allowing staff to carry out the procedure and should sign a statement to this effect. This is necessary in view of the fact that a SRN is personally liable in law for his/her actions. The employing authority should be made aware, through the District Nursing Officer*, that these nurses are undertaking duties outside their normal province and should be provided with a list of these duties.

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† In Scotland, a registered nurse.

* In Scotland and Wales, and in single-district Areas in England, other arrangements may apply.

11.3 Training should include instructions in the selection of donors, in all aspects of the operation and the various uses of cell separators, the associated hazards and the action to be taken in the event of possible or actual harm occurring to the donor.

Appendix I

The Memorandum on Selection, Medical Examination and Care of Donors has recently been revised by Regional Transfusion Directors. Final copies of the Memorandum are not yet available.

	CELL SEPARATING CENTRIFUGES			FILTRATION LEUCAPHERESIS
Manufacturer	Haemonetics Corporation 8 Erie Drive Natick, Mass., USA	American Instrument Co Silver Spring Maryland, USA	International Business Machines Inc. Eddnicott New York, USA	Travenol Laboratories Ltd Thetford Norfolk England
Operation				
Average collection time *+	2-3 hours	3-5 hours	3-5 hours	2-2½ hours
Average blood processed *	4 l.(large bowl)	8-10 l.	8-10 l.	8-10 l.
Average yield per** litre (l.)processed	1-3 x 10^9	0.5-2.0 x 10^9	0.5-2.0 x 10^9	3-4 x 10^9
Efficiency				
(a) Plateletpheresis	(a)3-4 x 10"(using 375 ml bowl x 4 or 225 ml bowl x 6).	(a) Not very satisfactory	(a) Not very satisfactory	(a) Not applicable
(b) Plasmapheresis	(b) Effective	(b) Effective	(b) Effective	(b) Not applicable
		Donors without red cell packing agent (dextran, HES)		
(c) Leucapheresis				
(i) Total leucocytes	(i) 8 x 10^9	(i) 10 x 10^9	(i) 10 x 10^9	(i) 20-30 x 10^9
(ii) Total granulocytes	(ii) 3 x 10^9	(ii) 2-10 x 10^9 (1-5 x 10^{11} from CGL)	(ii) 2-10 x 10^9 (2-7 x 10^{11} from CGL)	
		Donors with red cell packing agent		
(d) Leucapheresis				
(i) Total leucocytes	(i)16 x 10^9	(i) 20 x 10^9	(i) 20 x 10^9	
(ii) Total granulocytes	(ii) 7-13 x 10^9	(ii) 5-20 x 10^9	(ii) 5-20 x 10^9	

A replaceable bowl and harness for the Aminco machine (and therefore for the IBM machine) is currently being designed.

SOURCE: Dr G H Tovey, with additional information from Dr J M Goldman and Dr R Powles.
Operation data from Dr S J Urbaniak (Edinburgh and S E Scotland Blood Transfusion Service)

NOTES: * depends on donor blood flow: 40-60 cm3/min would be reasonable flow rates to achieve for CFC but higher rates are possible with filtration leucapheresis and Haemonetics
** values obtained with red cell packing agents (Haemonetics, Aminco and IBM) or steroids (Filtration)
+ time of donor "processing" only: does not include setting-up and dismantling time.

Appendix II

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APPENDIX III

STERILIZATION OF REUSABLE BOWL ASSEMBLIES FOR BLOOD CELL SEPARATING CENTRIFUGES

1. Stress cracking and surface crazing appear in the polycarbonate centrifuge bowl components after they have been in use for some time. This presents both a haematological and microbiological hazard to the patient.

2. A major factor in the cracking of these components is the differential expansion between the surface and interior when a material of low thermal conductivity and low tensile strength is rapidly heated, as would occur during a sterilizing process.

3. It is recommended that the centrifuge bowl components are processed in a sterilizer modified from one conforming to the requirements BS 3970: Part 1: 1966: 'Sterilizers for Porous Loads', by adopting a time and temperature relationship during the sterilizing stage of the cycle suitable for the material. This is changed from that in the Standard, 134 + 4 - 0°C for 3 minutes, to 121 + 2 - 0°C for 30 minutes. It should be noted that paper may be unsuitable for wrapping these components. Consequently to ensure satisfactory storage conditions and adequate penetration of steam during sterilization, a purpose made container should be used. eg a dressing drum to BS 3281:1960 requirements. Preheating the components slowly to about 80°C prior to sterilizing helps to reduce cracking and incidently aid the production of dry loads following sterilization. A suitable slow heating source would be a bottled fluid warming cabinet to BS 5076: 1974 which is to be found in most operating theatres.

4. It is important that the centrifuge bowl and components are carefully inspected after each treatment for signs of cracking. If ANY cracking is observed the component must be discarded after rendering it unfit for further use.

5. The use of any method of sterilization other than steam is NOT recommended.

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APPENDIX IV

DONOR CONSENT FORM (CELL SEPARATORS)

1. I .....
(full name)

of .....
(full address)

acknowledge that the nature and purpose of donation by means of a cell separator and the risks involved to the donor have been explained to me by Dr .....*

I volunteer to donate blood by means of a cell separator and for this purpose I agree to undergo a physical examination which will also involve giving a sample of my blood. I also agree that my general practitioner may be consulted about my fitness to donate by means of a cell separator.

Signature of volunteer donor .....

Date .....

Signature of witness .....

2. I have explained to the above named volunteer donor the nature and purpose of blood donation by cell separator and the risks involved.

Signature of doctor .....

Date .....

Signature of witness .....

* The explanation must be given by a medical practitioner.