Overview
WMDA accreditation

1. Objectives and Benefits for a Registry

2. How a grafting physician, requesting JACIE accreditation could benefit from Registry WMDA accreditation

C. RAFFOUX
France Greffe de Moelle
French Registry of Bone Marrow Donors

Bucharest April 30, 2012

WMDA accreditation
General objectives

1. Improve quality of patients outcome

   - Find for a maximum number of patients the most compatible donor (HLA, age, sex, CMV…)

WMDA accreditation
General objectives

2. Define standards based on consensus of Registry experts regarding donor search process

   - Standards adapted to the reality of a Registry
   - Standards based on long term experience
   - Standards dedicated to an optimal management

Scope of WMDA Standards

- General organization of Registry
- Donor recruitment
- Donor characterization
- Information technology
- Facilitation of search requests
- Second / subsequent donations
- Collection / processing / transport of stem cells
- Follow-up of patient / donor
- Financial / legal liabilities

WMDA accreditation
General objectives

3. Demonstrate quality of the Registry and adherence to guidelines

WMDA accreditation
Objectives toward search process

4. Guarantee the quality and timeless of all steps of the donor search process

   - From preliminary information of volunteer donors by Donor Centres
   - Up to HSC collection and follow-up of donor/patient

5. Obtain the most suitable donor while protecting the donor's health

WMDA accreditation objectives

6. Guarantee the quality of information provided to volunteer donor

- Experienced staff :
  - Specialized in donor wellcoming and selection
  - Regularly trained
  - Respectful of anonymity
  - Aware of HSC donation contra-indications

WMDA accreditation objectives

7. Guarantee the quality of Donor characterization

- HLA characterization
  - By accredited laboratories (EFI, ASHI…)
  - Well defined level of HLA typing

- Infectious disease markers (GP laboratories)

Benefits of accreditation for a Registry

1. Regular update of the Operation manual, made available at national and international level

   - Standardized procedures for wellcoming donors in Donor Centre (DC) at all stages
     - At the registration stage
     - At the complementary tests stage
     - At the selection stage
   - Standardized and updated medical questionnaire

Benefits of accreditation for a Registry

2. Development of DC accreditation process

   - To make sure that all Donor Centers do follow the WMDA standards
   - To be able to follow all changes in DC organization

Benefits of accreditation for a Registry

3. Respect of delays for :

- Results of complementary testing
- Blood sample shipment
- Payment of invoices

Benefits of accreditation for a Registry

4. Organization of Registry in different departments :

   - Medical
   - Information system
   - Administration and finance

   with well defined duties and responsibilities of each of them

Benefits of accreditation for a Registry

5. Continuing education
   - for the Registry staff
   - for physician recruiting donors

Benefits of accreditation for a Registry

6. Contracts between all partners of search process

- Describing responsibilities, and duties of each key personnel
- Checking how compliance is monitored over time

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JACIE

Joint accreditation Committee of Isct Europe
International Society for Cellular Therapy

Goals of JACIE Accreditation

1. Improve the quality of patients care
2. Improve collection procedures and transformation of blood products
3. Improve organization and connection between the three fields of competence : clinics, collection, processing and storage

JACIE

B6.000

Donor evaluation, Selection and Management

B6.110

There must be written criteria for donor evaluation and selection

WMDA

3.05

Requirements for Donor health affecting eligibility of donors must be established

1. Medical questionnaire
2. IDM results

QUESTIONNAIRE D'APTITUDE MEDICALE AU DON DE CELLULES SOUCHES HEMATOPOIETIQUES LORS DU RECRUTEMENT FINAL DU DONNEUR

STEM CELL DONOR HEALTH HISTORY QUESTIONNAIRE FOR USE AT TIME OF WORK-UP

RÉPONSES SUSCEPTIBLES DE PRÉSENTER UNE CONTRE-INDICATION FORMELLE

ANSWERS LIKELY TO LEAD TO A FORMAL DONATION CONTRA-INDICATION

Une réponse positive chez un donneur RECRUTÉ ou susceptible de l'être rapidement (sollicité pour envoi d'échantillons sanguins) nécessite l'avis d'un anesthésiste et/ou de la direction médicale de FGM.

Any positive answer concerning a pre-selected (CT) or FORMALLY RECRUITED stem cell donor requires to get the advise of the anaesthetist and/or of the FGM medical department.

PATHOLOGIES CARDIO-VASCULAIRES
CARDIO-VASCULAR PATHOLOGIES

Affections cardiaques sévères ? OUI / *YES* ☐ NON / *NO* ☐
Severe cardio-vascular diseases ?

Tension artérielle habituelle élevée ? OUI / *YES* ☐ NON / *NO* ☐
Chronic high blood pressure ?

Antécédents de phlébite ? OUI / *YES* ☐ NON / *NO* ☐
Past history of phlebitis ?

Antécédents d'embolie pulmonaire ? OUI / *YES* ☐ NON / *NO* ☐
Past history of pulmonary embolism ?

Antécédents familiaux répétés de / *Family repeated history of :*
- phlébite / *phlebitis ?* OUI / *YES* ☐ NON / *NO* ☐
- d'embolie pulmonaire / *pulmonary embolism ?* OUI / *YES* ☐ NON / *NO* ☐

PATHOLOGIES BRONCHO-PULMONAIRES
BRONCHO-PULMONARY PATHOLOGIES

Asthme / *Asthma ?* OUI / *YES* ☐ NON / *NO* ☐

Insuffisance respiratoire chronique ? OUI / *YES* ☐ NON / *NO* ☐
Chronic pulmonary insufficiency ?

PATHOLOGIES METABOLIQUES
METABOLIC DISORDERS

Déficit héréditaire enzymatique ? OUI / *YES* ☐ NON / *NO* ☐
Inherited enzymatic deficiency ?

Accouchement depuis moins de 6 mois ? OUI / *YES* ☐ NON / *NO* ☐
Delivery since less than 6 months ?

Séjour de plus d'un an cumulé dans les îles Britanniques entre 1980 et 1996 ? *Cumulated stay over than one year in the British Islands between 1980 and 1996 ?* OUI / *YES* ☐ NON / *NO* ☐

Comportement à risque dans les 12 derniers mois ? (partenaires multiples, homosexualité, emprisonnement, piercing, toxicomanie, tatouage…) *At risk behaviours during the past 12 months ? (multiple partners, homosexuality, imprisonment, piercing, drug addiction, tattoo…)* OUI / *YES* ☐ NON / *NO* ☐

REPONSES REPRESENTANT UNE CONTRE-INDICATION RELATIVE

ANSWERS REPRESENTING A RELATIVE CONTRA-INDICATION

(à discuter / *to be discussed)*

Affections de la cage thoracique / *Ribcage affections ?* OUI / *YES* ☐ NON / *NO* ☐

Affections de la colonne vertébrale / *Vertebral column affections ?* OUI / *YES* ☐ NON / *NO* ☐

Surcharge pondérale / *Overweight ?* (25 < IMC ≤ 30) OUI / *YES* ☐ NON / *NO* ☐

Anomalies de la filière ORL et du cou / *Neck and ENT abnormalities ?* OUI / *YES* ☐ NON / *NO* ☐

Difficultés d'abord veineux (CSP) / *Difficult veinous access (PBSC) ?* OUI / *YES* ☐ NON / *NO* ☐

QUESTIONS DIVERSES
OTHER QUESTIONS

Antécédents anesthésiques ? si oui, précisez la date : ___ / ___ / _____ et la raison : ……
Anaesthetic past history ? if yes, precise the date : ___ / ___ / _____ and the reason : …… OUI / *YES* ☐ NON / *NO* ☐

Vaccination depuis moins de 2 mois ? OUI / *YES* ☐ NON / *NO* ☐
Vaccination since less than 2 months ?

JACIE

B6.000

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3.05

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2. IDM results

DONOR FINAL CLEARANCE

❑ BONE MARROW ❑ PBSC ❑ LYMPHOCYTES

PATIENT	NAME : _____ REGISTRY : F G M	Intl ID : _____	
DONOR	CODE : _____	• Age : _____ • ABO Rh : _____	• Sex : ❑ Male ❑ Female and erythrocytic phenotype _____ • Weight (kg) : _____
	DONOR'S REGISTRY : _____	• Transfusions : ❑ yes number : _____ ❑ no	• Pregnancies : ❑ yes number : _____ ❑ no

DATE OF DONOR FINAL MEDICAL FITNESS : ____/____/____ COLLECTION DATE(S) : ____/____/____ ____/____/____

DONOR INFECTIOUS DISEASE MARKERS

	NOT DONE	DONE BY TC	POSITIVE	NEGATIVE	DATE OF BLOOD COLLECTION	*for PBSC and lymphocytes only*	
						name of techniques	*name of kits*
SYPHILIS	O	O	O	O			
HBS ANTIGEN	O	O	O	O			
ANTI-HBC	O	O	O	O			
ANTI-HCV *(1 serological technique)*	O	O	O	O			
ANTI-HIV1.V2	O	O	O	O		*1st technique :*	
(2 serological techniques)	O	O	O	O		*2nd technique :*	
HIV ANTIGEN P24 OR PCR	O	O	O	O			
ANTI-HTLV1.V2	O	O	O	O			
CMV ANTIBODIES	O	O	O O IgM O IgG	O O IgM O IgG			
EBV ANTIBODIES	O	O	O O IgM O IgG	O O IgM O IgG			
TOXOPLASMOSIS	O	O	O O IgM O IgG	O O IgM O IgG			
MALARIA *(optional)*	O	O	O	O			

DONOR CENTRE DATE : ____/____/____
LABORATORY PERFORMING THE TESTS
NAME : _____ Signature :
POSITION :

TRANSPLANT CENTRE (TC) DATE : ____/____/____
LABORATORY PERFORMING THE TESTS
NAME : _____ Signature :
POSITION :

DONOR FINAL CLEARANCE CONFIRMED ON : ___/___/___

DONOR WRITTEN FINAL INFORMED CONSENT GIVEN ON : ___/___/___

FRANCE GREFFE DE MOELLE
CF.12.00 014 19
11/04

JACIE

B6.160

The medical history must include at least the following :

- B6.161 Vaccination history
- B6.162 Travel history
- B6.163 Blood transfusion history
- B6.164 Questions to identify persons at high risk for significant transmissible infection

WMDA

3.05.3

A medical examination must be performed at the time of workup

DIVERS
OTHER

Antécédents sévères de lumbago, de hernies discales ? *Severe past history of lumbago, herniated disc ?*	OUI / *YES* ☐ NON / *NO* ☐
Maladie auto-immune / *Auto-immune disease ?*	OUI / *YES* ☐ NON / *NO* ☐
Anomalies caryotypiques connues ? *Known caryotypic abnormalities ?*	OUI / *YES* ☐ NON / *NO* ☐
Traitement régulier par / *Chronic treatment by :*	
- anti-agrégants, anti-coagulants ? *anti-agregants, anti-coagulants ?*	OUI / *YES* ☐ NON / *NO* ☐
- anti-dépresseurs, neuroleptiques ? *anti-depressants, neuroleptics ?*	OUI / *YES* ☐ NON / *NO* ☐
Grossesse en cours ? *Current pregnancy ?*	OUI / *YES* ☐ NON / *NO* ☐
Accouchement depuis moins de 6 mois ? *Delivery since less than 6 months ?*	OUI / *YES* ☐ NON / *NO* ☐
Séjour de plus d'un an cumulé dans les îles Britanniques entre 1980 et 1996 ? *Cumulated stay over than one year in the British Islands between 1980 and 1996 ?*	OUI / *YES* ☐ NON / *NO* ☐
Comportement à risque dans les 12 derniers mois ? (partenaires multiples, homosexualité, emprisonnement, piercing, toxicomanie, tatouage…) *At risk behaviours during the past 12 months ? (multiple partners, homosexuality, imprisonment, piercing, drug addiction, tattoo…)*	OUI / *YES* ☐ NON / *NO* ☐

REPONSES REPRESENTANT UNE CONTRE-INDICATION RELATIVE

ANSWERS REPRESENTING A RELATIVE CONTRA-INDICATION

(à discuter / *to be discussed)*

Vaccination depuis moins de 2 mois ?
Vaccination since less than 2 months ?

OUI / *YES* ☐ NON / *NO* ☐

JACIE

B6.160

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REPONSES REPRESENTANT UNE CONTRE-INDICATION RELATIVE

ANSWERS REPRESENTING A RELATIVE CONTRA-INDICATION

(à discuter / *to be discussed)*

Séjours en zones à risque infectieux (Paludisme, Chagas, Virus du Nil…) OUI / *YES* ☐ NON / *NO* ☐
Stays in countries at risk for infectious diseases (Malaria, Chagas, West Nile virus…)

IMPORTANT

Les antécédents de transfusion sanguine ne représentent pas une contre-indication au don de cellules souches hématopoïétiques non apparenté (absence de chaîne de transmissibilité).
Blood transfusion past history does not represent a contra-indication to unrelated haematopoietic stem cell donation (absence of transmissibility chain).

Les petits poids (< 50 Kg) ne sont pas une contre-indication.
Donors weighing less than 50 Kg should not be contra-indicated.

RAPPEL
REMINDER

La consultation d'anesthésie est OBLIGATOIRE et doit avoir lieu plusieurs jours avant le conditionnement du patient dans le mois qui précède l'intervention.
(Article D.712.40 du code de santé publique - 5 Décembre 1994)
The anaesthetic consultation is MANDATORY and must take place several days prior patient's conditioning starts and anyway during the month preceding the stem cell collection.
(French Public Health Code – article D.712.40 – 5 December 1994)

Nom du médecin : _____
Name of physician

Date : ___/___/___

Signature et cachet : _____
Signature and stamp

FGM / QMR / 01.05 4

JACIE

B6.160

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WMDA

3.05.3

A medical examination must be performed at the time of workup

REPONSES REPRESENTANT UNE CONTRE-INDICATION RELATIVE

ANSWERS REPRESENTING A RELATIVE CONTRA-INDICATION

(à discuter / *to be discussed)*

Antécédents transfusionnels ? OUI / *YES* ☐ NON / *NO* ☐

Blood transfusion past history ?

IMPORTANT

Les antécédents de transfusion sanguine ne représentent pas une contre-indication au don de cellules souches hématopoïétiques non apparenté (absence de chaîne de transmissibilité).
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WMDA

3.05.3

A medical examination must be performed at the time of workup

REPONSES SUSCEPTIBLES DE PRESENTER UNE CONTRE-INDICATION FORMELLE

ANSWERS LIKELY TO LEAD TO A FORMAL DONATION CONTRA-INDICATION

Comportement à risque dans les 12 derniers mois ? OUI / *YES* ☐ NON / *NO* ☐
(partenaires multiples, homosexualité, emprisonnement, piercing, toxicomanie, tatouage…) *At risk behaviours during the past 12 months ? (multiple partners, homosexuality, imprisonment, piercing, drug addiction, tattoo…)*

REPONSES REPRESENTANT UNE CONTRE-INDICATION RELATIVE

ANSWERS REPRESENTING A RELATIVE CONTRA-INDICATION

(à discuter / *to be discussed)*

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OTHER QUESTIONS

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Anaesthetic past history ? if yes, precise the date : ___ / ___ / _____ and the reason : ……
OUI / *YES* ☐ NON / *NO* ☐

Vaccination depuis moins de 2 mois ?
Vaccination since less than 2 months ?
OUI / *YES* ☐ NON / *NO* ☐

JACIE

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WMDA

3.05.3

A medical examination must be performed at the time of workup

JACIE

B6.170

Within 30 days prior to collection, each donor must be tested for evidence of infection by the following communicable disease agents : HIV 1, 2, HBs antigen, anti HCV, anti HTLV 1-2, syphillis, CMV

WMDA

4.05

IDT of donors selected for specific patients must include testing for diseases considered to be important to consider in HSC Transplantation… (HIV, Hepatatis B and C virus, CMV, syphillis)

- CF.12.00014

DONOR FINAL CLEARANCE

❑ BONE MARROW ❑ PBSC ❑ LYMPHOCYTES

PATIENT	NAME : _____	REGISTRY : F G M	Intl ID : _____
DONOR	CODE : _____ DONOR'S REGISTRY :	• Age : _____ • ABO Rh : _____ • Transfusions : ❑ yes number : _____	• Sex : ❑ Male ❑ Female and erythrocytic phenotype _____ • Pregnancies : ❑ yes number : _____ ❑ no • Weight (kg) : _____

S) : ____/____/____ ____/____/____

KERS

	NOT DONE	DONE BY TC
SYPHILIS	O	O
HBS ANTIGEN	O	O
ANTI-HBC	O	O
ANTI-HCV *(1 serological technique)*	O	O
ANTI-HIV1.V2 *(2 serological techniques)*	O O	O O
HIV ANTIGEN P24 OR PCR	O	O
ANTI-HTLV1.V2	O	O
CMV ANTIBODIES	O	O
EBV ANTIBODIES	O	O
TOXOPLASMOSIS	O	O
MALARIA *(optional)*	O	O

OOD / N	*for PBSC and lymphocytes only*	
	name of techniques	*name of kits*
	1st technique : *2nd technique :*	

TRE (TC) DATE : ____/____/____

THE TESTS

Signature :

POSITION :

POSITION :

DONOR FINAL CLEARANCE CONFIRMED ON : ___/___/___

DONOR WRITTEN FINAL INFORMED CONSENT GIVEN ON : ___/___/___

JACIE

B6.220

Labory tests required for donor selection must be performed by a laboratory accredited or licensed in accordance with applicable national and/or European Union regulations and directives and must include at least the following :

- B6.221 HLA-ABDR typing by an EFI accredited laboratory

WMDA

4.02.1

The HLA typing laboratory must be accredited by the EFI, ASHI or ASEATTA…

JACIE

B6.400

Donor consents

- B6. 411 Informed consent must be obtained and documented by a licensed physician

WMDA

3.04

Adults donors must be informed regarding their potential role int the donation of HSC and the risks involved in the donation

- Consent
- Licensed physician

FINAL CONSENT FORM

Bone marrow donor

(To be completed at the end of the medical interview)

I, the undersigned, certify that I volunteer to be a bone marrow donor for the benefit of a patient who is not related to me and who does not have a compatible donor in her/his family.

I freely consent to have my marrow harvested, in a Hospital Establishment habilitated to carry out marrow harvests, and transplanted to a compatible patient whom I shall never know and who is awaiting a bone marrow transplant.

I have been informed, this day, during a personal interview, by Doctor _____
of the Hospital Establishment of _____
about the procedures and sequence of operations of the marrow harvest.

I have been informed that :

- the that marrow harvest will be carried out under anesthesia which will be ratified by the Anesthesia Service of the Harvesting Hospital ;
- a biological sample will be kept for regular compatibility reevaluation, to keep pace with the evolution of scientific knowledge ;
- prior to my marrow donation I must attend my local Magistrate's Court to register my consent and certify that my decision has been freely made and that no pressure has been brought to bear on me ;
- I shall be hospitalized for 48 hours and will be granted a leave of absence from work, if applicable, the length of which will be determined by a physician ;
- bone marrow being rapidly reconstituted, my blood count will only be briefly affected. A compensatory auto-transfusion may be carried out during the harvest itself ;
- no expense pertaining to the marrow harvest and its preparation will be borne by myself and I am aware a marrow donation cannot generate any financial compensation.

I certify that I have been informed of the eventual consequences of a marrow harvest and that an insurance policy has been contracted for me by France Greffe de Moelle.
Moreover, I have been informed that, exceptionally, I may be solicited, in the near or far future, for a second donation of marrow or peripheral blood stem cells for the benefit of the same patient.

I, therefore, confirm my pledge today. I am aware that this consent is revocable at any time.

Hospital stamp :

Established at : _____ Date ____ /___ /____

First, last names : _____

Signature of marrow donor :

_____

FGM / EV / 03.03

COLLECTION OF PERIPHERAL BLOOD STEM CELLS (Unrelated voluntary donor) FIRST DONATION

INFORMATION NOTICE AND WRITTEN CONSENT OF A DONOR OF HEMATOPOIETIC PERIPHERAL STEM CELLS

Dear Madam or Sir,

You are a volunteer to donate your bone marrow to a patient who is not related to you.

A study of HLA tissue typings has established a sufficient compatibility between you and a patient who needs, within the framework of the treatment of her/his disease, a transplant of hematopoietic peripheral stem cells.

This is why, today, it is requested of you to donate peripheral stem cells to allow this patient to recover normal medullar functioning.

The purpose of this document is to give you the necessary information concerning the modalities of the procedure proposed to you today, that is to say: **the collection of stem cells from peripheral blood.**

This collection is carried out after injection to the donor of a medical product which transfers, transitorily, stem cells from the marrow to the blood. This medical product is called growth factors or G-CSF and is marketed under the names of GRANOCYTE or NEUPOGEN. It is produced by the pharmaceutical industry and its sale has been authorized by the French Bureau of Health Care Products Safety (AFSSAPS).

This method has been used for the past 10 years for auto transplants of tens of thousands of patients and for allo transplants of thousands of patients from healthy related donors.

However, certain diseases exclude the use of this medical product: this is why a targeted medical questionnaire and a specific biological and medical check-up will be carried out on the donor before prescription of G-CSF.

The donor's treatment, allowing for the mobilization of the stem cells in the blood, starts 4 or 5 days before the collection and consists of one injection per day of growth factors or G-CSF.
These sub-cutaneous injections may be made by a nurse at the donor's home.

JACIE

B6.400

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COLLECTION OF PERIPHERAL BLOOD STEM CELLS (Unrelated voluntary donor) FIRST DONATION

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INFORMED CONSENT OF AN UNRELATED DONOR

I, the undersigned, (name, first name) .....

accept, knowingly and freely, to receive the treatment proposed, under the conditions described in the attached document, for the benefit of a patient to whom I am not related.

I acknowledge to have been informed by Dr. .....
of (hospital) ..... in (city) .....
of the sequence of events of the collection and of its consequences as well as of the insurance policy contracted for me by the French National Registry of Hematopoietic Stem Cells Donors, France Greffe de Moelle.

I have well noted that this consent does not exonerate the physicians from their responsibilities.

I know that it is possible for me to refuse to receive this treatment.

No expenses related to the collection of peripheral stem cells and its preparation will be borne by me. I am aware that this donation cannot lead to any financial gain on my part.

Established at :..... Date :.....

Donor's Signature :

Signature & stamp of the physician :

FGM / CSP 1 / 03.03

JACIE

B6.413

The donor must have an opportunity to ask questions and the right to refuse to donate

WMDA

3.04.4

A donor must be free to withdraw at any time

- Consent 

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of the sequence of events of the collection and of its consequences as well as of the insurance policy contracted for me by the French National Registry of Hematopoietic Stem Cells Donors, France Greffe de Moelle.

I have well noted that this consent does not exonerate the physicians from their responsibilities.

I know that it is possible for me to refuse to receive this treatment.

preparation will be borne by me. I am aware that this donation cannot lead to any financial gain on my part.

Established at :..... Date :.....

Donor's Signature :

Signature & stamp of the physician :

FGM / CSP 1 / 03.03

JACIE

D4.620

All suspected clinical adverse reactions must be evaluated promptly according to SOP and review by the Laboratory Medical Director

WMDA

9.04

Adverse events affecting donors undergoing harvest of HSC and occuring long term as a consequence of the donation must be defined and must be recorded

- Adverse effects

SERIOUS EVENTS AND ADVERSE EFFECTS REGISTRY

SEAR

*The **S**erious **E**vents and **A**dverse **E**ffects **R**egistry is an anonymous central reporting system of the WMDA member organisations to the WMDA Clinical Committee to obtain insight into the occurrence of serious events and adverse effects in relation to stemcell donation by unrelated donors.*

Confidentiality and anonymous reporting is fundamental to success of this scheme. Please consult the SEAR manual for instructions on reports. (http://www.worldmarrow.org)

Use this form to report to WMDA serious events and adverse effects during or following donation of bone marrow, stimulated peripheral blood stem cells or blood cells. Fill this form, without names or numbers for identification and retain a copy for your records. Seal the form in the unidentified inner envelope and mail it in the outer envelope to the WMDA secretariat. The secretariat will, on receipt of the report, remove the postal envelope and discard it, placing the unopened inner envelope in a batch to be opened subsequently by the clinical committee of WMDA.

If this is a follow up report of a previously reported case, please include a copy of the previous report to avoid double reporting.

GENERAL INFORMATION				
G01	Type of donation			
	☐ First	☐ Marrow		
	☐ 2nd or consecutive	☐ G-CSF stimulated PBSC		
		☐ Unstimulated aferesis		
		☐ Whole blood		
G02	In case of 2nd or consecutive donation, what was the interval between the index donation and the previous donation? ☐ .....days ☐.....months What type of donation was this previous donation:			
G03	Donor gender ☐ M ☐ F	Donor age		
	Donor weight: .....kg	☐ 18-30	☐ 41-50	☐ 56-60
		☐ 31-40	☐ 51-55	☐ 61+
G04	Did the selection criteria or the medical examination for this donor differ in any way from your normal selection criteria? ☐ Yes ☐ No If so, please comment			
G05	Did the donor have any previous medical history or medical condition prior to donation that might have influenced the occurrence of the event notified ☐ Yes ☐ No If Yes, please describe:			
G06	Did the donor use any medication previous to the donation ☐ Yes ☐ No If yes, please give name of drug and details of use:			

Please continue with page 2, question G07

JACIE

D8.100

Labelling operations

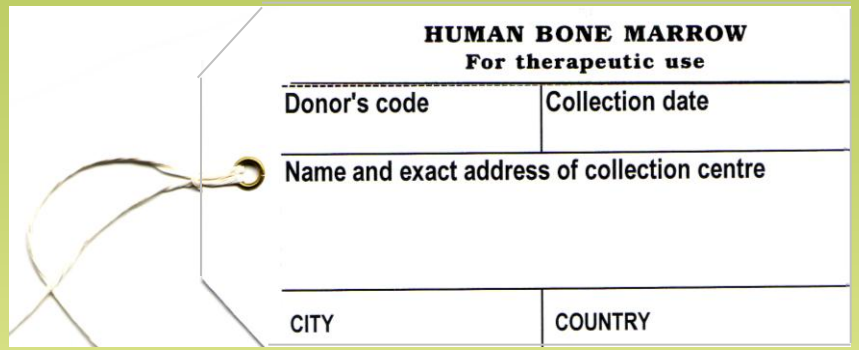
D8.110 Labelling operations must be conducted in a manner adequate to prevent mislabelling of products

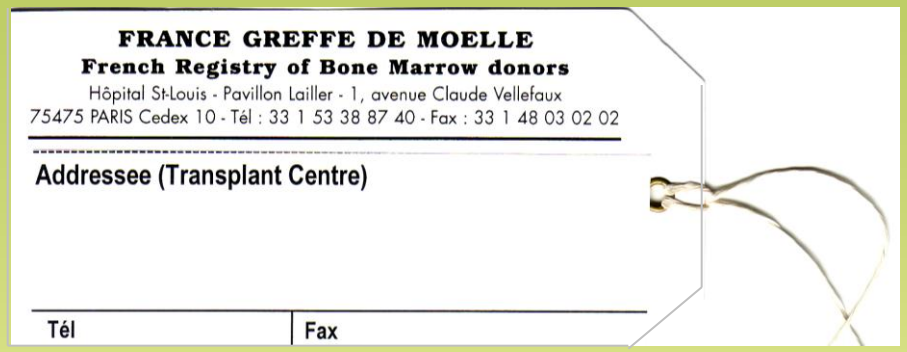
WMDA

8.05

Cells must be transported in a timely and reliable fashion to ensure the quality of the cell product. Policies and procedures documenting the transport process must be stipulated

- Labels
- Procedure





FRANCE GREFFE DE MOELLE

Moelle osseuse d'origine humaine

Human Bone Marrow

Hôpital préleveur :
Collection Centre :

Lieu/*location* :
Pays/*Country* :

Code donneur :
Donor 's code :
Receveur :
Recipient :

Date prélèvement :
Collection date :
Heure début prélèvement :
Harvesting time :

° Température de transport/*Transport temperature* : **ambiante / room t°**

Destinataire/Hôpital Greffeur :
Addressee/Transplant Centre :

JACIE

D8.100

Labelling operations

D8.110 Labelling operations must be conducted in a manner adequate to prevent mislabelling of products

WMDA

8.05

Cells must be transported in a timely and reliable fashion to ensure the quality of the cell product. Policies and procedures documenting the transport process must be stipulated

- Labels
- Procedure

FRANCE GREFFE DE MOELLE

FRENCH REGISTRY OF UNRELATED STEM CELL DONORS

DIRECTOR
C. RAFFOUX, M.D.
+33-1 53 38 87 40

ASSISTANT DIRECTORS
Medical :
E. MARRY, M.D.
+33-1 53 38 87 45
Accounts Dept :
E. ORTAVANT
+33-1 53 38 87 52

SECRETARIAT
Director Assistant :
C. du PONTAVICE
+33-1 53 38 87 40
Donors :
G. WATIN-AUGOUARD
+33-1 53 38 87 41

FINANCES
F. COZIC
+33-1 53 38 87 42
Ch. LOPES
+33-1 53 38 87 52
M. SOUBRANE
+33-1 53 38 87 46

COORDINATION
L. BONICEL
+33-1 53 38 87 48
M.-Ch. FABRE
+33-1 53 38 87 53
H.-J. LAMOTTE
+33-1 53 38 87 47
S. LAUNAY
+33-1 53 38 87 43
M. LOMBARD
+33-1 53 38 87 55
L. RANSON
+33-1 53 38 87 51

INFORMATION SYSTEM DEPT
A. BAOUZ
+33-1 53 38 87 50
F. DUFLOT
+33-1 53 38 87 49
M.-L. APPERT
+33-1 53 38 91 65

FAX
+33-1-48 03 02 02
E-mail
fgm@fgm.fr

Internet
http://www.fgm.fr

WORLD MARROW DONOR ASSOCIATION
WMDA
ACCREDITATION WMDA n°2004/002

DATE:

NAME OF COURIER:

LIFE-SAVING TRANSPLANT

TO WHOM IT MAY CONCERN

Ms XXXXXXXXX is carrying Human Blood Stem Cells from YYYYYYY (Country) to YYYYYYY (Country) via ZZZZZZZ (Country) and ZZZZZZZ (Country), where a patient is awaiting a transplant. It is imperative that the Blood Stem Cells be transported without delay and that they remains with the courier, at all times.

WARNING:

DO NOT IRRADIATE (X-RAY) BLOOD STEM CELLS.
IF INSPECTION IS REQUIRED AT SECURITY CHECKPOINT, THIS MUST BE DONE WITH THE UTMOST CARE.
ONLY THE CONTAINER, EMPTIED, MAY BE X-RAYED IF NECESSARY.

These Blood Stem Cells have been tested and found negative for anti-HIV (AIDS) and viral hepatitis.

If, for any reason, the courier was unable to depart on his/her scheduled flight, we request that you consider this life-saving transport as utmost urgent and do your utmost in helping this courier to reach his/her destination by the quickest possible means.

Thank you for your prompt attention to this matter and for any assistance you can give to the courier, should it be needed.

In case of a problem, please contact me by telephone: 33.1.53.38.87.45. at the French Bone Marrow Donor Registry.

Evelyne MARRY M.D.

HUMAN BLOOD STEM CELLS
therapeutic use

Headquarters: HÔPITAL SAINT-LOUIS – PAVILLON LAILLER – 1, AV CLAUDE VELLEFAUX - 75475 PARIS CEDEX 10
Postal Address: B.P. 10 - 75462 PARIS CEDEX 10 - FRANCE
Siret n° 341 517 464 00028 - APE : 851 L

Conclusion

- WMDA et JACIE accreditation have same and complementary objectives
- For a grafting physician having the intention to obtain JACIE accreditation, do not hesitate to rely on the expertise of WMDA accredited Donor Registry as far as unrelated donors are concerned