**APPLICATION FOR FIRST-TIME ACCREDITATION & RE-ACCREDITATION**

**Instructions for completing the Application Form**

**Note: C**entres applying for the first time must submit the completed **Inspection Checklist** before an application can be assessed and approved.

The Checklist can be downloaded from [www.ebmt.org/research/documents](http://www.ebmt.org/research/documents) and select “JACIE Committee” from “Group”.

Applications for re-accreditation should submit the Inspection Checklist with the pre-inspection documentation **within 30 days** of the application approval date.

# GENERAL DETAILS

|  |
| --- |
| Programme name[[1]](#footnote-1):  |
| Country:  |
| Working language of centre:  |

* 1. **Contact details**

There should be one designated person responsible for contact with the JACIE Office. Their details should be provided below. The applicant is responsible for ensuring that any changes to contact information are promptly communicated to the JACIE Office. Failure to do so may result in delays during the process.

|  |
| --- |
| Title:  |
| First Name:  |
| Family Name:  |
| Institution:  |
| Address 1:  |
| Address 2:  |
| City:  |
| Post-code:  |
| Phone: (+ )  |
| Fax: (+ )  |
| E-mail:  |

The Personal Data provided will be used for the purpose of management of the JACIE Accreditation process.

The personal data provided will be processed according to the General Data Protection Regulation (GDPR 2016/679) and stored in an electronic database property of EBMT which will be allocated in the EEA (European Economic Area) or in countries that are provided with the same level of protection for privacy such as countries that adhere to EU-US and Swiss-US Privacy Shield Frameworks.

Data Subjects have the right of access to his or her data and the right to rectification of any inaccurate or incomplete personal data. The Data Subject also has the right to withdraw consent, this wish will be respected, and the personal will no longer be made available. If the processing operation is unlawful the Data Subject has the right to request deletion of that data. Please write to data.protection@ebmt.org

For further information please go to the [Privacy Policy](https://www.ebmt.org/privacy-policy).

* 1. **Invoicing information**

|  |
| --- |
| Institution:  |
| Address 1:  |
| Address 2:  |
| City:  |
| Post-code:  |
| Phone: (+)  |
| Fax: (+ )  |
| E-mail:  |
| VAT number[[2]](#footnote-2): *see also the appendix*  |
| **Discount**: *Applications from centres whose staff members have participated in a JACIE inspection event(s) in the 4 years preceding submission of the new application qualify for a discount of 15% per event up to a maximum of 20%. Subject to verification by the JACIE Office.*Names of staff member that have been active JACIE inspectors in preceding 4 years:  |
| Any other references e.g. Purchase Order number that should appear on the invoice:  |

#### END OF SECTION 1

1. **Summary of Organisation of the Programme**
	1. **Accreditation goal**

**Activity(s) for which you are requesting accreditation** *(mark with an X as appropriate)***:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Area** | **Patient** | **HSCT** | **Immune Effector Cells** |
|  | **Allogeneic**  | **Autologous**  | **Allogeneic**  | **Autologous**  |
| Clinical | Adult |  |  |  |  |
| Paediatric |  |  |  |  |
| HPC, Marrow Collection | Adult |  |  |  |  |
| Paediatric |  |  |  |  |
| HPC, Apheresis Collection | Adult |  |  |  |  |
| Paediatric |  |  |  |  |
| Processing |   |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **CLINICAL** | **COLLECTION** | **PROCESSING[[3]](#footnote-3)** |
|  |  |  |  |
|  | AUTOLOGOUSTransplantation | ALLOGENICTransplantation | MARROWCollection | APHERESISCollection |  |
| **Total sites** |  |  |  |  |  |
|  | Inpatient | Outpatient | Inpatient | Outpatient |  |  |  |
| **Adult** |  |  |  |  |  |  |  |
| **Paediatric** |  |  |  |  |  |  |  |

* 1. If you do not collect marrow products, what process does your program follow in the event of an unexpected occurrence such as failed engraftment or a PBPC mobilization failure?
	2. Description of the interaction between clinical, collection and processing facilities.

Distance between facilities (if possible, please describe the distance, duration and mode e.g. 5km, 10 mins, by car)

|  |  |
| --- | --- |
| Collection Facility(s) to Clinical Unit(s) |   |
| Clinical Unit(s) to Intensive Care Unit – indicate also mode of transfer e.g. trolley, ambulance |  |
| Collection Facility(s) to Processing Facility(s) |   |
| Processing Facility(s) to Clinical Unit(s) |   |

Other information:

* 1. *Quality management system* (QMS): Please describe the quality management system in your programme. For instance, “There is one integrated QMS across the entire programme (clinical, collection and processing)” or “There is more than one QMS across the programme: one system for the hospital and another system for the blood bank that provides the laboratory service”:

* 1. If HPC, Marrow and HPC, Apheresis collection procedures are carried out on more than one site, please explain the organisation. Use organisational charts and maps to illustrate your answer. \_
		1. Are these services integrated[[4]](#footnote-4) or do you use external[[5]](#footnote-5) collection and/or processing facilities? \_
		2. If you use an external collection facility, please explain who is responsible for:
			1. donor evaluation \_
			2. mobilisation \_
			3. collection \_
			4. manufacturing \_

**END OF SECTION** 2

1. **CLINICAL TRANSPLANTATION PROGRAMME**

|  |
| --- |
| ***Note****: If there is more than one clinical site for transplantation, please complete a copy of Section* 3 *of this form for* ***each*** *site.*  |
| * 1. **Transplant Facility**
 |
| Name of facility:  |
| Institution:  |
| Address:  |
| Address:  |
| City:  |
| Post-code:  |

* 1. Is the clinical programme a member of the EBMT[[6]](#footnote-6)? If so, please enter the CIC number including the team number where applicable e.g. 483:2 \_\_\_\_[[7]](#footnote-7)
	2. Application for: First-time accreditation \_ Reaccreditation \_

*For centres applying for Reaccreditation only*

* + 1. Have there been any significant physical alterations to your site(s) or has the service moved to a new facility since the last JACIE inspection?Yes \_ No \_ N/A \_
		If yes, please provide more details:
		2. Have there been any changes of key personnel in the programme since the last JACIE inspection?

Yes \_ No \_
If yes, please provide more details:

* 1. Year transplant transplantation programme began: \_\_\_\_
	2. **Distribution of patients:**
		1. Are adults and paediatrics cared for on the same site? Yes \_ No \_
			+ *If no, please complete a copy of Section* 3 *of this form for* ***each*** *site.*
		2. Are allogeneic and autologous patients cared for on the same site? Yes \_ No \_ N/A \_
			+ *If no, please complete a copy of Section* 3 *of this form for* ***each*** *site.*
	3. **Transplant activity**

Standard B1.5 / B1.6: Complete the following table regarding the total number of new patients transplanted by your programme in the calendar year (Jan-Dec) up to this application

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient** | **Cell source** | **HSCT** | **Immune Effector Cells** |
| **Adult** | **Allogeneic\***  | **Autologous\***  | **Allogeneic**  | **Autologous**  |
|  |  | Related | Unrelated |  |  |  |
|  | **HPC(M)** |  |  |  |  |  |
| **HPC(A)** |  |  |  |  |  |
|  | **HPC(M) + Cord blood** |  |  |  |  |  |
|  | **Cord Blood** |  |  |  |  |  |
| **Paediatric** | **Allogeneic\***  | **Autologous\***  | **Allogeneic**  | **Autologous**  |
|  |  | Related | Unrelated |  |  |  |
|  | **HPC(M)** |  |  |  |  |  |
|  | **HPC(A)** |  |  |  |  |  |
|  | **HPC(M) + Cord blood** |  |  |  |  |  |
|  | **Cord Blood** |  |  |  |  |  |
| **\*ALLOGENEIC**If the Clinical Program requests accreditation for allogeneic HPC transplantation, a minimum of ten (10) new allogeneic patients shall have been transplanted before initial accreditation and annually thereafter:. A Clinical Program that is accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation. See APPENDIX I of the Standards for more details. | **¥AUTOLOGOUS**If the Clinical Program requests accreditation for only autologous HPC transplantation, a minimum of five (5) new recipients of autologous transplantation shall have been transplanted before initial accreditation and annually thereafter: See APPENDIX I of the Standards for more details. |

* + 1. If allogeneic transplant is performed, where is HLA typing carried out? \_
			1. Is this laboratory EFI or ASHI accredited? Yes \_ No \_
	1. **Key personnel**

| **Position** | **Title:** | **First Name:** | **Family Name:** | **Qualifications** | **Number of years’ experience in HSCT** | **Number of years as Programme Director** |
| --- | --- | --- | --- | --- | --- | --- |
| Clinical Facility Director |  |  |  |  |  |  |
| Designated person for quality management: |  |  |  |  |  |  |
| Responsible person for nursing staff: |  |  |  |  |  |  |
| Other consultant/senior physicians: |  |  |  |  |  |  |
| `` |  |  |  |  |  |  |
| `` |  |  |  |  |  |  |
| `` |  |  |  |  |  |  |

*To add more key personnel, add more lines to the end of the table.*

IMPORTANT NOTE: It is the responsibility of the centre to ensure that the Key personnel listed in the table above agrees to provide their personal data to JACIE for the management of the JACIE Accreditation process.

|  |
| --- |
| * 1. Describe your **inpatient transplant** unit in terms of number of beds, bathrooms and air handling:
 |

|  |
| --- |
| * 1. What are the indications for transplantation in your programme?
 |

* 1. **Other services supporting the transplant programme**

|  |
| --- |
| HPC, Apheresis Facility(s) utilised by your centre:  |
| HPC, Marrow Collection Facility(s) utilised by your centre:  |
| Cell Processing Laboratory(s) utilised in your centre:  |

* 1. **More-than-minimally-manipulated products**

|  |
| --- |
| Are more-than-minimally-manipulated products[[8]](#footnote-8) administered by the Clinical Unit e.g. immune effector cells? Yes \_ No \_ |
| If yes, is the facility where these products are processed GMP-licensed? Yes \_ No \_ N/A \_ |
| Please provide details of the licence: |

**END OF SECTION** 3

1. **HPC, MARROW COLLECTION**

|  |
| --- |
| ***Note:*** *If there is more than one site for HPC, Marrow collection, please complete a copy of Section* 4 *of this form for each site.* |
| * 1. **HPC, Marrow Collection Facility name**:
 |
| Institution:  |
| Address:  |
| Address:  |
| City:  |
| Post-code:  |

* 1. Application for: First-time accreditation \_ Reaccreditation \_

*For centres applying for Reaccreditation only*

* + 1. Have there been any significant physical alterations to your site(s) or has the service moved to a new facility since the last JACIE inspection?Yes \_ No \_ N/A \_
		If yes, please provide more details:
		2. Have there been any changes of key personnel in the programme since the last JACIE inspection?

Yes \_ No \_
If yes, please provide more details:

* 1. Year collection activity began: \_\_\_\_
	2. HPC, Marrow collection activity

Complete the following table regarding the total number of procedures carried out by your collection.

*Initial accreditation:* A minimum of one (1) marrow collection procedure shall have been performed in the calendar year (Jan-Dec) up to this application.

|  |  |  |
| --- | --- | --- |
| **Time Period** | **ALLOGENEIC HPC(M)** | **AUTOLOGOUS HPC(M)** |
|  |  |  |

*Reaccreditation:* The Marrow Collection Facility shall perform a minimum average of one (1) marrow collection procedure per year within each accreditation cycle.

|  |  |  |
| --- | --- | --- |
| **Time Period of previous accreditation** | **ALLOGENEIC HPC(M)** | **AUTOLOGOUS HPC(M)** |
| Year 1 |  |  |
| Year 2 |  |  |
| Year 3 |  |  |
| Year 4 |  |  |

* 1. Bone marrow is harvested from: Adults \_ Paediatrics \_
	2. **Key personnel**

| **Position** | **Title:** | **First Name:** | **Family Name:** | **Qualifications** | **Number of years’ experience in HPC(M) harvest:** |
| --- | --- | --- | --- | --- | --- |
| HPC(M) Collection Facility Medical Director |  |  |  |  |  |
| Designated person for quality management: |  |  |  |  |  |
| HPC, Marrow collection staff |  |  |  | \_ Medical\_ Nursing |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*To add more key personnel, simply add more lines to the end of the table.*

IMPORTANT NOTE: It is the responsibility of the centre to ensure that the Key personnel listed in the table above agrees to provide their personal data to JACIE for the management of the JACIE Accreditation process.

|  |
| --- |
| * 1. Is your HPC, Marrow Collection Facility accredited, licensed or authorised by any other organisation (professional and/or regulatory)? Yes ­­\_ No \_
 |
| If yes, please provide details:  |

* 1. **Other services associated with the marrow collection facility**

|  |
| --- |
| * + 1. What Cell Processing Laboratory(s) is used by your HPC, Marrow Collection facility?
 |
|  |
| * + 1. What Clinical Programmes (hospitals) does your HPC, Marrow Collection Facility supply?
 |
|  |
| * + 1. Does your facility collect on behalf of a Donor Registry(s)? Yes \_ No \_
 |
| If yes, please provide details:  |

#### END OF SECTION 4

1. **HPC, APHERESIS COLLECTION**

|  |
| --- |
| ***Note:*** *If there is more than one site for HPC, Apheresis**collection, please complete a copy of Section* 5 *of this form for each site.* |
| * 1. **HPC, Apheresis Collection Facility name**:
 |
| Institution:  |
| Address:  |
| Address:  |
| City:  |
| Post-code:  |

* 1. Application for: First-time accreditation \_ Reaccreditation \_

*For centres applying for Reaccreditation only*

* + 1. Have there been any significant physical alterations to your site(s) or has the service moved to a new facility since the last JACIE inspection?Yes \_ No \_ N/A \_
		If yes, please provide more details:
		2. Have there been any changes of key personnel in the programme since the last JACIE inspection?

Yes \_ No \_
If yes, please provide more details:

* 1. Year collection activity began: \_\_\_\_
	2. HPC(A) Collection activity

 Complete the following table regarding the number of procedures carried out by your collection.

*Initial accreditation:* For apheresis Collection Facilities, a minimum of ten (10) cellular therapy products shall have been collected by apheresis in the calendar year (Jan-Dec) up to this application

|  |  |  |
| --- | --- | --- |
| **Time Period** | **ALLOGENEIC HPC(A)** | **AUTOLOGOUS HPC(A)** |
|  |  |  |

*Reaccreditation:* For Apheresis Collection Facilities, a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within each accreditation cycle.

|  |  |  |
| --- | --- | --- |
| **Time Period of previous accreditation** | **ALLOGENEIC HPC(A)** | **AUTOLOGOUS HPC(A)** |
| Year 1 |  |  |
| Year 2 |  |  |
| Year 3 |  |  |
| Year 4 |  |  |

* 1. Apheresis is performed on: Adults \_ Paediatrics \_
	2. **Key personnel**

| **Position** | **Title:** | **First Name:** | **Family Name:** | **Qualifications** | **Number of years’ experience in apheresis:** |
| --- | --- | --- | --- | --- | --- |
| HPC(A) Collection Facility Director |  |  |  |  |  |
| HPC(A) Collection Facility Medical Director |  |  |  |  |  |
| Designated person for quality management: |  |  |  |  |  |
| HPC(A) Collection Facility staff |  |  |  | \_ Medical\_ Nursing |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*To add more key personnel, simply add more lines to the end of the table.*

IMPORTANT NOTE: It is the responsibility of the centre to ensure that the Key personnel listed in the table above agrees to provide their personal data to JACIE for the management of the JACIE Accreditation process.

|  |
| --- |
| * 1. Is your collection facility accredited, licensed or authorised by any other organisation (professional and/or regulatory)? Yes \_ No \_
 |
| If yes, please provide details:  |

* 1. **Other services associated with the apheresis collection facility**

|  |
| --- |
| * + 1. What Cell Processing Laboratory(s) is used by your HPC, Apheresis Collection facility:
 |
|  |
| * + 1. What Clinical Programmes (hospitals) does your HPC, Apheresis Collection facility supply?
 |
|  |
| * + 1. Does your facility collect on behalf of a Donor Registry(s)? Yes \_ No \_
 |
| If yes, please provide details:  |

|  |
| --- |
| * 1. Are other blood components collected by apheresis by the same medical/nursing staff at your facility?

Yes \_ No \_ |
| If yes, please list:  |

#### END OF SECTION 5

1. **CELL PROCESSING**

|  |
| --- |
| ***Note****: If there is more than one site for cell processing, please complete a copy of Section* 6 *of this form for each site.* |
| * 1. **Cell Processing Facility name:**
 |
| Institution:  |
| Address:  |
| Address:  |
| City:  |
| Post-code:  |

* 1. Application for: First-time accreditation \_ Reaccreditation \_

*For centres applying for Reaccreditation only*

* + 1. Have there been any significant physical alterations to your site(s) or has the service moved to a new facility since the last JACIE inspection?Yes \_ No \_ N/A \_
		If yes, please provide more details:
		2. Have there been any changes of key personnel in the programme since the last JACIE inspection?

Yes \_ No \_
If yes, please provide more details:

* 1. Year laboratory commenced processing cellular therapy products:
	2. Total number of facility staff:
	3. Who is responsible for all aspects of cell processing? Select all that apply.

Facility Director \_

External person(s) \_ *If selected, please provide more details:*

* 1. **Key personnel**

| **Position** | **Title:** | **First Name:** | **Family Name:** | **Qualifications** | **Number of years’ experience in HSCT processing:** |
| --- | --- | --- | --- | --- | --- |
| Laboratory Facility Director: |  |  |  |  |  |
| Laboratory Medical Director: |  |  |  |  |  |
| Designated person for quality management: |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*To add more key personnel, simply add more lines to the end of the table.*

IMPORTANT NOTE: It is the responsibility of the centre to ensure that the Key personnel listed in the table above agrees to provide their personal data to JACIE for the management of the JACIE Accreditation process.

|  |
| --- |
| * 1. Is your laboratory accredited, licensed or authorised by any other organisation (professional and/or regulatory)? Yes \_ No \_
 |
| If yes, please provide details:  |

|  |
| --- |
| * 1. Which components are processed in your laboratory?
 |
| \_ Human HPC, Marrow \_ Human blood progenitor cells \_ Human cord and placental blood cells |
| Which processes are carried out in your facility? |
| Plasma depletion | \_ | T-Cell depletion | \_ |
| Red cell depletion | \_ | Other cell selection | \_ |
| Buffy coat preparation | \_ | Ex-vivo expansion | \_ |
| Density separation | \_ | Gene manipulated cells | \_ |
| Cryopreservation | \_ | Positive selection (e.g.: CD34+) | \_ |
| Other | \_ | Specify:  |
| Modifications | \_ | List:  |
| How many components are processed per year?  |

* 1. **More-than-minimally-manipulated products**

|  |
| --- |
| Are more-than-minimally-manipulated products[[9]](#footnote-9) processed by this Laboratory e.g. immune effector cells? Yes \_ No \_ |
| If yes, is the facility GMP-licensed? Yes \_ No \_ N/A \_ |
| Please provide details of the licence: |

* 1. **Gene therapy products**

|  |
| --- |
| Are gene modified cellular products processed by this Laboratory? Yes \_ No \_ |
| If yes, do these products form any part of the transplant treatment pathway? Yes \_ No \_ N/A \_ |
| If required, what authorisation(s) does the laboratory have to handle such products? |

|  |
| --- |
| * 1. In which laboratory(s) / facility(s) are tests performed on the product, other than those tests performed by the processing facility described in this application?
 |
| Is this testing laboratory(s) / facility(s) accredited, licensed or authorised by any other organisation (professional and/or regulatory)? Yes \_ No \_ |
| If yes, please specify the body(s):  |

|  |
| --- |
| * 1. Who is responsible for progenitor cell thawing?
 |
|  |
| * 1. Who is responsible for progenitor cell infusion?
 |
|  |
| * 1. What Clinical Programmes (hospitals) does your processing facility supply?
 |
|  |
| * 1. Does your processing facility serve a Donor Registry(s)? Yes \_ No \_
 |
| If yes, please provide details:  |

**END OF SECTION** 6

Additional information:

1. Programme name should be used to describe an application including where there are multiple sites or institutions e.g. the Central City BM Transplantation Programme. Note that this is the name that will appear on the eventual **certificate** of accreditation. [↑](#footnote-ref-1)
2. VAT (Value Added Tax) is the number used for tax purposes and is applied to sales of goods and services. The VAT number should refer to the entity that will pay the accreditation fee.

It may be called something different in each country. Information on format and the local equivalents of VAT can be found at https://www.gov.uk/vat-eu-country-codes-vat-numbers-and-vat-in-other-languages and https://en.wikipedia.org/wiki/Value-added\_tax (accessed 04/01/2016) [↑](#footnote-ref-2)
3. Minimal processing only. More-than-minimal processing does not fall within the scope of this certification [↑](#footnote-ref-3)
4. Integrated refers to services which are part of the same institution e.g. the clinical, collection and processing unit all belong to the same university hospital [↑](#footnote-ref-4)
5. External refers to services provided by third parties e.g. regional blood service operates the collection and/or processing units while the clinical unit belongs to a hospital [↑](#footnote-ref-5)
6. Applications that include clinical units that are not EBMT members are subject to higher fees. [↑](#footnote-ref-6)
7. Check CIC number at https://www2.clinicalresearch.nl/members/ [↑](#footnote-ref-7)
8. More than minimally manipulated: Processing that does alter the relevant biological characteristics of cells or tissues. [↑](#footnote-ref-8)
9. More than minimally manipulated: Processing that does alter the relevant biological characteristics of cells or tissues. For structural tissue, processing that does alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement. Products that are more than minimally manipulated are referred to as Advanced Therapy Medicinal Products in the European Union. [↑](#footnote-ref-9)