**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

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

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| * 1. **Contact details[[2]](#footnote-2)**   *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: (+ ) |
| E-mail: |

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| * 1. **Programme Director[[3]](#footnote-3)**   *The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations. Please see section B3.1 of the JACIE standards for further information.* |
| Title: |
| First Name: |
| Family Name: |
| Institution: |
| E-mail: |

*The Personal Data provided will be used for the purpose of management of the JACIE Accreditation process and processed according to the General Data Protection Regulation (GDPR 2016/679). The data will be 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.*

*Data Subjects have the right of access, rectification, erasure, restriction, portability and objection to the processing of his or her personal data. If you wish to exercise any of the rights listed above please write to data.protection@ebmt.org*

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

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| * 1. **Invoicing information** |
| Institution: |
| Address 1: |
| Address 2: |
| City: |
| Post-code: |
| Phone: (+) |
| Fax: (+ ) |
| E-mail: |
| VAT number[[4]](#footnote-4): *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(s) that have been active JACIE inspectors in preceding 4 years: |
| Any other references e.g. Purchase Order number that should appear on the invoice: |

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#### END OF SECTION

# SUMMARY OF ORGANISATION OF THE PROGRAMME

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| --- | --- | --- | --- | --- | --- | --- |
| Accreditation goal *Activity(s) for which you are requesting accreditation (mark 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 |  | |  |  |

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| --- | --- |
| 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: | |

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| Quality management system (QMS): *Please click the corresponding option:* |
| There is one integrated QMS across the entire programme (Clinical, Collection and Processing) |
| There is more than one QMS across the programme. Please describe: |

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| HPC Marrow and HPC Apheresis *Please click the corresponding option:* |
| HPC, Marrow and HPC, Apheresis collection procedures are carried out in one site.  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[[5]](#footnote-5) or do you use external[[6]](#footnote-6) collection and/or processing facilities? \_ |

**END OF SECTION**

# CLINICAL TRANSPLANTATION PROGRAMME

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

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| Is the clinical programme a member of the EBMT[[7]](#footnote-7)? |
| If so, please enter the CIC number including the team number where applicable (e.g. 483:2)  Click here to type text.[[8]](#footnote-8) |

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| Application for: |
| First-time accreditation  Reaccreditation |

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| **ONLY for centres applying for Reaccreditation** |
| * + 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? |
| N/A  NO  YES  If YES please provide more details: |
| * + 1. Have there been any changes of key personnel in the programme since the last JACIE inspection? |
| NO  YES  If YES please provide more details: |

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| Year transplant transplantation programme began |
| Click here to type text. |

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| * 1. **Distribution of patients:** |
| * + 1. Are adults and paediatrics cared for on the same site? |
| NO  YES  *If NO, please complete a copy of Section* 3 *of this form for* ***each*** *site* |
| * + 1. Are allogeneic and autologous patients cared for on the same site? |
| N/A  NO  YES  *If no, please complete a copy of Section* 3 *of this form for* ***each*** *site* |

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| * 1. **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** | | |
| **Allogeneic\*** | | | **Autologous\*** | **Allogeneic** | **Autologous** | |
| **Adult** | |  | 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. | | | |

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| * 1. **Key personnel**   *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.* | | | | | | |
| **Position** | **Title** | **First Name** | **Family Name** | **Qualifications** | **Number of years’ experience in HSCT** | **Number of years as Programme Director** |
| Clinical Director |  |  |  |  |  |  |
| Designated person for quality management |  |  |  |  |  |  |
| Responsible person for nursing staff |  |  |  |  |  |  |
| Other consultant/senior physicians |  |  |  |  |  |  |

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| * 1. **Does the centre perform transplantation for any indications not included in the EBMT Indications for haematopoietic stem cell transplantation for haematological diseases, solid tumours and immune disorders[[9]](#footnote-9)** |
| N/A  NO  YES  If YES please provide more details: |

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| * 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: |

**END OF SECTION**

# HPC, MARROW COLLECTION

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

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| Application for: |
| First-time accreditation  Reaccreditation |

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| **ONLY for centres applying for Reaccreditation** |
| * + 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?** |
| N/A  NO  YES  If YES please provide more details: |
| * + 1. **Have there been any changes of key personnel in the programme since the last JACIE inspection?** |
| NO  YES  If YES please provide more details: |

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| --- |
| Year collection activity began |
| Click here to type text. |

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| --- | --- | --- |
| 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** | | **TOTAL NUMBER OF PROCEDURE (AUTO and ALLO)** |
| Click here to type time period. | |  |
| **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** | **TOTAL NUMBER OF PROCEDURES (AUTO and ALLO)** | |
| Click here to type Year 1 |  | |
| Click here to type Year 2 |  | |
| Click here to type Year 3 |  | |
| Click here to type Year 4 |  | |

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| Bone Marrow is harvested from: |
| Adults  Paediatrics |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Key personnel *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.* | | | | | |
| **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 |  |

|  |
| --- |
| Is your HPC, Marrow Collection Facility accredited, licensed or authorised by any Regulatory organisation? |
| NO  YES  If YES please provide more details: |
| EU Tissue Establishment Code:  *For EU Members States only. Please check* [*https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml*](https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml) |

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| 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? |
|  |

|  |
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| Does your facility collect on behalf of a Donor Registry(s)? |
| NO  YES  If YES please provide more details: |

#### END OF SECTION

# HPC, APHERESIS COLLECTION

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

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| Application for: |
| First-time accreditation  Reaccreditation |

|  |
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| **ONLY for centres applying for Reaccreditation** |
| 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? |
| N/A  NO  YES  If YES please provide more details: |
| Have there been any changes of key personnel in the programme since the last JACIE inspection? |
| NO  YES  If YES please provide more details: |

|  |
| --- |
| Year collection activity began |
| Click here to type text. |

|  |  |
| --- | --- |
| Collection by apheresis activity Complete the following table regarding the total 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 twelve (12) months period preceding accreditation. Please indicate the number of products collected by apheresis in the previous 12 months. | |
| **Time Period** | **TOTAL NUMBER OF PROCEDURE (AUTO and ALLO)** |
| Click here to type time period. |  |
| **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** | **TOTAL NUMBER OF PROCEDURE (AUTO and ALLO)** |
| Click here to type Year 1 |  |
| Click here to type Year 2 |  |
| Click here to type Year 3 |  |
| Click here to type Year 4 |  |

|  |
| --- |
| Apheresis is performed on: |
| Adults  Paediatrics |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Key personnel *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.* | | | | | |
| **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 |  |

|  |
| --- |
| Is your collection facility accredited, licensed or authorised by any Regulatory organisation? |
| NO  YES  If YES please provide more details: |
| EU Tissue Establishment Code:  *For EU Members States only. Please check* [*https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml*](https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml) |

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| Other services associated with the Apheresis collection facility |
| What Cell Processing Laboratory(s) is used by your Apheresis Collection facility? |
|  |
| What Clinical Programmes (hospitals) does your Apheresis Collection Facility supply? |
|  |

|  |
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| Does your facility collect on behalf of a Donor Registry(s)? |
| NO  YES  If YES please provide more details: |

#### END OF SECTION

# CELL PROCESSING

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

|  |
| --- |
| Application for: |
| First-time accreditation  Reaccreditation |

|  |
| --- |
| **ONLY for centres applying for Reaccreditation** |
| 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? |
| N/A  NO  YES  If YES please provide more details: |
| Have there been any changes of key personnel in the programme since the last JACIE inspection? |
| NO  YES  If YES please provide more details: |

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| --- |
| Year laboratory commenced processing cellular therapy products |
| Click here to type text. |

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| --- | --- | --- | --- | --- | --- |
| Key personnel 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. | | | | | |
| **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: |  |  |  |  |  |

|  |
| --- |
| Is your laboratory accredited, licensed or authorised by any Regulatory organisation? |
| NO  YES  If YES please provide more details: |
| EU Tissue Establishment Code:  *For EU Members States only. Please check* [*https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml*](https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml) |

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| 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 (regulatory)? |
| NO  YES  If YES please specify the body(s):: |

|  |
| --- |
| What Clinical Programmes (hospitals) does your processing facility supply? |
|  |
| Does your processing facility serve a Donor Registry(s)? |
| NO  YES  If YES please provide more details |

**END OF SECTION**

Additional information:

# FOR JACIE OFFICE USE ONLY

|  |  |  |
| --- | --- | --- |
| Application Information | | |
| **Date of Reception:** | Click here to enter date. | |
| **CIC** | Click here to enter number | Up to date |
| **ID** | Click here to enter number | |
| **EUTEC Status** | Authorized  Suspended | Revoked  Ceased activity |
| **Active inspectors working at Centres** |  | |

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| Application Changes and/or Rejection *Give summary of all changes in the application form since first reception and all clarifications brought by the applicant. And/or describe the reasons for rejection if applicable.* |
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| --- | --- | --- |
| Application Review | | |
|  | **Date** | **Initials** |
| **1st Review** | Click here to enter date. | Click here to enter initials |
| **2nd Review** | Click here to enter date. | Click here to enter initials |

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. Spanish center ́s applying for the JACIE-FCAT joint process: please note that the contact details will be shared with FCAT. [↑](#footnote-ref-2)
3. The Program Director will be listed in the JACIE website. [↑](#footnote-ref-3)
4. 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-4)
5. 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-5)
6. 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-6)
7. Applications that include clinical units that are not EBMT members are subject to higher fees. [↑](#footnote-ref-7)
8. Check CIC number at https://www2.clinicalresearch.nl/members/ [↑](#footnote-ref-8)
9. Indications for haematopoietic stem cell transplantation for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2019. Bone Marrow Transplant. 2019 Apr 5. doi: 10.1038/s41409-019-0516-2. [Epub ahead of print] [↑](#footnote-ref-9)