**APPLICATION FORM – INITIAL ACCREDITATION & RE-ACCREDITATION**

**Instructions for completing this Application Form**

INITIAL ACCREDITATION (first time applying): Centres applying for the first time must submit the completed Inspection Checklist (self-assessment checklist) together with this Application Form.

RE-ACCREDITATION: Centres applying for re-accreditation will be requested to submit the Inspection Checklist (self-assessment checklist) later in the process.

# GENERAL DETAILS

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| Programme name[[1]](#footnote-2): |  |
| Country: |  |
| Working language of centre: |  |

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| * 1. **Contact details[[2]](#footnote-3)**   *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**   *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*](mailto: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[[3]](#footnote-4): |  |
| **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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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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| --- | --- | --- | --- |
| Number of sites *Number of sites for which you are requesting accreditation:* | | | |
| **Area** | **Patient** | **Number of sites** | **Name & Location of the site** |
| Clinical | Adult |  |  |
| Paediatric |  |  |
| Administration of IEC | 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. Please describe the* ***distance, duration and mode*** *e.g.5km, 10 mins, by car.*  *As indicated in the accreditation manual “different clinical sites ideally should be no more than one hour traveling distance in each direction, and they should exist within a single metropolitan area. Advancement in technology and travel may allow for more geographically dispersed sites, but such programs would be expected to provide unequivocal evidence of integration. An organizational chart depicting the relationship between program sites will facilitate documentation of integration and site locale.”* | | |
| Collection Facility(s) ↔ Clinical Unit(s) |  | |
| Clinical Unit(s) ↔ Intensive Care Unit – *also indicate mode of transfer e.g., trolley, ambulance* |  | |
| Collection Facility(s) ↔ Processing Facility(s) |  | |
| Processing Facility(s) ↔ 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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| Integrated or External Services *Please click the corresponding option:* |
| Services integrated[[4]](#footnote-5)  We use external[[5]](#footnote-6) collection and/or processing facilities? |

**END OF SECTION**

# CLINICAL TRANSPLANTATION PROGRAMME

Please only complete this section according to what you completed under section 2.1

|  |  |
| --- | --- |
| Transplant Facility *If there is more than one clinical site for transplantation, please complete a copy of this entire 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[[6]](#footnote-7)? |
| Yes. CIC number is:  No |

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| Application for: |
| **Initial accreditation (first-time):**  Clinical  IEC (Immune effector cells)  **Re-accreditation:**  Clinical  IEC (Immune effector cells) |

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| * 1. **Distribution of patients**   Please only complete this section according to what you completed under section 2.1 |
| * + 1. Adults and Paediatric patients are cared for: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Adults & Paediatric patients.  **Personnel:**  By the same team.  By a different team  NA because the accreditation scope does not include both Adults & Paediatric patients. |
| * + 1. Allogeneic and Autologous patients are cared: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Allogeneic & Autologous patients.  **Personnel:**  By the same team.  By a different team.  NA because the accreditation scope does not include both Allogeneic & Autologous patients. |
| * + 1. Do you work with any post-transplant care units? |
| No  Yes, where patients are transferred **after** achieving stable engraftment.  Note: Inspectors will want to see that you have Agreements with these Centres  Please include their names and location here:    Yes, where patients are transferred **before** achieving stable engraftment.  Note: These units will need to be inspected to ensure Compliance against the Standards in patient care. Please complete a copy of the “Section 3. CLINICAL TRANSPLANTATION PROGRAMME” (applicable sections) for each applicable post-transplant care site where patients are transferred prior to achieving stable engraftment. |

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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:*  ***Initial Accreditations: Please fill in the activity for the last calendar year or 12 months period in cell "Y1".***  ***Re-accreditations: Please fill in the activity for the last 4 calendar years*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PATIENT** | | **CELL SOURCE** | **HSCT** | | | | | | | | | | | | | | | | | | | | | **Immune Effector Cells** | | | | | | | | | | | |
| **Allogeneic\*** | | | | | | | | | | | | | | **Autologous\*** | | | | | | | **Allogeneic** | | | | | | | **Autologous** | | | | |
| **Adult** | | Related | | | | | | Unrelated | | | | | | | |
| Y1 | Y2 | Y3 | | Y4 | | Y1 | Y2 | Y3 | | | Y4 | | Y1 | | Y2 | | Y3 | | Y4 | | Y1 | | Y2 | | Y3 | | Y4 | Y1 | Y2 | Y3 | Y4 | |
| **HPC (Marrow)** |  |  |  | |  | |  |  |  | | |  | |  | |  | |  | |  | |  | |  | |  | |  |  |  |  |  | |
| **HPC (Apheresis)** |  |  |  | |  | |  |  |  | | |  | |  | |  | |  | |  | |  | |  | |  | |  |  |  |  |  | |
| **HPC (Marrow) + Cord blood** |  |  |  | |  | |  |  |  | | |  | |  | |  | |  | |  | |  | |  | |  | |  |  |  |  |  | |
| **Cord Blood** |  |  |  | |  | |  |  |  | | |  | |  | |  | |  | |  | |  | |  | |  | |  |  |  |  |  | |
| **Paediatric** | | **CELL SOURCE** | **Allogeneic\*** | | | | | | | | | | | | | | **Autologous\*** | | | | | | | **Allogeneic** | | | | | | | **Autologous** | | | | |
| Related | | | | | | Unrelated | | | | | | | |
| Y1 | Y2 | | Y3 | | Y4 | Y1 | Y2 | | Y3 | | | Y4 | | Y1 | | Y2 | | Y3 | | Y4 | Y1 | Y2 | | Y3 | | Y4 | | Y1 | Y2 | Y3 | Y4 | |
| **HPC (Marrow)** |  |  | |  | |  |  |  | |  | | |  | |  | |  | |  | |  |  |  | |  | |  | |  |  |  |  | |
| **HPC (Apheresis)** |  |  | |  | |  |  |  | |  | | |  | |  | |  | |  | |  |  |  | |  | |  | |  |  |  |  | |
| **HPC (Marrow) + 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 Programme Director |  |  |  |  |  |  |
| Quality Manager |  |  |  |  |  |  |
| Responsible person for nursing staff |  |  |  |  |  |  |
| Other consultant/senior physician (s) |  |  |  |  |  |  |
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| * 1. **Other services supporting the transplant programme**   *Please complete the information below even if all fall under the same “umbrella”.* | | |
| **Services** | **Facility Name** | **Facility ID number7** |
| HPC, Apheresis Facility |  |  |
| HPC, Marrow Collection Facility |  |  |
| Cell Processing Laboratory(s) |  |  |

**END OF SECTION**

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*7If there services outside the scope of this application, please check here if they are JACIE accredited* [*https://www.ebmt.org/jacie-accredited-centres*](https://www.ebmt.org/jacie-accredited-centres) *and provide their reference (ID number) .*

# HPC, MARROW COLLECTION

Please only complete this section according to what you completed under section 2.1

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

|  |
| --- |
| Application for: |
| Initial Accreditation (first-time) Re-accreditation |

|  |
| --- |
| * 1. **Distribution of patients**   Please only complete this section according to what you completed under section 2.1 |
| * + 1. Adults and Paediatric patients are cared for: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Adults & Paediatric patients.  **Personnel:**  By the same team.  By a different team staff.  NA because the accreditation scope does not include both Adults & Paediatric patients. |
| * + 1. Allogeneic and Autologous patients are cared: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Allogeneic & Autologous patients.  **Personnel:**  By the same team  By a different team.  NA because the accreditation scope does not include both Allogeneic & Autologous patients. |

|  |  |
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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 Procedures (Auto + Allo)** |
|  |  |
| **Reaccreditation**  *A minimum average of one (1) marrow collection procedure per year within each accreditation cycle.* | |
| **Time Period of previous accreditation (indicate each the for years below)** | **Total number of Procedures (Auto + Allo)** |
|  |  |
|  |  |
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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 HPC(M) harvest** |
| HPC Marrow Collection  Facility Medical Director |  |  |  |  |  |
| Quality Manager |  |  |  |  |  |
| HPC Marrow collection staff |  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |

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| --- |
| Is your HPC Marrow Collection Facility accredited, licensed or authorised by any Regulatory organisation? |
| Yes. Further information:  No |

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| --- | --- | --- |
| Other services supporting the marrow collection facility *Please complete the information below even if all fall under the same “umbrella”.* | | |
| **Service** | **Facility Name** | **Facility ID number8** |
| What Cell Processing Laboratory(s) is used by your HPC marrow collection facility? |  |  |
| 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)? |
| Yes. Further information:  No |

#### END OF SECTION

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8 *If there services outside the scope of this application, please check here if they are JACIE accredited* [*https://www.ebmt.org/jacie-accredited-centres*](https://www.ebmt.org/jacie-accredited-centres) *and provide their reference (ID number) .*

# HPC, APHERESIS COLLECTION

Please only complete this section according to what you completed under section 2.1

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

|  |
| --- |
| Application for: |
| Initial Accreditation (first-time)  Re**-**accreditation |

|  |
| --- |
| * 1. **Distribution of patients**   Please only complete this section according to what you completed under section 2.1 |
| * + 1. Adults and Paediatric patients are cared: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Adults & Paediatric patients.  **Personnel:**  By the same team.  By a different team staff.  NA because the accreditation scope does not include both Adults & Paediatric patients.  **Equipment:**  With the same equipment.  With distinct equipment.  NA because the accreditation scope does not include both Adults & Paediatric patients. |
| * + 1. Allogeneic and Autologous patients are cared: |
| **Location:**  At one (1) unit/site.  At another/different site. In this case, *please complete a copy of this entire Section* 3 *of this form* ***for each site***  NA because the accreditation scope does not include both Allogeneic & Autologous patients.  **Personnel:**  By the same team  By a different team.  NA because the accreditation scope does not include both Allogeneic & Autologous patients  **Equipment:**  With the same equipment.  With distinct equipment.  NA because the accreditation scope does not include both Allogeneic & Autologous patients. |

|  |  |
| --- | --- |
| 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 Procedures (Auto + Allo)** |
|  |  |
| **Re-accreditation**  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 (indicate each the for years below)** | **Total number of Procedures (Auto + Allo)** |
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|  |  |
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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 apheresis** |
| HPC Apheresis Collection Facility Director |  |  |  |  |  |
| HPC Apheresis Collection Facility Medical Director |  |  |  |  |  |
| Quality Manager |  |  |  |  |  |
| HPC Apheresis Collection staff |  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |
|  |  |  | Medical  Nursing |  |

|  |
| --- |
| Is your collection facility accredited, licensed or authorised by any Regulatory organisation? |
| Yes. Further information:  No |

|  |  |  |
| --- | --- | --- |
| Other services supporting the apheresis collection facility *Please complete the information below even if all fall under the same “umbrella”.* | | |
| **Service** | **Facility Name** | **Facility ID number9** |
| What Cell Processing Laboratory(s) is used by your Apheresis Collection facility? |  |  |
| What Clinical Programmes (hospitals) does your Apheresis Collection Facility supply |  |  |

|  |
| --- |
| Does your facility collect on behalf of a Donor Registry(s)? |
| Yes. Further information:  No |

#### END OF SECTION

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9 *If there services outside the scope of this application, please check here if they are JACIE accredited* [*https://www.ebmt.org/jacie-accredited-centres*](https://www.ebmt.org/jacie-accredited-centres) *and provide their reference (ID number) .*

# CELL PROCESSING

Please only complete this section according to what you completed under section 2.1

|  |
| --- |
| Cell Processing Facility name: *If there is more than one apheresis collection site, please complete a copy of this entire section of the form f****or each site*** |
| Institution: |
| Address: |
| Address: |
| City: |
| Post-code: |

|  |
| --- |
| Application for: |
| Initial Accreditation (first-time)  Re**-**accreditation |

|  |  |  |  |  |  |
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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 Facility Medical Director |  |  |  |  |  |
| Quality Manager |  |  |  |  |  |
| Laboratory Technician/technologist/scientist |  |  |  |  |  |

|  |
| --- |
| Is your laboratory accredited, licensed or authorised by any Regulatory organisation? |
| Yes. Further information:  No |

|  |
| --- |
| 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)? |
| Yes. Name of the body:  No |

|  |  |
| --- | --- |
| What Clinical Programmes (hospitals) does your processing facility supply? *Please complete the information below even if all fall under the same “umbrella”.* | |
| **Facility Name** | **Facility ID Number10** |
|  |  |
|  |  |

|  |
| --- |
| Does your processing facility serve a Donor Registry(s)? |
| Yes. Further information:  No |

**END OF SECTION**

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10 *If there services outside the scope of this application, please check here if they are JACIE accredited* [*https://www.ebmt.org/jacie-accredited-centres*](https://www.ebmt.org/jacie-accredited-centres) *and provide their reference (ID number) below.*

Additional information:

# FOR JACIE OFFICE USE ONLY

|  |  |
| --- | --- |
| Application Information | |
| **Date of Reception:** |  |
| **CIC** |  |
| **ID** |  |
| **Active inspectors working at Centre** |  |
| **Version of Standards** |  |

|  |
| --- |
| Application Changes and/or Rejection *Give summary of all changes in the application form since first reception and all clarifications brought by the applicant.*  *Describe the reasons for rejection if applicable.* |
|  |

|  |  |  |
| --- | --- | --- |
| Application Review | | |
|  | **Date** | **Initials** |
| **Review** |  |  |

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-2)
2. Spanish centre ́s applying for the JACIE-FCAT joint process: please note that the contact details will be shared with FCAT. [↑](#footnote-ref-3)
3. 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)
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-5)
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-6)
6. Applications that include clinical units that are not EBMT members are subject to higher fees. [↑](#footnote-ref-7)