JACIE

Joint Assurance Committee

ISCT | EBMT

JACIE IEC CERTIFICATION PROCESS

Applicant's guide

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Introduction

This guide is intended for centres applying for JACIE certification limited to Immune Effector Cell (IEC) activities under the stand-alone IEC pathway. It is aligned with the 3rd edition FACT–JACIE IEC Standards and should be read in conjunction with the IEC Accreditation Manual.

Its purpose is to guide centres through all stages of the certification process (Figure 1).

For updates, reference documents, or support, visit the JACIE Certification section at www.ebmt.org/jacie.

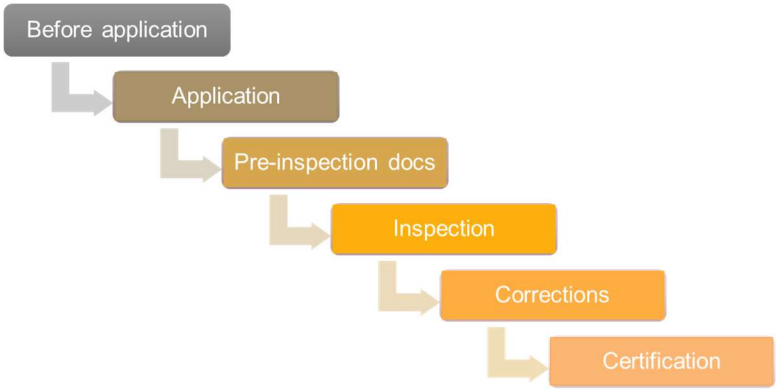


Figure 1. Stages of the JACIE Certification process

1. Section 1 – Pre-inspection

1.1. Eligibility criteria

The unit/s perform/s administration/collection/manufacturing of immune effector cell (IEC) therapies (e.g., CAR-T, TCR-T, NK-cell therapies)

The unit/s do/es **not** perform hematopoietic stem cell transplantation (HSCT)

1.2. Scope of Certification

The scopes for certification in the IEC certification pathway are:

Clinical	Collection	Processing
Administration of Immune effector cells in adult patients	Collection, Marrow	Processing, more than minimal manipulation
Administration of Immune effector cells in paediatric patients	Collection, Apheresis	
	Collection,Other tissues	

Additional information:

- *A Clinical unit eligible may rely on third-party entities for cell collection and/or processing that are JACIE certified*
    - *If the Clinical unit uses Collection and/or Processing units that are not JACIE certified, the Clinical unit will not receive Certification until these are JACIE certified*
- *When IEC are manufactured by a Company, the processing scope will not need to be certified*
- *Collection units will be inspected for all activities they perform.*

1.3. Sending the JACIE Application

To submit their application, centres should send the completed **JACIE IEC-only Application form and the JACIE IEC-only Checklist to jacie@ebmt.org**

The last version of these documents can be downloaded from the Document Centre

Before submitting an application, the applicant should ensure that they can clearly demonstrate compliance in all areas of the Standards but particularly in the following key areas:

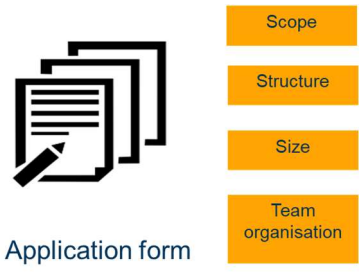
- Minimum transplant activity – see the current version of the FACT – JACIE Standards. The programme is required to meet the minimum transplant activity numbers before getting certified. If a centre wants to apply for certification but foresees a difficulty to reach the minimum activity, they should contact jacie@ebmt.org.

1.3.1. Application form

The information provided in the Application form will determine scope of certification, invoicing and inspection team.

When completing the Application form, the applicant should:

- Include the most up to date information
- Pay special attention when defining the layout of the programme (Scope, number of sites, distance between sites, number of Quality Management Systems)
- Review that no sections have been left empty. All fields need to be completed, if it is not applicable, please note N/A and the reason for this N/A



1.3.2. Checklist

Applicant should self-assess compliance against all standards under the scope of their certification and indicate if they are compliant, non-compliant, or if the Standard is not

applicable. Applicant should make sure that they are able to document how they meet each standard, for example by noting a specific SOP, training record, meeting record, etc. These explanations, references and other information should be entered into the Inspection Checklist to help the inspector easily find supporting documents and evidence of compliance with the standards. It is also especially important to indicate the reason why Standards are Not applicable or Non-Compliant.



Checklist

- If a centre has more than one unit for the Clinical, Collection or Processing parts, the applicant should complete one tab of that part for each unit.



To complete the Inspection Checklist assign someone to complete each section and someone to review all areas and ensure consistency when needed.



The Application form and Checklist shall be completed in English.



The Application form and Checklist will be reviewed by the JACIE Office, and the applicant will be contacted should any clarifications be needed. If an applicant does not respond to the queries within two weeks, it will result in the rejection of the application by the JACIE Office.



JACIE fees and discounts can be found at JACIE Certification Fees.

1.4. Signing the Standard Agreement

Once the application has been pre-approved by the JACIE Office, the applicant will be asked to sign a Standard agreement. By signing the agreement, the centre accepts the quotation, which can be found as an annex at the end of the document. The Agreement will then be signed by EBMT and the application will be considered approved.

The applicant should not pay the Quotation attached to the agreement. They will be directly invoiced by the EBMT Finance Office at the time of inspection. Please ensure that the details of the finance office/individual responsible for acting on the invoice are correct on the application form.

JACIE does not provide translation services. The Centre can translate the Agreement if they require, but EBMT will only sign the English version. Additionally, all requests related to the Financial requirements and Legal requirements shall be in English.



The applicant should sign and return the Standard Agreement to the JACIE Office within 30 days of receiving it. When an Applicant does not follow this deadline, their Application will be considered abandoned.

1.5. Preparing the pre-inspection documentation

Once the Application form has been approved, the applicant shall upload the pre-inspection documents required according to the "Appendix I - **Table 1: Pre-inspection document**" and organise them following the folder structure previously provided by the JACIE Office in SharePoint.

Each folder's name will include a (#nn) that refers to a document from **Table 1 - Pre-inspection Documentation List**

- The selected documentation to be sent to JACIE should be the latest version available and up to date.
- The documents should be organised following the JACIE requirements to allow easy identification of area-specific documents.
- Folders from the Folder structure shall not be deleted.
- All folders should be populated. When an applicant cannot or does not need to provide a document for a specific folder, they should indicate the reason for this in a Text note/Word document stored in that folder.
- For additional information, Centres should find the Standard referenced and/or the
- guidance in the Accreditation Manual related to that Standard.
- It is the responsibility of the centre to ensure that the documentation provided to JACIE has appropriate security measures in place before the transfer and to make certain that the respective national laws are followed.
- **Documents submitted shall not have any patient data. Please black out any personal data before uploading the documents.**

JACIE Coordinators will review the documentation for completeness and will contact the centre if documents appear to be missing.

The applicant is responsible to send any updated documents to the JACIE Office before the Inspection.



The pre-inspection documentation will be prepared in the language of the centre. In those cases where there are no inspectors that speak the language of the centre available, JACIE will request the pre-audit documentation in English.



The completed pre-inspection documentation should be provided to the JACIE office within 60 days after the Standard Agreement has been signed by both parties. Failure to provide the documents timely will result in the rejection of the application

The files are stored electronically by the JACIE Office in the folders created for each centre after application. On occasion, these files may also be consulted by members of the JAC. In the event of an appeal to the JACIE WP, the WP members may also be given access to these files. National representatives will also have access to information related to your application. You can refer to this page to consult the list of members involved: http://www.ebmt.org/jacie-organization-office.

1.6. Preparing for the Inspection

Once the pre-inspection documentation has been received the JACIE Office will ask the applicant to submit or prepare the following:

- Notification of any inspector with whom the applicant has Conflict of Interest
- **Set of dates when Centre cannot accommodate the Inspection because of bank holidays or other scheduled inspections**
    - Personnel being on annual leave will not be an acceptable reason for rejecting inspection dates, as the Standards stipulate that delegates or replacements should be assigned to cover roles in the program.
- Additional documents if required by the inspectors, up until two weeks prior to the inspection.

Onsite inspections:

- Recommendations of accommodation for the inspection team in a convenient and a business class hotel
- Information for the inspectors on how to get to the facility. When possible, make arrangements to pick up the team at their hotel. Otherwise, provide information about available transportation and estimate time that will be required to reach the facility to be inspected.
- Reservation of a room for the inspectors for the duration of the audit for reviewing case notes, procedures, manuals, and documents. In addition, reservation of a room for the initial meeting and the exit interview that is adequate in size to accommodate the entire inspection team, key programme personnel and others that the team wishes to invite.
- Arrangement of a modest business lunch for the inspection team. Inspectors will utilise the lunch hour as a working lunch.

Remote inspections:

- Arrangement of a quiet room for all teleconferences with proper sound, camera, internet connection, headphones.
- Video recording of the facilities using the Video requirement document



In those cases where there are no inspectors available that speak the language of the centre and the inspection needs to be conducted in English, the centre will have to identify facilitators. The facilitators do not need to be professional translators and the only restriction is that they can't be from the transplant programme (other doctors/nurses from the other departments, e.g. oncology, could be an option). The Centre should provide the facilitators' contact details.

When the Centre does not provide facilitators, they must provide written confirmation that all staff involved in the inspection process speak English.

When the Inspection has been confirmed, the applicant will receive notification of the inspection dates and team. Please note that final dates will depend on the availability of the inspectors.

2. Section 2 – Inspection

The Inspection will follow the agenda indicated in the Inspection Plan.

2.1. Opening meeting

- Should by attended by all key personnel of the Programme and members of the Inspection Team.
- The Programme Director should introduce the members of the Programme and present the programme to the inspection team. It is helpful to review the structure of the programme, the location of the applicant sites (particularly if these issues are complex and/or there are any off-site locations), identify the key personnel and present the activity. This presentation should not exceed 20-30 minutes.

2.2. During the inspection

- Each inspection team member should always have a knowledgeable member of staff available to answer questions, find documents or procedures, etc.
- Documents to provide evidence to Standards should be readily available to Inspectors during the inspection (SOPs, training records, validation studies, audits,…). Be prepared to gather additional documentation requested by the team during the time that they are present in your facility.
- Be prepared to have someone escort the inspectors to each of the sites during an onsite inspection. If there are distant sites, be prepared to transport the inspectors there and accompany them at those sites.
- Inspectors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites.
- Assume that the inspectors will want some closed session time during the lunch hour, though they may also wish to use a portion of this time to communicate with the applicant. Be available. Be sure to check with the inspection team for questions or concerns related to completing the inspection visit before you leave for your own lunch break. Make sure inspectors have good internet connection and some drinking water available.

2.3. Closing meeting

- At the end of the inspection, before the Closing meeting, the inspectors might meet privately with the Programme Director and/or designated directors if there are issues to be raised that may be of a sensitive or confidential nature.
- The Closing meeting is open to all personnel involved in the programme and the inspectors will summarise their major findings and outline the remainder of the certification process. The inspectors will submit their observations to the JACIE Office and these will be reviewed by the JAC, who will assess the applicant centre's level of compliance and make recommendations for the correction of any deficiencies.

3. Section 3 - Post-inspection

3.1. Feedback form

After the inspection, the applicant will receive an Inspection Evaluation form. The form should be used by the applicant to formally state satisfaction or to raise any issues that may have occurred during the inspection visit. It also gives the applicant an opportunity to give feedback on the process overall. This information is used by the JACIE Office for the continuous improvement of the process.



Feedback and complaints can also be sent to jacie@ebmt.org at any time during the process.

3.2. Summary Report

Once the Inspectors have submitted the completed Report and Checklist to the JACIE Office, these will be reviewed by the Report assessors and the JAC. Sporadically, clarification may be required from the centre during this phase.

Once the JAC has assessed the level of compliance and made recommendations for the correction of deficiencies, the Summary Report and Checklist will be sent back to the centre.

3.3. Evidence of corrections

The applicant is given a timeline to address the deficiencies identified during Inspection and is expected to provide evidence to demonstrate that these have been addressed.

The evidence of corrections will be reviewed by the original inspection team.

The applicant should never contact the Inspectors directly during the Evidence of Corrections phase. Please ensure that you contact your JACIE Coordinator with your requests so that they can coordinate the process.

In some cases, a reinspection may be required to look at a very specific aspect of the programme or where a wider review is necessary. This will be arranged by the JACIE office on a date that is convenient for the applicant centre and the inspectors. Costs arising from the focussed reinspection will be payable by the centre. These costs will be limited to the inspector's travel, accommodation, and subsistence costs.

Centres are asked to submit their corrections within 6 months after receiving the Summary Report.

Where an applicant delays in submitting evidence of corrections to the JACIE Office more than 6 months after receiving the Summary Report, there will be a penalisation and certification will be awarded for a reduced period of time.

Where an applicant delays more than 12 months in demonstrating full compliance with the FACT-JACIE Standards after receiving the Summary Report, the certification process of the centre will be considered expired, and the centre must restart the process.

If this evidence is satisfactory and the centre is assessed as compliant against all standards, a final recommendation for certification will be sent to the JACIE Director for approval and the centre will be informed of the outcome. Please note that the certification is only granted after the Centre has paid the relevant certifications fees.

3.4. Receiving the JACIE Certificate

Once the centre has been granted JACIE Certification, it will be listed in the List of Certified Centres in the JACIE website and will receive the JACIE Certificate as well as JACIE 23 - JACIE Certification Policies and Brand Usage Guidelines.

4. Section 4 – Post certification

4.1. Surveillance

As part of the ongoing monitoring the Centres will be required to prepare a surveillance report at the end of the second year of the certification period. The purpose of this report is to ensure that the Facility has continued to comply with the Standards.

JACIE reserves the right to suspend the certification for Facilities that do not show continued compliance with the Standards.

4.2. Changes in certification

Certified centres are required to proactively inform JACIE of any changes (e.g. facilities, staff etc) in their centre or to their program by filling out a Report of Changes. The Report of Changes can be downloaded here: JACIE Document Centre

4.3. Re-certification

It is recommended that proceedings for Re-certification are initiated at least one year prior to expiry to minimize the possibility of lapses between certification cycles. Please bear in mind that such lapses are subject to the timing of document submission, availability of inspectors, the findings of the inspection and the applicant's submission of documentary evidence of corrections.

5. Section 5 – Frequently asked questions

Question	Answer
Can a centre without any transplant activity apply for IEC-only certification?	Yes. This certification pathway is designed for centres that do not perform HSCT but wish to deliver IEC therapies.
If my programme only delivers IEC therapies, what Standards do I need to use?	Centres should use the IEC-specific checklist aligned with the 3rd edition standards.
Can we combine IEC and HSCT certification?	If the centre provides both services, these can be combined under the Certification pathway for HCT.

Appendix I - TABLE 1 - Pre-inspection Documentation List - Clinical, Collection – Bone Marrow, Apheresis, Other tissues – Processing.

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	General documentation folder				
1	Centre licence(s)/ certification(s) for relevant IEC activity	B1.2.1, C1.2.1 D1.2.1	✓	✓	✓
2	Programme Organigramme/s that include/s key personnel (position and name) (All applicable Organigrammes to the scope of certification: B, C, D)	B4.3 C4.3 D4.3	✓	✓	✓
3	Floor plan of all Programme facilities, with IEC activity areas highlighted. If facilities are not located in the same building, include a map showing locations of all sites. Identification/ description of each of the following services including their location relative to the clinical site(s): Emergency Department Blood Bank or transfusion service Intensive Care Unit(s) Pharmacy Investigational Drug Pharmacy	B1.6 C1.6 D1.6	✓	✓	✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	C7, CM7 & D7 Labels				
4	SOP for labelling (and/or re-labelling)	C5.1.9 D5.1.6	✓	✓	
	Listing of all labels that are applied to each step of collection, processing and distribution: ***NOTE: Please black out any patient identifiers.***	C7 D7			
5	Primary collection container label, applied at the completion of collection	Appendix II	✓	✓	
6	Label applied at completion of processing of IECs.	Appendix II		✓	
7	Labels attached prior to distribution/ Labels applied prior to transport of cellular therapy products, including inner and outer shipping labels, if applicable	Appendix II and III		✓	
8	Documentation that accompanies product at distribution, if applicable	Appendix IV		✓	
9	Biohazard and warning labels and method of notifying Clinical staff of biohazard if not written on label. Labels with incomplete eligibility and positive infections markers	Appendix II	✓	✓	
	PART B, PART C, PART D				
	B3, CM3, C3, D3 - Personnel				
	Clinical Program Director, Facility Directors, Medical Directors (Clinical/Collection/Processing)				
10	Copy of current Medical License for Medical Directors	B3.1.1 C3.2.1 D3.2.1	✓	✓	✓
11	Copy(s) of current certificate(s) of higher specialist training	B3.1.1 C3.1.1 C3.2.1 D3.1.1 D3.2.1	✓	✓	✓
12	Curriculum vitae of all directors.		✓	✓	✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
13	Written documentation of regular participation in educational activities related to the field of cellular therapy, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity ○ Date of activity ○ Approximate number of hours of activity	B3.1.5 C3.1.3 C3.2.1.2 D3.1.4 D3.2.4	✓	✓	✓
	All other Attending Physicians (specify adult and paediatric programmes, if applicable):	**B3.2**			
14	Copy(s) of current certificate(s) of higher specialist training	B3.2.1			✓
15	Curriculum vitae	B3.2.1			✓
16	Copy of current Medical License	B3.2.1			✓
17	Written documentation of regular participation in educational activities related to the field of cellular therapy, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity ○ Date of activity ○ Approximate number of hours of activity	B3.2.3			✓
	Nurses	**B3.6**			✓
18	Document describing the following: ○ Number of nurses per patient ○ Number of permanent staff / rotational staff ○ Employment of relief nurses ○ Documentation of nurses trained in the management of patients receiving cellular therapy	B3.6			✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
19	Nursing Guidelines for care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and non-infectious processes, mucositis, nausea and vomiting, and pain management	B3.6.2.5			✓
	Pharmacists	**B3.7**			
20	Copy of current license	B3.7.1			✓
21	Written documentation of regular participation in educational activities related to the field of cellular therapy, including the minimum information for each activity B3.8.4 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity ○ Date of activity ○ Approximate number of hours of activity	B.3.7.4			✓
	Consulting Specialists	**B3.8**			
	Documentation of appropriate credentialing of the consulting specialists and/or specialist groups:				
22	Cardiology	B3.8.1.1			✓
23	Infectious Diseases	B3.8.1.4			✓
24	Intensive Care	B3.8.1.5			✓
25	Nephrology	B3.8.1.6			✓
26	Neurology	B3.8.1.7			✓
27	Palliative and end of life care	B3.8.1.10			✓
28	Pathology	B3.8.1.11			✓
29	Psychiatry	B3.8.1.12			✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
30	Pulmonary Medicine	B3.8.1.13			✓
31	Radiology	B3.8.1.15			✓
32	Surgery	B3.8.1.16			✓
33	Transfusion medicine	B3.8.1.17			✓
	Quality Manager	**B3.9**			
34	Curriculum vitae	B3.9.3	✓	✓	✓
35	Written documentation of regular participation in educational activities related to the field of cellular therapy and quality management, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example webinar, meeting, grand round, etc.) ○ Topic of activity ○ Date of activity ○ Approximate number of hours of activity	B.3.9.3 C3.3.3 D3.3.3	✓	✓	✓
	Data Manager	**B3.10**			
36	Curriculum vitae	B3.10.2			✓
37	Written documentation of regular participation in educational activities related to the field of cellular therapy and data management, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example webinar, meeting, grand round, etc.) ○ Topic of activity ○ Date of activity ○ Approximate number of hours of activity	B3.10.2			✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	B4, CM4, C4, D4, Quality Management				
38	**QM Plan:** Complete copy of the facility's Quality Management Plan/Manual	B4.2 C4.2 D4.2	✓	✓	✓
39	**SOP for training and competency:** SOP for Training (including Initial training, competency, and retraining of all employees)	B4.4 C4.4 D4.4	✓	✓	✓
40	**Third Parties:** Description of any service(s) (i.e., collection or processing) that is performed for the Clinical Program by another facility under a contract.				✓
41	**Third Parties:** Description of any service(s) (i.e., collection or processing) that the applicant program provides for other facilities by contract.	B4.6 C4.6 D4.6	✓	✓	
42	**Third Parties:** Service Level Agreement (SLA) or contracts with an external service provider e.g. microbiology testing laboratory, manufacturing company		✓	✓	✓
43	**Outcome review:** Written criteria/SOP used for reviewing cellular therapy product safety, product efficacy, and/or the clinical outcome and including frequency of review.	B4.7.1			✓
44	**Outcome review:** Most recent outcome analysis/report, including the endpoint(s) of clinical function as approved by the Clinical Program Director	B4.7.3.1			✓
45	**Audits:** A list of audits performed in the 12 months prior to document submission including scope of the audit, date, audit log and follow up done.	B4.8 C4.8 D4.8	✓	✓	✓
46	**Audits:** A calendar of audits to be performed in the future and their scope. See Standard B4.8.5, C4.8.5, D4.8.5 for minimum required audits to be reflected.	B4.8 C4.8 D4.8	✓	✓	✓
47	**Traceability, chain of custody:** SOP/Policies for traceability, chain of custody, chain of identity	B4.11 C4.11 D4.11	✓	✓	✓

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
48	**Validation:** Validation protocol or SOP	C4.15 D4.15	✓	✓	
49	**Validation:** Example of one completed validation study performed by the collection and processing facility staff. An example may be of the validation of a process or procedure	C4.15 D4.15	✓	✓	
50	**Quarterly QM:** Quarterly QM Activity Reports, Samples of QM meeting minutes	B4.17 C4.17 D4.17	✓	✓	✓
51	**Annual Report:** Report from last annual review of the effectiveness of the overall Quality Management Program.	B4.18 C4.18 D4.18	✓	✓	✓
	B5, C5, D5 Policies and SOPs				
52	**Administration of IEC:** SOP(s) for receipt and administration of IEC	B5.1.5 B7.6			✓
53	**Receipt of IEC by pharmacy:** Detailed description of the pharmacy procedure for receipt of IEC products at the hospital, storage policy and pharmacy oversight if storage is outside the pharmacy	B7.6			✓
54	**Management of IEC toxicities:** SOP for management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.	B5.1.10 B5.1.11 B7.8			✓
55	**Disaster plan:** SOP for emergency procedures and disaster plan	B5.1.17 C5.1.20 D5.1.19	✓	✓	✓
56	**Collection:** SOP(s) for adult/paediatric cellular therapy product collection	C5.1.6	✓		
57	**Cryopreservation and thawing:** SOP(s) for cryopreservation and thawing	D5.1.3.1		✓	
58	**Storage:** SOP(s) for cellular therapy product storage	C5.1.11 D5.1.8	✓	✓	
59	**Transport and Shipping:** SOP(s) for packaging, transportation and shipping	C5.1.13 D5.1.10	✓	✓	
60	**Waste disposal:** SOP(s) for disposal of medical and biohazard waste (include IEC if applicable)	C5.1.14/19 D5.1.12/17	✓	✓	

#	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
61	**Environmental control:** SOP for environmental control, including a description of the environmental monitoring plan	C5.1.16 D5.1.16	✓	✓	
62	**List of SOPs** including Title, version number and date of last revision for each applicable facility	B5.2 C5.2 D5.2	✓	✓	✓
63	**SOP about SOPs:** SOP describing the process of writing SOPs	B5.3 C5.3 D5.3	✓	✓	✓
	B6, CM6 & C6 Donors selection, evaluation and management		✓	✓	✓
64	Unsigned consent forms for consent to be a cellular therapy product donor, including the form and any information given to the donor **AND** unsigned consent forms for the cellular therapy product collection procedure	B6.1 C6.1	✓		✓
65	SOP (or documents) used to determine donor eligibility and suitability	B5.1.4 C5.1.3	✓		✓

Contact

In case of queries or questions, please do not hesitate to contact the JACIE Office:

JACIE Office
Parc Científic de Barcelona, Edifici Torres R+D+I
Carrer de Baldiri Reixac, 4-8
08028, Barcelona, Spain
jacie@ebmt.org

Centres can also raise issues of national importance to JACIE through their National Representatives.