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Introduction

Centres applying for accreditation are required to submit documentation in advance of the inspection. This documentation is requested so that the inspectors can understand the centre's activity and organization and also to check compliance with some of the standards before the on-site visit.

The requested documentation includes:

- Selection of key SOPs
- Evidence of staff training and qualifications
- Official facility licenses and authorizations
- Quality Management Manual or Handbook
- Basic evidence that the QM system is functioning
- Consent forms and related information
- Sample labels
- Plans or maps of the Centre
- Sample agreements with third-party service providers

See below for full details.

Language

Document should be in the language of the Centre since JACIE would expect to assign inspectors that speak and understand the language. However, there may be exceptions to this:

- Centre is in a country where no inspectors are available
- JACIE may not have inspectors anywhere that speak the Centre's language
- The transplant community in a given country has requested that only external inspectors be assigned to avoid conflicts of interest

In these cases, we must resort to other inspectors to perform the inspection. For these inspectors, one of the key parts of their preparation is reading documents made available in advance. Without this it is very difficult for them to arrive on-site adequately prepared, and this would clearly affect the quality of the inspection.

In such cases, JACIE will ask the Centre to translate a selection of the documents provided to the inspectors in advance of the inspection and will request the Centre to provide local experts to facilitate interviews and understanding of documentation.
Please contact the Accreditations Coordinator at jacie@ebmt.org if you have any doubts about this aspect.

Standard folder structure

Applicant will be requested to complete the pre-inspection standards folder structure in SharePoint. JACIE will be providing a Microsoft 365 license to each applicant once their application is approved.

The pre-inspection folder structure consists of folders and sub-folders relevant to each part of the standards: Clinical, Immune effector cells, Collection – Bone Marrow and Apheresis, Processing, General, Donors selection-evaluation-management, Labels and coding

By following the folder layout, you will be able to group and classify your documents in such a way that the inspectors can easily identify the document and its purpose.

See the Table 1 and Table 2 below to understand how the folders are organized.

Please note that you might have to save the same document into more than one folder. This could be because:

1. The document is relevant to two different sections e.g., labelling for collection and for processing
2. A single document might cover several different areas e.g., donor and patient consent
3. Different inspectors will assess different areas e.g., the clinical inspector will also look at bone marrow while the collection inspector will only look at apheresis

By copying the document to the relevant files, you will make it easier for the inspectors to find the document relevant to their part of the inspection.

Once you have the files uploaded into their relevant folders, please inform the Accreditation Coordinator.

When do I have to upload these documents?

Documents should be uploaded to SharePoint within 90 days after formal approval of the application form. Failure to provide the documents in a timely manner could result in the rejection of the application.

What about if I upload a document and then it is updated in our system?

Any revised documents should be uploaded to SharePoint at least 4 weeks before the inspection date.

What does JACIE do with these documents?

Firstly, the JACIE Office checks the folders contents. The staff does not assess the quality of the documentation, only that a file or document is present. The inspectors assess the contents of the documents. If documents appear to be missing, the JACIE Office will contact the centre to ask for the documents.
After this check, JACIE removes the access of the applicant to the pre-audit documentation folder in SharePoint and grants access to the Inspection Team members to prepare for the inspection. On occasion, these files may also be consulted by JACIE Report Assessors, JACIE Technical Consultants and/or JACIE Accreditation Committee members. In all cases, anyone given access to the files is reminded of their obligation to keep confidential any information contained therein. These files are maintained indefinitely.

How does JACIE store and distribute these documents?

JACIE uses the Microsoft 365 cloud-based service for document storage and distribution. This system is secured using industry-standard encryption combined with other measures to protect data. See https://www.microsoft.com/en-us/trust-center for their full security specifications.
While our strong preference is to use SharePoint to distribute files to inspectors, there may be technical or other reasons that do not permit us to do so. In these cases, documents may also be distributed via WeTransfer (or similar), email (as attachments) or on CD or USB memory sticks via regular postal or messenger services.

Please note that it is the responsibility of the centre to ensure that the documentation provided to JACIE has appropriate security measures in place before the upload / transfer and to make certain that the respective national laws are followed.

Important note: JACIE will no longer include the MED-A review as part of the inspection process, so no documentation/information regarding MED-A is required. Inspectors will continue to check that centres have performed their own audit of accuracy at a minimum annually as per B4.8.3.2 Audit of the accuracy of the data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Med-A Forms of the EBMT.

Contact details

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TABLE 1 - Pre-inspection Documentation List: Clinical, Collection – Bone Marrow and Apheresis, Processing, General, Donors selection-evaluation-management, Labels and coding.

Instructions

- Please do not use patient names on the documents submitted
- If your facility utilizes electronic records, hard copies of the primary source data must be assembled, flagged, and ready for inspector review before the onsite inspection (not applicable for remote inspections)
- Inspectors can request additional information prior to the inspection and during the inspection. Those items not provided for inspector review by the end of the inspection will be marked as a deficiency
- For additional information, see the Standard referenced and/or the guidance in the Accreditation Manual related to that Standard
- Contact the JACIE Office if you have any questions

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	General				
1	Health authorities license/certification of facilities, where applicable	B1.3.1, CM1.3.1 C1.3.1 D1.2.1	✓	✓	✓
2	Programme organizational chart that includes key personnel (position and name)	B4.3 C4.3 D4.3	✓	✓	✓
	Quality Manual, Policies and Procedures:				
3	Quality Management: Complete copy of the facility's Quality Management Plan/Manual	B4 CM4 C4 D4	✓	✓	✓
4	Report from last annual review of the effectiveness of the overall Quality Management Program.	B4.18 C4.18 D4.18	✓	✓	✓
5	List of SOPs including Title, version number and date of last Revision for each applicable facility		✓	✓	✓
6	SOP describing the process of writing SOPs		✓	✓	✓

7	SOP for Training	B4.4 C4.4 D4.4	✓	✓	✓
8	**Validation:** The validation or qualification protocol and an example of one completed validation or qualification study performed by the collection or processing facility staff. An example may be of the validation or qualification of a process, piece of equipment, reagent(s), or supplies used in the Collection or Processing Facility.	C4.14 D4.14	✓	✓	
9	**Cryopreservation:** SOP(s) for each cryopreservation procedure performed in the Processing Facility.	D5.1.3.1		✓	
10	Unsigned consent forms for consent to be a cellular therapy product donor, including the form and any information give to the donor.	B6.2 CM6.2 C6.2	✓ (if not the exclusive responsibility of the clinical unit)		✓
11	Unsigned allogeneic and/or autologous consent forms for the cellular therapy product collection procedure (if not previously submitted with the Clinical Program documentation).	B6.2.1 CM6.2.1 C6.2.1	✓ (if not the exclusive responsibility of the clinical unit)		
12	Agreement between donor and storage facility on the storage duration. (It can be included in a more general consent form to be signed before the product collection)	D12.1.1	✓ (if not the exclusive responsibility of the clinical unit)	✓ (if not the exclusive responsibility of the clinical unit)	✓
	Labelling & Product Information				
13	Labelling SOP	C5.1.9 D5.1.6	✓	✓	
14	Completed example of each label used by the processing facility NOTE: Use unique patient identifiers; do not use patient names.	C7 D7			
15	Primary collection container label, applied at the completion of collection of cells for allogeneic use	Appendix II	✓		
16	Primary collection container label applied at the completion of collection of cells for autologous use	Appendix II	✓		
17	Label applied at completion of processing of allogeneic cells.	Appendix II		✓	
18	Label applied at completion of processing of autologous cells.	Appendix II		✓	

19		Labels attached prior to distribution.	Appendix II		✓
20		Biohazard and warning labels and method of notifying Clinical staff of biohazard if not written on label.	Appendix III	✓	✓
21		Labels applied prior to transport of cellular therapy products, including inner and outer shipping labels, if applicable.	Appendix II and III	✓	✓
22		Documentation that accompanies product at distribution, if applicable	Appendix IV	✓	✓
23	Listing of all labels that are applied to each of the following cellular therapy product types:				
24		Autologous cellular therapy product from a fully eligible donor at distribution for administration			✓
25		Autologous cellular therapy product from a donor with a positive infectious disease marker at distribution for administration			✓
26		Allogeneic cellular therapy product from a fully eligible donor at distribution for administration			✓
27		Allogeneic cellular therapy product from a donor with a positive infectious disease marker at distribution for administration			✓
28		Allogeneic cellular therapy product from a donor with a positive history for infectious disease risk but with negative testing at distribution for administration			✓
29		Allogeneic cellular therapy product from a donor not tested within 30 days at the time of distribution for administration			✓
30		Copy of current circular of information in use at your facility	D11.2.4		
	Electronic Records If an electronic record system is used, documentation of validation of the system must be available onsite as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following FACT-JACIE Standards:				
31	Validated procedures for and documentation of:		D13.3.9		

32	Systems development	D13.3.9.1		✓	
33	Numerical designation of system versions if applicable	D13.3.9.2		✓	
34	Prospective validation of system including hardware, software, and databases	D13.3.9.3		✓	
35	Installation of the system	D13.3.9.4		✓	
36	Training and continuing competency of personnel in the use of the system	D13.3.9.5		✓	
37	Monitoring of data integrity	D13.3.9.6		✓	
38	Back-up of the electronic records system on a regular schedule	D13.3.9.7		✓	
39	System maintenance and operations	D13.3.9.8		✓	
40	System assignment of unique identifiers	D13.3.9.9		✓	
	Audits				
41	A list of audits performed in the 12 months prior to document submission including scope of the audit and date	B4.8 C4.8 D4.8	✓	✓	✓
42	A calendar of audits to be performed and their scope	B4.8 C4.8 D4.8	✓	✓	✓
	Site plans & maps				
43	General physical floor plan of all Programme facilities. If facilities are not located in the same building, include a map showing locations of all sites.		✓	✓	✓
44	Description of each of the following services including their location relative to the clinical program site(s):				
45	Radiation Oncology				✓
46	Emergency Department				✓
47	Blood Bank or transfusion service				✓
48	Intensive Care Unit(s),				✓
49	Pharmacy				✓
50	Investigational Drug Pharmacy				✓
	Third Party Agreements				
51	Description of any service(s) (i.e., collection or processing) that is performed for the Clinical Program by another facility under a contract.				✓

52	Description of any service(s) (i.e., collection or processing) that the applicant program provides for other facilities by contract.		✓	✓	
53	Sample Service Level Agreement (SLA) or contract with an external service provider e.g. microbiology testing laboratory	B4.6 C4.6 D4.6	✓	✓	✓
54	HLA laboratory: For allogeneic transplant programmes, a copy of the HLA laboratory's current ASHI or EFI accreditation certificate	B2.12			✓
	Personnel				
	Director or Heads of Service (Clinical/Collection/Processing)	B3.1			
55	Copy of current Medical License for Medical Directors	B3.1.1 C3. .1 CM3.1 D3.2.1	✓	✓	✓
56	Curriculum vitae, if not previously submitted, of all directors.	B3.3 C3.2 D3.2	✓	✓	✓
57	Documented experience including the size and complexity of the program as well as the approximated number of transplant patients the person has managed and photocopies of five (5) representative publications from the field of hematopoietic progenitor cell transplantation extending over ten (10) years.	B3.1 C3.1 CM3.1 D3.1			✓
58	Written documentation of one (1) year of specific clinical training as defined by Standard B3.3 *or* Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.1.2.	B3.3 B3.1.2			✓
59	Written documentation of regular participation In	B3.1.6 CM3.1.4 C3.1.4	✓	✓	✓

	educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	D3.1.4	✓	✓	✓
	All Other Attending Physicians (specify adult and paediatric programmes if applicable):	B3.2			
60	Copy(s) of current certificate(s) of higher specialist training	B3.2.1			✓
61	Copy of documentation of completion of requisite residency and fellowship	B3.2.1			✓
62	Copy of current medical license.	B3.2.1			✓
63	Written documentation of one (1) year of specific clinical training as defined by Standard B3.2 *or* Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.2.1 Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity:B3.2.2 o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	B3.2 B3.2.1 B3.2.3			✓
	Physician Training for Clinical Programme Directors and Attending Physicians	B3.3			

65	Written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.3 for each attending physician including Programme Director.	B3.3	
66	For Programmes requesting allogeneic transplantation accreditation, written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.4.	B3.3.4 B3.2.3	✓
67	Written documentation of knowledge in the procedural skills listed in Standard B3.3.5.	B3.3	✓
	Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners, certified nurse midwives, and clinical nurse specialists.	B3.5	
68	Copies of national certification/license to practice as required by the jurisdiction of the Programme.	B3.5.1	
69	Documentation of training and competency in transplant related cognitive and procedural skills they routinely practice, including but not limited to skills listed in Standards B3.3.4-B3.5.5	B3.3.4 B3.3.5	✓
70	Written documentation of regular participation in	B3.5.3.1	✓

	educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity:B3.5.3.1 o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity		✓
	Consulting Specialists	B3.8	
71	Documentation of appropriate credentialing of the consulting specialists and/or specialist groups. Clinical Programs are not required to submit documentation for individual consultants unless requested by the inspector.	B3.8.1 B3.8.2	✓
72	Surgery	B3.8.1.16	✓
73	Pulmonary Medicine	B3.8.1.13	✓
74	Intensive Care	B3.8.1.5	✓
75	Gastroenterology	B3.8.1.3	✓
76	Nephrology	B3.8.1.6	✓
77	Infectious Diseases	B3.8.1.4	✓
78	Cardiology	B3.8.1.1	✓
79	Pathology	B3.8.1.11	✓
80	Psychiatry	B3.8.1.12	✓
81	Radiology	B3.8.1.15	✓
82	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	B3.8.1.14	✓
83	Transfusion medicine	B3.8.1.17	✓
84	Neurology.	B3.8.1.7	✓
85	Ophthalmology	B3.8.1.9	✓
86	Obstetrics/Gynecology	B3.8.1.8	✓
87	Dermatology	B3.8.1.2	✓
88	Palliative and end of life care	B3.8.1.10	✓

	Nurses	B3.6	
89	Document describing the following: o Number of nurses per patient o Number of permanent staff / rotational staff o Employment of relief nurses o Number of nurses with specialist qualifications in oncology and/or haematology	B3.6	✓
	Pharmacists	B3.7	
90	Copy of current license.	B3.7.1	✓
91	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity B3.8.4.1 o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	B.3.7.4	✓
	Quality Manager	B3.9	
92	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity o Title of activity o Type of activity (for example webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	B.3.9.3	✓
	Support Services Staff	B3.11	

	Documentation of appropriate credentialing of the support services staff. Clinical Programs are not required to submit documentation for individual consultants unless requested by the inspector.		✓
93	The Clinical Program shall have one (1) or more designated staff with appropriate training and education to assist in the provision of pre-transplant recipient evaluation, treatment, and post-transplant follow-up and care. Designated staff shall include:	B3.11.1.	✓
94	Dietary staff	B3.11.1.1	✓
95	Social Services staff.	B3.11.1.2	✓
96	Psychology Services staff.	B3.11.1.3	✓
97	Physical Therapy staff.	B3.11.1.4	✓

TABLE 2 - Pre-inspection Documentation List: Immune Effector Cells

	DOCUMENTATION	STANDARD
	Quality Manual, Policies, Guidelines and Procedures:	
1.	Quality Management: Complete copy of the facility's Quality Management Plan/Manual highlighting where this describes IEC usage	B4.2
2.	List of SOPs including Title, version number and date of last revision for each applicable facility and highlighting any IEC-related SOPs	B5.1
3.	SOP for Management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.	B5.1.12
4.	Guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.	B7.8.5
5.	Written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit, emergency department, or equivalent when appropriate	B2.7.1
6.	Nursing Guidelines for care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumour 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
	Clinical monitoring and outcome review	
7.	Written criteria used for reviewing cellular therapy product safety, product efficacy, and/or the clinical outcome and including frequency of review.	B4.7.1
8.	For immune effector cells, the endpoint(s) of clinical function as approved by the Clinical Program Director	B4.7.3.2
	Third Party Agreements	
9.	Description of any service(s) (i.e., manufacturing) that is performed for the Clinical Program by another facility under a contract.	-
10.	Sample Service Level Agreement (SLA) or contract with a third-party provider of cellular therapy products	B1.2.1
	Training and Education	
11.	Documentation of Clinical Program Directors' and attending physicians' educational activities related to IEC, including the minimum information for each activity: o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	B3.2.3
12.	Documentation of Clinical Program Directors' and attending physicians' specific training and competency in the competencies included in Standard B3.3.3 as follows: • B3.3.4.19 Monitoring and management of neurologic toxicity, including immune effector cell associated neurotoxicity syndrome (ICANS). • B3.3.4.20 Monitoring and management of cardiac dysfunction • B3.3.4.21 Monitoring and management of renal dysfunction • B3.3.4.22 Monitoring and management of anaphylaxis	B3.3.4

	DOCUMENTATION	STANDARD
	• B3.3.4.26 Evaluation of post-transplant and other cellular therapy outcomes • B3.3.4.27 Monitoring and management of cytokine release syndrome • B3.3.4.28 Monitoring and management of tumor lysis syndrome and macrophage activation syndrome / hemophagocytic lymphohistiocytosis.	
	Consulting Specialists	
13.	Documentation of the specific support arrangements in place to support IEC therapy from the following specialties: • Intensive Care • Neurology	B3.8.1.5 B3.8.1.7
	Nurses	
14.	Nurse staffing policy describing the following: o Number of nurses per patient o Number of permanent staff / rotational staff o Number of nurses with specialist qualifications in oncology and/or haematology Employment of relief nurses	B3.6
	Pharmacists	
15.	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	-
16.	Documentation of pharmacists' regular participation in educational activities related to the cellular therapy process, cytokine release syndrome, and neurological toxicities, including the minimum information for each activity o Title of activity o Type of activity (for example, webinar, meeting, grand round, etc.) o Topic of activity (for example, hematology, cell transplantation, etc.) o Date of activity o Approximate number of hours of activity	B3.7.4