Name of Document: G-010-01-IEC Pre-inspection documentation guide Approved by: Eoin McGrath Responsible: Eva Controle Entry: Pre-Inspection documentation list	Creation date: 20/06/2018 Effective date: 20/06/2018 Review date: 25/10/2019 Modification: -	JACIE Joint Accreditation Committee ISCT | EBMT

Pre-inspection documentation for Immune Effector Cell (IEC) inspections

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 organisation and also to check compliance with some of the standards before the on-site visit.

The requested documentation includes:

- Selection of key documents
- Evidence of staff training and qualifications in IECs
- Quality Management Manual or Handbook
- 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 located 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.

When do I have to send these documents?

Documents should be sent to the JACIE Office within 30 working days after formal request by JACIE. Failure to provide the documents in a timely manner could result in the inspection date being postponed.

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

Any revised documents should be sent to the JACIE Office before the inspection clearly indicating what changes have been made and what document should be replaced.

What does JACIE do with these documents?

Firstly, staff at the JACIE Office check the contents. Staff do 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, the documents are distributed to the Inspection Team members for their preparations. The files are also stored electronically by the JACIE Office in the folders created for each centre after application. On occasion, these files may also be consulted by the Inspection Report Assessors when they review the Inspection Reports and by members of the Accreditation Committee. In the rare event of an appeal to the JACIE Committee, the Committee members may also be given access to these files if necessary.
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 for as long as necessary during the accreditation process and are deleted once the process has been closed.

How does JACIE store and distribute these documents?

JACIE uses the Dropbox 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.dropbox.com/security for their full security specifications.
While our strong preference is to use Dropbox 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 email as attachments or on CD or USB memory sticks via regular postal or messenger services.

Important notice: The centre should consider if there are any documents that require special handling. It is recommended that an internal discussion among the centre team be held before documents are submitted. Unless JACIE is told otherwise, we will assume that all documents can be stored and distributed using the above services. It is the responsibility of the centre to notify the JACIE Office if exceptions to this policy are required. In those cases, alternatives will be considered and discussed with the centre.

List of pre-inspection documents

	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.	B5.1.10
4.	Guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.	B7.11
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 B2.8
6.	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.	B3.7.3.4
	Clinical monitoring and outcome review	
7.	Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.	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.	B1.2.1
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: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.3.3
12.	Documentation of Clinical Program Directors' and attending physicians' specific training and competency in the competencies included in Standard B3.3.3 as follows: ○ B3.3.4.18 Cytokine release syndrome. ○ B3.3.4.19 Tumor lysis syndrome and macrophage activation syndrome. ○ B3.3.4.20 Neurologic toxicity. ○ B3.3.4.21 Cardiac dysfunction. ○ B3.3.4.22 Renal dysfunction. ○ B3.3.4.23 Respiratory distress. ○ B3.3.4.24 Anaphylaxis. ○ B3.3.4.28 Evaluation of post-transplant cellular therapy outcomes. ○ B3.3.4.29 Evaluation of late effects of cellular therapy	B3.3.4
	Consulting Specialists	
13.	Documentation of the specific support arrangements in place to support IEC therapy from the following specialties:	B3.9.1
14.	○ Intensive Care	B3.9.1.3
15.	○ Neurology	B3.9.1.13

	DOCUMENTATION	STANDARD
	Nurses	
16.	Nurse staffing policy describing the following: ○ Number of nurses per patient ○ Number of permanent staff / rotational staff ○ Number of nurses with specialist qualifications in oncology and/or haematology Employment of relief nurses	B3.7
	Pharmacists	
17.	Description of the pharmacy procedure for receipt of IEC products at the hospital, storage policy and pharmacy oversight if storage is outside the pharmacy	B3.8.3
18.	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 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.8.4

Contact details

JACIE Accreditation Office
EBMT Secretariat,
Edifici Dr. Frederic Duran i Jordà
Passeig Taulat, 116,
08005 Barcelona
Spain
Tel: +34 93 453 8570
Email: jacie@ebmt.org
www.ebmt.org/jacie-accreditation