


Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
---	---	---

Standard Agreement for JACIE Accreditation

Related document: Appendix A: quotation for application fees ID

The parties in this Agreement are:

The Stichting European Society for Blood and Marrow Transplantation, hereafter referred to as the 'EBMT', established under the laws of The Netherlands, and having its corporate seat at Rijnsburgerweg 10, 2333 AA Leiden, The Netherlands, legally represented by the EBMT Executive Director

and

[INSTITUTION] hereafter referred to as the

"applicant", established in [CITY] , for EBMT internal

processes also known under JACIE ID¹ [...], and legally represented by


[NAME & FAMILY NAME]:,

[POSITION]:

- Given that The EBMT, through the work of the Joint Accreditation Committee ISCT & EBMT, a Committee of the EBMT (hereafter 'JACIE'), has the goal of contributing to the improvement of the quality of care and services related to haematopoietic cellular therapy provided by transplant programmes and facilities;
- The FACT-JACIE International Standards are international standards that apply to all phases of collection, processing, storage, and administration of hematopoietic cellular therapy products; Published on the EBMT website and assumed known between parties (hereafter 'FACT-JACIE Standards');
- JACIE offers accreditation of compliance with the FACT-JACIE Standards by periodically inspecting transplant programmes or their component units and sites on request (hereafter 'accreditation process');
- The applicant wishes to participate in the accreditation process;
- EBMT awards accreditation to the applicant if conformity is determined to exist with the FACT-JACIE Standards through the accreditation process;
- A durable relationship is required between the EBMT and the applicant characterized by integrity, trust and rigour.

The parties therefore wish to establish the rights and obligations in this Agreement and have agreed as follows:

¹ Provided by the JACIE Office

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	---

Standard Agreement for JACIE Accreditation

1. Accreditation process


- 1.1. JACIE will perform the accreditation process applying the edition of the FACT-JACIE Standards current at the time of receipt of the application for accreditation.
- 1.2. The applicant agrees to meet the obligations in or pursuant to this Agreement, and the continued performance of the accreditation process and the subsequent award - if any - are subject to such full and continued compliance with such obligations.

2. Respective obligations in the accreditation process

- 2.1. Parties agree that it is material to their relationship to each have a contact person communicating on behalf of that party, and hence parties shall each have such contact person assigned at all times during the term of this Agreement.
- 2.2. Parties shall keep each other informed about the contact details of their respective contact person. Although information may be exchanged between several individuals of both parties, at first request of one party, the other parties' contact person shall forthwith confirm or correct information on behalf of that party.
- 2.3. JACIE shall ensure to the best of its abilities that all tasks within the accreditation process are performed by persons qualified to do this.
- 2.4. JACIE will nominate an inspection team to perform the on-site inspection of the applicant's facilities, at its sole discretion. However the applicant will be invited to consult the public list of JACIE inspectors and indicate to JACIE those inspectors to whom the applicant objects – giving reasons if so requested - to participating in the inspection team on the grounds of conflict of interest or other reasons.
- 2.5. The applicant will provide the JACIE inspection team with all the information, arrange for the cooperation of all members of staff, offer documents for inspection – within the limits of any applicable legal regulations – and give the JACIE inspection team access to all areas that require inspection in order to adequately perform the accreditation process. The applicant is also expected to proactively provide any information which they reasonably understand to be important for the assessment of JACIE about the accreditation.
- 2.6. The applicant will facilitate the task of the JACIE inspection team including but not limited to providing access to relevant (digital) information sources, private meeting space, meals and refreshments, internet connection and electrical power supply.
- 2.7. JACIE will ensure that the provision of the Summary Report and the decision about accreditation status take place within a reasonable amount of time.

3. Accreditation status


- 3.1. The JACIE Accreditation Committee shall assess, based on all information available to them, whether they are satisfied that all aspects have been assessed to reach a conclusion on the applicant being compliant with the FACT-JACIE Standards.
- 3.2. Should the JACIE Accreditation Committee determine that the applicant meets the FACT-JACIE Standards, JACIE will award accreditation. Such award will be for a

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	---

Standard Agreement for JACIE Accreditation

specific period of time not exceeding 4 years, for the sites and activities indicated in the award certificate, and may be subject to required actions and/or additional inspections and assessments.

- 3.3. Until the applicant has received formal notice of accreditation from JACIE in the form of the accreditation certificate, the applicant is not permitted to communicate or create the impression that they have been granted accreditation.
- 3.4. The aforementioned accreditation certificate will state the site(s) it applies to, the time period, and which activities are covered by the accreditation drawn from the list below:
 - Autologous and/or Allogeneic Transplantation in Adult Patients
 - Autologous and/or Allogeneic Transplantation in Paediatric Patients
 - Immune Effector Cells administration
 - Collection of HPC, Marrow
 - Collection of HPC, Apheresis
 - Cell Processing - minimally manipulated
- 3.5. The applicant shall not make any statements regarding accreditation beyond that which is specified in the accreditation certificate.
- 3.6. When, and for as long as, the applicant is accredited, the applicant may use the logo of JACIE within the guidelines of JACIE, using the format as provided by JACIE free of charge.
- 3.7. When, during the time period the accreditation is awarded for, facts or circumstances occur or change or facts or circumstances become known which the applicant in all reasonableness understands to be important for the assessment of JACIE about the accreditation or the conditions attached to it, the applicant will report them to JACIE in writing within one month after such fact becomes known or such circumstances change. For avoidance of doubt, the aforementioned change include but is not limited to changes to the representations as stipulated in clause 6.1 below.
- 3.8. JACIE may decide to suspend or withdraw the accreditation, either immediately or granting a period of time in which the situation must be resolved, on the grounds of one or several of the following circumstances:
 - 3.8.1. the applicant not meeting the conditions attached to the accreditation by JACIE;
 - 3.8.2. in response to complaints or information that an applicant may be non-compliant with FACT-JACIE Standards.
- 3.9. The decision for suspension or withdrawal comes into force as soon as this decision and the reasons for it are communicated to the applicant through written notice. For avoidance of doubt it is established that any disagreement with aforementioned decision is considered a dispute under this Agreement.

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	---

Standard Agreement for JACIE Accreditation

4. Publicity and confidentiality


- 4.1. Except as needed to perform the accreditation process, JACIE shall not divulge the status of a centre's application, except its (re-) accreditation, to third parties without the express permission of the applicant.
- 4.2. Accredited centres will be listed publically on the EBMT web site indicating the valid dates and accredited activities.
- 4.3. Applicants pursuing reaccreditation and not yet reaccredited will be listed publically on the EBMT website.
- 4.4. With due regard to the publication policy, JACIE will observe confidentiality about all non-public knowledge gained about the application in the course of the accreditation process. JACIE will have all persons having access to such non-public knowledge, sign a declaration of confidentiality, which remains in force after their affiliation with JACIE has ceased.

5. Payments

- 5.1. JACIE has issued a quotation with ID attached hereto as Annex A, as may be amended or renewed from time to time on mutual Agreement between Parties.
- 5.2. The applicant agrees to pay the amount stated in aforementioned quotation and agreed amendments thereto if any, within 30 days of receipt of an invoice thereto and into the bank-account and with reference as indicated in such invoice. Late payment may result in the application process being suspended. Amounts paid are non-refundable.
- 5.3. In the quotation fee all the costs for the accreditation process are included with the exception of expenses associated with follow-up onsite visits other than the full inspections. In the event of a revisit being required following the full inspection, the applicant shall reimburse all reasonable travel, subsistence and accommodation costs of the inspectors to JACIE.
- 5.4. If the applicant wishes to restart a paused application after 12 months have passed since the effective date of this Agreement, the applicant must submit a new application form and checklist and pay any difference between any fees already paid and the fees applicable at the time of resubmitting the application where such a difference exists.

6. Compliance with Laws

- 6.1. The applicant represents and warrants that it and its directors, officers, employees and agents:
 - 6.1.1. Are not currently excluded, debarred, or otherwise been determined ineligible to participate in health care programs;
 - 6.1.2. Are not under investigation or otherwise aware of any circumstances which may result in being excluded from participation in health care programs;


Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	---

Standard Agreement for JACIE Accreditation

- 6.1.3. Have not been convicted of a criminal offense related to the provision of health care items or services; and
 - 6.1.4. Are otherwise in compliance with local laws, rules and regulations that may relate to the FACT-JACIE Standards.
- 6.2. JACIE shall perform the accreditation process assuming local laws and regulations do not provide obligatory limitations or specific requirements for this type of activity. Parties agree that it is the responsibility of the applicant to investigate and inform JACIE of any obligatory limitation or requirement under legislation applicable to the accreditation process. Unless JACIE was informed up-front of the specific limitation or requirement causing damages, the applicant shall indemnify and hold JACIE blameless for damages that are attributable to non-compliance with such legislation.

7. Liability, warranty disclaimer, indemnity

- 7.1. EBMT shall not in any circumstances have any liability for any losses or damages which may be suffered by the applicant (or any person claiming under or through the applicant), whether the same are suffered directly or indirectly or are immediate or consequential, and whether the same arise in contract (including warranties), tort (including negligence) or otherwise howsoever, which fall within any of the following categories:
 - 7.1.1. special damage even if EBMT was aware of the circumstances in which such special damage could arise,
 - 7.1.2. loss of profits,
 - 7.1.3. loss of anticipated savings,
 - 7.1.4. loss of business opportunity or any other repercussion attached especially to the granting, expiration, suspension, or withdrawal of an accreditation,
 - 7.1.5. loss of goodwill,
 - 7.1.6. loss or corruption of data.
- 7.2. In any case the total liability of EBMT in connection with this Agreement, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the sums actual paid by the applicant in the 12 (twelve) months preceding to the damage causing event.
- 7.3. The exclusions in clause 7.1 shall apply to the fullest extent permissible by law, but does not exclude EBMT's liability for death or personal injury caused by the negligence of EBMT, its officers, employees, contractors or agents; or for fraud or fraudulent misrepresentation;
- 7.4. A grant of accreditation by JACIE is recognition of the applicant's performance at the time of application; accreditation does not constitute a warranty of complete or continuous compliance. EBMT EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, SATISFACTORY QUALITY, ACCURACY, TITLE AND

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	---


Standard Agreement for JACIE Accreditation

FITNESS FOR A PARTICULAR PURPOSE. In addition, EBMT does not guarantee that JACIE accreditation will be accepted by any third party for reimbursement purposes. The applicant is solely responsible for ensuring the quality and safety of its products and services, and determining the reimbursement requirements applicable to it.

- 7.5. Applicant shall indemnify and hold harmless EMBT, its employees, contractors, suppliers, agents, JACIE inspectors, members of the JACIE Accreditation Committee and other affiliated partners and persons (the ‘indemnities’) against all claims, demands, actions or proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of any individual, or private or public legal entity, in connection with damages, including financial consequences of personal injury or death, arising out of any clinical intervention or procedure performed at the sites that are or were part of an accreditation process under this Agreement.
- 7.6. The limitation of liability, disclaimer of warranty and indemnity shall survive the termination or expiration of this Agreement.

8. Duration and termination of Agreement

- 8.1. This Agreement comes into effect on the date of the last signature hereunder and will remain in full force and effect until expired or terminated in accordance with this Agreement.
- 8.2. This Agreement will expire on the latter of (i) the end of the accreditation process, or (ii) the end of the period for which an accreditation is awarded.
- 8.3. The Agreement may be prematurely terminated by EBMT providing notice thereto to the applicant:
 - 8.3.1. If the applicant despite repeated appeals does not meet one or more of the obligations reasonably needed for JACIE to determine compliance with the FACT-JACIE Standards, or any other breach of a material term;
 - 8.3.2. In case of failure by the applicant to progress to an onsite inspection within twelve (12) months from approval of the application by JACIE;
 - 8.3.3. If, during a continuous period of at 12 months from issuance of the Summary Report, the applicant has not achieved accreditation and no reasonable prospect exists that the applicant will be granted it;
 - 8.3.4. When an accreditation has been withdrawn.
- 8.4. The applicant may terminate this Agreement at any time for an objectively justified reason upon thirty (30) days prior written notice to EBMT.
- 8.5. Upon termination or expiration of this Agreement any accreditation still in existence shall be deemed withdrawn. Consequently the applicant will then cease to communicate or give the impression that it is (still) accredited by JACIE, and will actively remove all reference thereto.

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
---	---	---

Standard Agreement for JACIE Accreditation


- 8.6. Termination of this Agreement shall be without prejudice to any claim or right of action of either party against the other party for any prior breach of this Agreement.
- 8.7. Any term or condition that by its nature is meant to survive the termination or expiration of this Agreement shall continue to be in force after such termination or expiration.

9. Miscellaneous.

- 9.1. **Non assignment.** EBMT may not assign this Agreement, in whole or in part, without the prior written consent of the applicant. The applicant may assign this Agreement without EBMT's consent to any the applicant's Affiliate or to a third party successor to substantially all of its business to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction.
- 9.2. **Notices.** Any notices between parties shall be given through registered letter or overnight courier to the address of the relevant parties first stated above. Otherwise it is understood that e-mail communication shall be acceptable for all other types of communications between parties.
- 9.3. **Severability.** If any of the provisions or portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected.
- 9.4. **Amendments and waivers.** No modification of this Agreement will be deemed effective unless in writing and signed by each of the parties. No waiver under this Agreement shall be effective unless in writing and signed by the party to be bound. No such waiver shall be construed as a waiver of any right beyond that which is expressly waived in that signed writing.
- 9.5. **Entire Agreement.** The Agreement constitutes the entire Agreement between the parties with respect to the subject matter hereof and supersedes all prior negotiations, representations or agreements, written or oral, regarding the subject matter hereof.
- 9.6. **Prevailing Language.** The English language version of this Agreement shall be controlling in all respects and shall prevail in case of any inconsistencies with translated versions, if any.

10. Disputes

- 10.1. Complaints about the implementation of the accreditation process, any suspension or withdrawal, about the publication of information about the applicant or any other aspect of how JACIE functions, can be lodged with EBMT and will be dealt with according to the procedure regarding complaints and appeals.
- 10.2. Complaints arising from the accreditation process should be directed in writing to the JACIE Office. The first response will come from the JACIE Office. If warranted, the complaint can be escalated by the applicant or by the JACIE Office to the JACIE

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	--

Standard Agreement for JACIE Accreditation

Committee for consideration and response.

In the event of an appeal regarding a decision on accreditation status, the same process as described above applies. The ultimate arbitrator is the EBMT Board whose decision will be binding.

- 10.3. The Agreement will be governed and construed in accordance with the laws of The Netherlands, excluding any choice of law rules which may direct the application of the laws of another jurisdiction. Any controversy, dispute or claim which may arise out of or in connection with this Agreement, or the breach, termination, or validity thereof, shall – when such can apparently not be resolved through the process referred to in clause 10.1 above – be submitted to the competent courts of The Hague, The Netherlands who shall have exclusive jurisdiction.

DONE and SIGNED for agreement by the duly authorized representatives of parties:

On behalf of << INSTITUTION >>

Name:

Position:

In:

Date:

Signature:

On behalf of EBMT:


Name: Andreu Gusi, MA

Position: Director

In: Barcelona

Date:

Signature:

Name of Document: F-009-05-Standard Agreement for JACIE Accreditation Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 01/05/2018 Modification: n/a	
--	---	--

Standard Agreement for JACIE Accreditation

APPENDIX A: quotation for application fees

[PLEASE INSERT QUOTATION HERE]