



DELIBERAZIONE DEL DIRETTORE GENERALE

286/DG
Numero31 MAR. 2017
data**Oggetto:** Processo di accreditamento JACIE - CNT/CNS del Laboratorio di Manipolazione e Criopreservazione Cellulare. Sottoscrizione Accordo EBMT (European Society for Blood and Marrow Transplantation).Esercizio 2017 Conto 502020302Centro di Costo 10033400

Sottoconto n° _____

Budget:

- Assegnato € 310.926,97- Utilizzato € 304.766,97- Presente Atto € 6160,00

- Residuo € _____

Ovvero schema allegato Scostamento Budget NO SI Il Direttore della U.O.C. Economico
Finanziaria e PatrimonialeData... 29/3/17U.O.S.D: Qualità e Formazione
D.ssa Gloria Putzu
Estensore

Il Responsabile del procedimento

Data 28.3.17

Firma

Il Responsabile della U.O.S.D.
D.ssa Francesca PofiData 28.3.17

Firma

Proposta n° 234

del

16/03/17

PARERE DEL DIRETTORE SANITARIO

FavorevoleData 29.3.17
IL DIRETTORE SANITARIO
Dott. Stefano Pompili

PARERE DEL DIRETTORE AMMINISTRATIVO

Data 29/3/17
IL DIRETTORE AMMINISTRATIVO
Dott. Cristiano CamponiLa presente deliberazione si compone di n° 12 di cui n° 07 di pagine di allegati e una pagina attestante la pubblicazione e l'esecutività che ne formano parte integrante e sostanziale.

VISTO il Decreto Legislativo 30 dicembre 1992, n. 502 e successive modificazioni ed integrazioni;

PREMESSO che con Delibera n. 348/DG del 06/05/2016 è stato deliberato l'avvio del processo di accreditamento JACIE e CNT/CNS del Laboratorio di Manipolazione Cellulare in ottemperanza alle direttive Europee 2006/86/CE, 2006/17/CE e 2004/23/CE recepite dai D.lgs. 191/2007 e D.lgs 16/2010;

l'accreditamento FACT-JACIE è un accreditamento scientifico e pertanto può essere rilasciato solo dalla società scientifica di riferimento;

che per tale accreditamento le società scientifiche di riferimento sono esclusivamente JACIE e EBMT;

che per proseguire con il suddetto accreditamento è necessario procedere alla sottoscrizione di un accordo standard con EBMT (European Society for Blood and Marrow Transplantation);

che il costo totale di tale accreditamento è pari ad € 6160,00= così ripartito: € 3850,00= per la Registration Free e € 2310,00= per il Cell-Processing Laboratory;

che il Direttore Sanitario ha espresso parere favorevole;

RITENUTO pertanto necessario, al fine di procedere all'accreditamento JACIE - CNT/CNS del Laboratorio di Manipolazione e Criopreservazione Cellulare, sottoscrivere l'Accordo Standard per l'Accreditamento JACIE con la EBMT allegato al presente atto che ne costituisce parte integrante e sostanziale;

ATTESTATO che il presente provvedimento, a seguito dell'istruttoria effettuata, nella forma e nella sostanza è totalmente legittimo e utile per il servizio pubblico, ai sensi dell'art. 1 della legge 20/94 e successive modifiche ed integrazioni, nonché alla stregua dei criteri di economicità e di efficacia di cui all'art. 1 della legge 24/90 e successive modifiche ed integrazioni;

ATTESTATO in particolare che il presente provvedimento è stato predisposto nel pieno rispetto delle indicazioni e dei vincoli stabiliti dai decreti del Commissario ad acta per la realizzazione del Piano di Rientro dal disavanzo del settore sanitario della Regione Lazio;

PROPONE

per i motivi dettagliatamente esposti in narrativa che costituiscono parte integrante e sostanziale del presente provvedimento:

- di poter procedere alla sottoscrizione dell'Accordo Standard per l'Accreditamento JACIE con la EBMT (allegato al presente atto che ne costituisce parte integrante e sostanziale) con un impegno economico pari ad ad € 6160,00= ;
- di individuare il Direttore della UOC Medicina Trasfusionale, quale responsabile della corretta esecuzione della progetto assumendo la piena responsabilità in termini di spesa e liquidazione.



Deliberazione n.

del



L'onere complessivo di spesa pari ad € € 6160,00= derivante dal presente provvedimento trova riferimento al conto 502020302 "Formazione (esternalizzata e non) da privato" macro 19 sub-autorizzazione n. 15 Bilancio di previsione esercizio 2017.

Il Responsabile della U.O.S.D.
(D.ssa Francesca Pofi)

IL DIRETTORE GENERALE

VISTO il Decreto Legislativo 30 dicembre 1992, n. 502 e successive modificazioni ed integrazioni;

IN VIRTU' dei poteri conferitigli con decreto del Presidente della Regione Lazio n. T00031 del 30.01.2014 e prorogato con decreto del Presidente della Regione Lazio n.T00019 del 30 gennaio 2017;

PRESO ATTO che il Dirigente proponente il presente provvedimento, sottoscrivendolo, attesta che lo stesso a seguito dell'istruttoria effettuata, nella forma e nella sostanza è totalmente legittimo e utile per il servizio pubblico, ai sensi dell'art. 1 della legge 20/94 e successive modifiche ed integrazioni, nonché alla stregua dei criteri di economicità e di efficacia di cui all'art. 1 della legge 241/90 e successive modifiche ed integrazioni;

PRESO ATTO altresì che il Dirigente proponente il presente provvedimento, sottoscrivendolo attesta, in particolare, che lo stesso è stato predisposto nel pieno rispetto delle indicazioni e dei vincoli stabiliti dai decreti del Commissario ad acta per la realizzazione del Piano di Rientro dal disavanzo del settore sanitario della Regione Lazio;

VISTO il parere favorevole del Direttore Amministrativo e del Direttore Sanitario;


ritenuto di dover procedere

DELIBERA

di approvare la proposta così come formulata, rendendola disposta.

La U.O.S.D. Affari Generali curerà tutti gli adempimenti per l'esecuzione della presente deliberazione.

IL DIRETTORE GENERALE
Dott.ssa Ilde Coiro

Name of Document: F-009-03-Standard Agreement for JACIE Accreditation-755 Approved by: Eoin McGrath Responsible: Eoin McGrath Entry: Apply for JACIE Accreditation	Creation date: 22/12/2015 Effective date: 07/03/2016 Review date: 30/03/2016 Modification: include signature	
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Standard Agreement for JACIE Accreditation

Related document: quotation for application fees ID 2017010

The parties in this agreement are:

The European Society of Blood and Marrow Transplantation, hereafter referred to as 'the EBMT', established in Leiden, The Netherlands, and being the legal entity for the Joint Commission of the ISCT and EBMT, a Committee of the EBMT, hereafter referred to as "JACIE", legally represented by the EBMT Executive Director

and

[INSTITUTION] A.O. SAN GIOVANNI ADDOLORATA JACIE ID¹ [755] hereafter referred to as "the applicant", established in [CITY] ROMA and legally represented by [NAME & FAMILY NAME]: ILDE COIRO,

[POSITION]: DIRETTORE GENERALE

Given that


- The EBMT, through the work of the JACIE Committee and the JACIE accreditation programme, 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;
- JACIE offers accreditation of compliance with international standards by periodically inspecting transplant programmes or their component units and sites on request, via a standardised and established process and on the basis of pre-established standards
- The applicant wishes to participate in the JACIE accreditation programme;
- JACIE awards accreditation to the applicant if conformity is determined to exist with the standards;
- 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 to the following:

1. Participation in accreditation programme

1.1. JACIE will assess the applicant's activities for conformity with the edition of the FACT-JACIE International Standards valid at the time of the application and will apply the pre-established and publicised procedure and method to all centres in an equal

¹ Provided by the JACIE Office

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Standard Agreement for JACIE Accreditation

manner. All of the activities in relation to this procedure will hereafter be referred to as the 'accreditation process'


- 1.2. By participating in the programme, the applicant agrees to meet the obligations in or pursuant to this agreement.

2. Respective obligations in the accreditation process

- 2.1. JACIE shall assign an Accreditation Coordinator who will serve as the principle contact person in JACIE for the applicant.
- 2.2. The applicant will designate a contact person for each accreditation cycle to communicate on behalf of the applicant and will notify JACIE of any changes to this contact in a timely manner.
- 2.2.1. JACIE will not be responsible for internal communication within the applicant's team
- 2.3. The applicant shall give JACIE and its representatives all the cooperation necessary within reason to carry out the accreditation process and in particular in determining whether the applicant meets the requirements set by JACIE.
- 2.4. JACIE shall ensure to the best of its abilities that all tasks within the accreditation process are performed by persons qualified to do this.
- 2.5. JACIE will nominate an inspection team to perform the on-site inspection of the applicant's facilities.
- 2.5.1. The applicant will be invited to consult the public list of JACIE inspectors and indicate to JACIE those inspectors to whom the applicant objects to participating in the inspection team on the grounds of conflict of interest or other reasons.
- 2.5.1.1. JACIE reserves the right to seek further information on the reasons for rejection of inspector candidates and to assess whether the objection is reasonable.
- 2.6. 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 JACIE access to all areas that require inspection in order to adequately follow the accreditation process. The applicant is also expected to proactively provide any information which they reasonably understand to be important for the assessment of compliance.
- 2.7. The applicant will facilitate the task of the JACIE inspection team including but not limited to providing access to relevant information sources, private meeting space, meals and refreshments, and electrical power supply.
- 2.8. JACIE will ensure that the provision of the Summary Report and the decision about accreditation status take place within a reasonable amount of time (expected to be within 90 days of the inspection ending)

3. Accreditation status




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Standard Agreement for JACIE Accreditation

- 3.1. Should JACIE determine that the applicant meets the standards, JACIE will award accreditation for a specific period of time for the sites and activities indicated in the Application Form and subjected to inspection and assessment.
 - 3.1.1. JACIE reserves the right to place conditions on the accreditation status in the form of time period or required actions.
- 3.2. Until the applicant has received formal notification of accreditation from the JACIE Office in the form of the accreditation certificate and letter, the applicant is not permitted to communicate or create the impression that they have been granted accreditation.
- 3.3. The accreditation status will be granted for a specific period but not exceeding 4 years from final confirmation by the Accreditation Committee that they are satisfied that all aspects have been assessed to be compliant with the Standards.
- 3.4. For each specific period, the applicant will receive an accreditation certificate from JACIE stating the accreditation status of the applicant and which activities are covered by the accreditation drawn from the list below:
 - Autologous & Allogeneic Transplantation in Adult Patients
 - Autologous & Allogeneic Transplantation in Paediatric Patients
 - Collection of HPC, Marrow
 - Collection of HPC, Apheresis
 - Cell Processing - minimally manipulated
- 3.5. The applicant shall not use the accreditation information in such a manner as to bring JACIE into disrepute and shall not make any statement regarding accreditation that JACIE may consider misleading or unauthorized.
- 3.6. 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 terms of validity of the accreditation status, facts or circumstances occur or change or facts or circumstances become known which the applicant in all reasonableness understands to be important for the judgement of JACIE about the accreditation status 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.
- 3.8. JACIE may decide to suspend or withdraw the accreditation status on the grounds of one or several of the following circumstances:
 - 3.8.1. the applicant not meeting the conditions attached to the accreditation status by JACIE;
 - 3.8.2. the discovery of facts and circumstances about the applicant which are of such a serious nature that they lead to the presumption that the accreditation status cannot be maintained
 - 3.8.2.1. JACIE reserves the right to grant the applicant a period of time in which the situation must be resolved, and during which period accreditation will be suspended;



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Standard Agreement for JACIE Accreditation

- 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 health care organisation via certified mail or post. In the decision, JACIE will state the procedure and period of time in which the applicant can appeal the decision.
- 3.10. In the case of and during the period of the suspension or following withdrawal, the applicant is not permitted to communicate or give the impression that they continue to maintain their accreditation status.


4. Publicity and confidentiality

- 4.1. JACIE shall not divulge the status of a centre's application, except its accreditation status, to third parties without the express permission of the applicant.
- 4.2. Accredited centres will be listed publically on the JACIE web site indicating the valid dates and accredited activities.
- 4.3. With due regard to the publication policy, JACIE will observe confidentiality about all the knowledge gained about the organisation in the context of the accreditation process. This is in relation to all information which is not legally accessible for the public or third parties. For this purpose, JACIE will have all persons connected to JACIE, in whatsoever capacity, sign a declaration of confidentiality, which remains in force after the affiliation with JACIE has ceased.
- 4.4. JACIE will file information about the organisation in a reliable manner which is not accessible for unauthorized persons and should the case arise, ensure that it is adequately destroyed.

5. Payments

- 5.1. The organisation will remunerate EBMT with a registration fee and an accreditation fee at the time of application and in advance of the scheduled inspection date. Fees are based on the fees established by the Board of EBMT as published on the JACIE web site on the invoice date. Payment is required within 30 days of when JACIE issues the invoice to the organisation. Non-payment of fees within the 30 day period may result in the application process being suspended.
- 5.2. Acceptance of this agreement implies acceptance of the accreditation fees as indicated in Quotation ID 2017010 referred to at the start of this document.
- 5.3. In the registration fee and the accreditation fee, all the costs for the accreditation programme 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, travel, subsistence and accommodation costs of the inspectors will be charged to the organisation.
- 5.4. The Registration Fee is non-refundable.
- 5.5. If there is a considerable change in the size or function of the organisation that may affect the accreditation fee (for example, in the case whereby the number of locations and/or care provisions change) the organisation shall notify JACIE so that any necessary adjustments can be made.



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Standard Agreement for JACIE Accreditation

- 5.6. If the agreement is terminated for whatever reason, then the obligations which were already due should be met and there will be no right to restitution for payments which have already been met on account of this agreement.
- 5.7. If the organisation wishes to restart a paused application after 12 months from date of approval by JACIE and if JACIE fees have increased since the date of application, the applicant must pay any difference between the previous fees and the fees at the time of resubmitting the application.


6. Liability

- 6.1. The EBMT is not liable for any damage the organisation suffers during the accreditation process, unless intentional or gross negligence can be said to exist on the part of one or more persons appointed by JACIE.
- 6.2. The EBMT is not liable for any repercussions the organisation suffers by participating in the accreditation programme, through JACIE granting, continuing or deferring the accreditation status or not and through EBMT continuing or terminating this agreement.
- 6.3. The organisation safeguards the EBMT from all agreements with third parties which stem from the participation of the organisation in the accreditation programme and the decisions which JACIE takes in this context.
- 6.4. Payment of application fees does not guarantee that accreditation will be granted. Accreditation is subject to demonstrated compliance with the standards and approval by the Accreditation Committee.

7. Duration and termination of agreement

- 7.1. This agreement applies to the duration of the accreditation process and any eventual accreditation award period related to the application for accreditation.
- 7.2. Terminating the agreement on the part of EBMT shall not take place other than on the following grounds:
- 7.2.1. If the organisation persistently, and despite repeated appeals, does not promptly or adequately meet one or more of the obligations in this agreement;
- 7.2.2. Failure by the applicant to progress to an onsite inspection within twelve (12) months from approval of the application by JACIE
- 7.2.3. If, during a continuous period of at 12 months from issuance of the Summary Report, the organisation has not achieved accreditation and no reasonable prospect exists that the organisation will be granted it;
- 7.2.4. If facts, circumstances or behaviour occur at the organisation whereby JACIE in all reasonableness cannot be expected to continue the agreement.
- 7.3. The organization may terminate this Agreement at any time for an objectively justified reason upon thirty (30) days prior written notice to EBMT.
- 7.4. After terminating the agreement, the organisation is not permitted to communicate or give the impression that it has achieved JACIE accreditation.



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Standard Agreement for JACIE Accreditation

8. Changes to the agreement and unforeseen circumstances

- 8.1. The terms and conditions of this agreement may only be amended by the mutual written consent of the parties to this agreement. For avoidance of doubt EBMT reserves the right to amend the accreditation standard as referred to in Clause 3.1 hereinabove (among others) unilaterally at its sole discretion..
- 8.2. Where circumstances arise which are not described in this agreement, the EBMT Board will arrive at a decision, after having received a written notification from the organisation describing their position.

9. Disputes

- 9.1. Complaints about the implementation of the accreditation process, about the publication of information about the organisation or any other aspect of how JACIE functions, can be lodged with JACIE and will be dealt with according to the procedure regarding complaints and appeals.
- 9.2. Appeals against decisions by EBMT can be registered with EBMT and will be dealt with according to the procedure regarding complaints and appeals.
- 9.3. Dutch law is applicable to this agreement.
- 9.4. All disputes which may occur as a result of this agreement will exclusively be submitted to the competent court in The Hague, The Netherlands.

Drawn up and signed in duplicate:

On behalf of << INSTITUTION >>

Name: ILDE COIRO
Position: DIRETTORE GENERALE
In: ROMA
Date:
Signature:

On behalf of EBMT:

Name: Andreu Gusi, MA
Position: Director
In: Barcelona
Date:
Signature:





QUOTATION



European Society for Blood and Marrow Transplantation
 JACIE Accreditation Office
jacie@ebmt.org

Azienda Ospedaliera S. Giovanni-Addolorata
 USO Trapianto Cellule Staminali
 Emopoietiche UOC Ematologia - RTN
 Via Amba Aradam 8
 00184 Rome
 Italy

Quotation date. 08/02/2017
 Quotation ref. JACIE:
A0000207/2017010

Your VAT no. 04735061006

Description	VAT	Total (Euro)
Registration Fee	0 %	3.850,00
Cell-Processing Laboratory	0 %	2.310,00
Total (excl. VAT)		6.160,00
NL EU 3b+ICP		0,00

Total (incl. VAT) Euro 6.160,00

IF VAT reverse charge has been applied, this is according EU VAT Directives. The accreditation service provided is subject to VAT in the country where the centre is registered. Please ensure any local VAT regimes are respected.

Elementi di selezione: dettaglio conti

Subautorizzazione				Data ass.	Importo subaut.	Descrizione
Uff.Autor.	Anno	Numero	Sub.			
UA1	2017	19	15	28/03/2017	6 160,00	Processo di accreditamento JACIE - CNT/CNS del Laboratorio di Manipolazione e Criopreservazione Cellulare. Sottoscrizione Accordo EBMT

Provvedimento

Tipo	Anno	Numero	Esec.	Data	Descrizione
11	2016	1075	S	28/12/2016	Piano Formativo Aziendale anno 2017

Conto: 502020302 - Formazione (esternalizzata e non) da privato

Importo Previsione:	310 926,97
Somme	310 926,97
Disponibilità:	0,00
Importo	6 160,00



SISTEMA SANITARIO REGIONALE

AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

UOSD *AC* Generali



REGIONE
LAZIO

DELIBERAZIONE

N. 286/159 DEL 31 MAR. 2017

Si attesta che la deliberazione: è stata
pubblicata sull'Albo Pretorio on-line in data

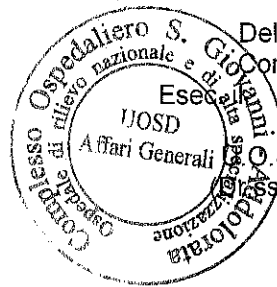
03 APR. 2017

- è stata inviata al Collegio Sindacale in data:

03 APR. 2017

- data di esecutività:

03 APR. 2017



Deliberazione originale
Composta di n. 12 fogli
03 APR. 2017

Il Dirigente della
O.S.D. Affari Generali
(*Giuseppina Maria Rita Corsetti*)

Plenti

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