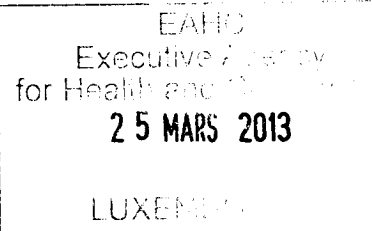


EUROPEAN COMMISSION  
EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

Director



Luxembourg,  
EAHC DM/ga Ares (2013)

501034

Professor Enrico Garaci  
Istituto Superiore di Sanita  
(ISS/CNT)  
Viale Regina Elena, 299  
00161 Rome  
ITALY



**Subject: Signature of grant agreement n° 2012 21 01**  
Registered with Acknowledgement of receipt

Dear Professor Garaci

Thank you very much for returning the signed originals of the grant agreement n° 2012 21 01.

I am pleased to enclose herewith a copy for your perusal duly signed by myself.

I take this opportunity to thank you for your efficient collaboration in the negotiation process and wish you all possible success with your undertaking.

Yours sincerely,

Luc Briol

Enclosure: grant agreement



EUROPEAN COMMISSION  
EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

Director

## GRANT AGREEMENT FOR AN ACTION - MULTIPLE BENEFICIARIES

AGREEMENT NUMBER – 2012 21 01

The Executive Agency for Health and Consumers (EAHC) (hereinafter referred to as "the Executive Agency"), acting under powers delegated by the Commission of the European Union (hereafter referred to as "the Commission"), and represented for the purposes of signature of this agreement by Mr. Luc Briol, Director, or his duly authorised representative,

of the one part,

and

1. **Istituto Superiore di Sanita' (ISS/CNT)**  
Viale Regina Elena, 299, 00161 Roma  
Italy

Public Law Body  
VAT number: 03657731000  
Registration number: 80211730587

hereinafter called "the co-ordinator", represented for the purposes of the signature of the present agreement by **Prof Enrico GARACI**, President

and the following "co-beneficiaries":

2. Országos Vérellátó Szolgálat \* Hungarian National Blood Transfusion Service (**OVSZ**) – established in Hungary
3. Hellenic Transplant Organisation (**EOM**) – established in Greece
4. Stichting Eurotransplant International Foundation (**ETI**) – established in The Netherlands
5. Agence de la Biomédecine (**ABM**) – established in France
6. Koordinační Středisko Transplantací \* Czech Transplantation Coordinating Center (**KST**) – established in Czech Republic

7. Zavod Republike Slovenije Za Presaditve Organov in Tkiv \* Institute for Transplantation of Organs and Tissues of the Republic of Slovenia (**ST**) – established in Slovenia
8. Deutsche Stiftung Organtransplantation (**DSO**) – established in Germany
9. Public Health, Food Chain Safety and Environment, DG Organisation of Health Care Establishments (**PFS PH**) – established in Belgium
10. Ministarstvo Zdravlja Republika Hrvatska \* Ministry of Health of the Republic of Croatia (**MOH RC**) - established in Croatia
11. Bulgarian Executive Agency for Transplantation (**BEAT**) – established in Bulgaria
12. Nacionalinis Transplantacijos Biuras \* National Transplant Bureau under the Ministry of Health of the Republic of Lithuania (**NTB**) – established in Lithuania
13. Ministry for Health, The Elderly & Community Care (**MHEC**) – established in Malta
14. Instituto Português do Sangue e da Transplantação, IP (**IPST**) – established in Portugal
15. Slovenská Zdravotnícka Univerzita \* Slovak Medical University (**SMUSCOT**) - established in Slovakia
16. NHS Blood and Transplant (**NHSBT**) – established in the United Kingdom
17. Centrum Organizacyjno-Koordynacyjne Do Spraw Transplantacji \* Polish Transplant Coordinating Center (**POLTRANSPLANT**) – established in Poland
18. Institutul Clinic Fundeni \* Fundeni Clinical Institute (**FCI**) – established in Romania

who have conferred powers of attorney for the purposes of the signature of the present agreement to the representative of the co-ordinator.

collectively “the beneficiaries”, and each individually identified as “beneficiary” for purposes of this agreement where a provision applies without distinction to the co-ordinator or a co-beneficiary

of the other part.

collectively "*the parties to the agreement*"

HAVE AGREED

the **Special Conditions, General Conditions** and **Annexes** below:

- Annex I** Description of the action [Technical Annex]
- Annex II** Estimated budget of the action [Financial Annex]
- Annex III** Reporting requirements
- Annex IV** Letters of mandates conferring powers of attorney from the co-beneficiaries to the co-ordinator
- Annex V** Instructions concerning the eligibility of travel and subsistence expenses (if Commission's rules apply)
- Annex VI** Unilateral commitment (only for beneficiaries with the status of non-governmental bodies - if applicable)
- Annex VII** Financial independence form (only for beneficiaries with the status of non-governmental bodies - if applicable)

which form an integral part of this agreement ("the agreement").

The terms set out in the Special Conditions shall take precedence over those in the other parts of the agreement.

The terms of the General Conditions shall take precedence over those in the Annexes.

## I – SPECIAL CONDITIONS

### ARTICLE I.1 – PURPOSE OF THE GRANT

- I.1.1 The Executive Agency has decided to award a grant, under the terms and conditions set out in the Special Conditions, the General Conditions and the Annexes to the agreement, which the beneficiaries hereby declare that they have taken note of and accept, for the action entitled "**Facilitating exchange of organs donated in EU member states – FOEDUS**" (*"the action"*).
- I.1.2 The beneficiaries accept the grant and undertake to do everything in their power to carry out the action as described in Annex I, acting on their own responsibility.

### ARTICLE I.2 – DURATION

- I.2.1 The agreement shall enter into force on the date when the last party signs.

Without prejudice to Article II.16.5, unless otherwise agreed by the parties in writing, the agreement expires four months after the date of notification by the Executive Agency of the final amount of the grant determining the amount of the payment of the balance or the recovery order pursuant to Article II.17, or failing that four months after the date on which the payment of the balance was received.

- I.2.2 The action shall run for **36 months** from the latest of the following dates **01 May, 2013** / the first day following the date when the last party signs the agreement (*"the starting date of the action"*).

### ARTICLE I.3 – ROLE OF THE BENEFICIARIES

- I.3.1 The co-ordinator shall 'inter alia':
- a) have full responsibility for ensuring that the action is implemented in accordance with the agreement;
  - b) be the intermediary for all communication between the co-beneficiaries and the Executive Agency in accordance with Article I.8. Any claims that the Executive Agency might have in respect of the agreement shall be addressed to, and answered by, the co-ordinator, save where specifically stated otherwise in the agreement;
  - c) be responsible for supplying all documents and information to the Executive Agency which may be required under the agreement, in particular in relation to the requests for payment. The co-ordinator shall not delegate any part of this task to the co-beneficiaries or to any other party. Where information from the co-beneficiaries is required, the co-ordinator shall be responsible for obtaining and verifying this information and for passing it on to the Executive Agency;

- d) inform the co-beneficiaries of any event of which the co-ordinator is aware that is liable to substantially affect the implementation of the action;
- e) inform the Executive Agency of transfers between items of eligible costs, as provided in Article I.4.4;
- f) make the appropriate arrangements for providing the financial guarantee or the joint guarantee of the beneficiaries participating in the action, when requested, under the provisions of Article I.5;
- g) establish the payment requests on behalf of the beneficiaries, detailing the exact share and amount assigned to each beneficiary, in accordance with the agreement, and in particular the estimated eligible costs as foreseen in Annex II, and the actual costs incurred. All payments by the Executive Agency are made to the bank account(s) referred to in paragraph 1 of Article I.7;
- h) where designated the sole recipient of payments on behalf of all of the beneficiaries, ensure that all the appropriate payments are made to the co-beneficiaries without unjustified delay in accordance with paragraph 3 of Article I.7 and shall inform the Executive Agency of the distribution of the Union financial contribution between the co-beneficiaries and of the date of transfer;
- i) be responsible, in the event of audits, checks or evaluations, as described in Articles II.20 and II.6, for providing all the necessary documents, including the accounts of the co-beneficiaries, the original accounting documents and signed copies of sub-contracts, if any have been concluded by the beneficiaries in accordance with Article II.9.

I.3.2 The co-beneficiaries shall 'inter alia':

- a) agree upon appropriate arrangements between themselves for the proper performance of the action;
- b) forward to the co-ordinator the data needed to draw up the reports, financial statements and other documents provided for in the agreement including its Annexes;
- c) ensure that all information to be provided to the Executive Agency is sent via the co-ordinator, save where the agreement specifically stipulates otherwise;
- d) inform the co-ordinator immediately of any event liable to substantially affect or delay the implementation of the action of which they are aware;
- e) inform the co-ordinator of transfers between items of eligible costs, as provided in Article I.4.4;
- f) provide the co-ordinator with all the necessary documents in the event of audits, checks of evaluations, as described in Articles II.20 and II.6.

## ARTICLE I.4 – BREAKDOWN OF COSTS – FINANCING THE ACTION

- I.4.1 The total cost of the action is estimated at **EUR 1.707.856,30 (one million seven hundred and seven thousand eight hundred and fifty-six Euros thirty cents)**, as shown in the estimated budget in Annex II. The estimated budget shall give a detailed breakdown of the costs that are eligible for Union funding under the terms of Article II.14, of any other costs that the action may entail, and of all receipts, so that receipts and costs balance.

The estimated budget in Annex II shall include a table indicating the breakdown of estimated eligible costs and receipts between each beneficiary. The table shall be agreed collectively by the beneficiaries and shall be deemed to form an integral part of the estimated budget of the agreement.

- I.4.2 The total eligible costs of the action for which the Executive Agency grant is awarded are estimated at **1.707.856,30 (one million seven hundred and seven thousand eight hundred and fifty-six Euros thirty cents)**, as shown in the estimated budget in Annex II.

Indirect costs are eligible for flat-rate funding up to a maximum of 7 % of the total direct costs eligible, subject to the conditions laid down in Article II.14.3.

- I.4.3 The Executive Agency shall contribute a maximum of **EUR 1.149.902,30 (one million one hundred and forty-nine thousand nine hundred and two Euros thirty cents)**, equivalent to **67,33 %** of the estimated total eligible costs indicated in Article I.4.2. The final amount of the grant shall be determined as specified in Article II.17, without prejudice to Article II.20.

The Union grant may not finance the entire costs of the action. The amounts and sources of co-financing other than from Union funds shall be set out in the estimated budget referred to in Article I.4.1.

- I.4.4 By way of derogation from Article II.13, the co-ordinator may, in agreement with the co-beneficiaries, when carrying out the action, adjust the estimated budget by transfers between items of eligible costs, provided that this adjustment of expenditure does not affect the implementation of the action and the transfer between items does not exceed **20 %** of the amount of each item of estimated eligible costs for which the transfer is intended, and without exceeding the total eligible costs indicated in Article I.4.2. The co-ordinator shall inform the Executive Agency in writing.

## ARTICLE I.5 – PAYMENT ARRANGEMENTS

- I.5.1 Pre-financing:

Within 45 days of the latest of the following dates: the date when the last of the parties signs the agreement / the starting date of the action a pre-financing payment of **EUR 459.960,92 (four hundred and fifty-nine thousand nine hundred and sixty Euros ninety-two cents)** shall be made to the co-ordinator, representing **40,00%** of the amount specified in Article I.4.3.

### I.5.2 Further pre-financing payments:

Pre-financing may be paid in several instalments. In that case, payment of each further instalment to the co-ordinator may not be made until at least 30 % of the previous pre-financing payment has been used up. Where the consumption of the previous pre-financing is less than 70 %, the amount of the new pre-financing payment shall be reduced by the unused amounts of the previous pre-financing<sup>1</sup>.

Every request for payment of a further pre-financing instalment must be accompanied by the documents specified in Article II.15.2.

Within 45 days after the Executive Agency receives the request for payment of a further instalment, together with the documents referred to in the previous subparagraph, the compliance of the technical implementation of the action with Annex I will be assessed. Next, upon approval of the technical implementation, within 45 days **the further pre-financing payment of EUR 344.970,69 (three hundred and forty-four thousand nine hundred and seventy Euros sixty-nine cents)** shall be made to the co-ordinator, equivalent to **30,00 %** of the amount specified in Article I.4.3.

The period for payment referred to in the previous sub-paragraph of this article may be suspended by the Executive Agency in accordance with the procedure in Article II.16.2.

### I.5.3 Payment of the balance:

The request for payment of the balance shall be accompanied by the documents specified in Article II.15.4.

The Executive Agency shall have 45 days to approve or reject the technical and financial implementation report or to request additional supporting documents or information under the procedure laid down in Article II.15.4. In that case, the co-ordinator shall have 20 days to submit the additional information or a new report.

A payment representing the balance of the grant determined in accordance with Article II.17 shall be made to the co-ordinator within 45 days following approval by the Executive Agency of the technical implementation report accompanying the request for payment of the balance. The Executive Agency may suspend the period for payment in accordance with the procedure in Article II.16.2.

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<sup>1</sup> The new pre-financing instalment shall be reduced by the amount corresponding to the difference between the 70 % threshold and the amount that was actually consumed. (Example: previous pre-financing 300 of which 100 (<70 %) was consumed; calculation: 210 (70 % threshold of 300) – 100 consumed = deduction of 110 from following pre-financing instalment).



## ARTICLE I.6 – SUBMISSION OF REPORTS AND OTHER DOCUMENTS

The provisions relating to the submission of the technical implementation reports, financial statements and other documents referred to in Article I.5 are contained in Annex III.

The technical implementation reports, financial statements and other documents referred to in Article I.5 must be submitted by the co-ordinator in **2** copies in **English** on the following dates:

- Interim reports and other documents related to a request for the first further pre-financing as specified in Article I.5.2. within 2 months following a period of 18 months after the starting date of the action specified in Article I.2.2., covering the period **M1 – M18**;
- Final reports and other documents related to a request for payment of the balance as specified in Article I.5.3. within 2 months following the closing date of the action specified in Article I.2.2., covering the whole project duration.

## ARTICLE I.7 – BANK ACCOUNT

I.7.1 All payments shall be made to the co-ordinator's bank account or sub-account denominated in euros, as indicated below:

|   |   |
|---|---|
| Name of bank:                               | Banca d'Italia – Tesoreria Centrale dello Stato |
| Address of the branch:                      | Via Dei Mille, 52, 00185 Roma, Italia           |
| Precise denomination of the account holder: | Istituto Superiore de Sanita'                   |
| IBAN account code:                          | <b>IT65 U010 0003 2453 5020 0022 349</b>        |

I.7.2. This account or sub-account must identify the payments made by the Executive Agency for carrying out the action for which the grant is awarded. If the funds paid to this account yield interest or equivalent benefits under the law of the State on whose territory the account is opened, such interest or benefits shall, if they are generated by the share of pre-financing not transferred to the co-beneficiaries at the end of the delay set in Article I.7.3, be deducted from the payment of the balance or recovered by the Executive Agency as specified in Article II.16.4.

I.7.3. Within 45 days of the day on which the bank account under I.7.1 has been credited, the co-ordinator shall transfer to each co-beneficiary the amounts corresponding to their participation in the action in accordance with their pro rata share of the estimated costs as defined in the breakdown in Annex II when pre-financing payments are made, and their share of validated costs actually incurred when other payments are made.

## ARTICLE I.8 – GENERAL ADMINISTRATIVE PROVISIONS

I.8.1. Any communication in connection with the agreement shall be in writing, indicating the number of the agreement, the title and acronym of the action and shall be sent to the following addresses:

For the Executive Agency:

Technical reports, requests for payment and any other correspondence must be addressed to:

Executive Agency for Health and Consumers (EAHC)  
Health Unit  
DRB A3/050  
L-2920 Luxembourg  
eahc@ec.europa.eu

Ordinary mail shall be considered to have been received by the Executive Agency on the date on which it is formally registered by the Executive Agency unit responsible referred to above.

For the co-ordinator:

**Mr Alessandro NANNI COSTA, MD**  
Director  
**Italian National Transplant Centre / CNT**  
Via Gianio della Bella, 34, 00161 Rome, Italy  
Tel.: +39 06 49 90 40 40  
Fax: +39 06 44 90 41 01  
E-mail: [centronazionale.trapianti@iss.it](mailto:centronazionale.trapianti@iss.it)

I.8.2 Any communication from the Executive Agency to the co-ordinator and/or co-beneficiaries and vice versa shall be made via the co-ordinator, save where specifically indicated otherwise in the agreement.

## ARTICLE I.9 – LAW APPLICABLE AND COMPETENT COURT

The grant is governed by the terms of the agreement, the Union law applicable and, on a subsidiary basis, by the law of Luxembourg relating to grants.

The beneficiaries may bring legal proceedings regarding decisions by the Executive Agency concerning the application of the provisions of the agreement and the arrangements for implementing it before the General Court of the European Union and, in the event of appeal, the Court of Justice.

## ARTICLE I.10 – DATA PROTECTION<sup>2</sup>

- I.10.1. Any personal data included in the agreement shall be processed pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the agreement by the Executive Agency, without prejudice to possible transmission to the bodies charged with monitoring or inspection task in application of Union law.
- I.10.2. The beneficiaries shall have the right of access to their personal data and the right to rectify any such data. Should the beneficiaries have any queries concerning the processing of their personal data, they shall address them to the Executive Agency.
- I.10.3. The beneficiaries shall have the right of recourse at any time to the European Data Protection Supervisor.
- I.10.4. Where the agreement requires the processing of personal data by the beneficiaries, the beneficiaries may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data, and the means by which the data subject may exercise his/her rights.
- I.10.5. The beneficiaries shall limit access to the data to the staff strictly necessary for the implementation, management and monitoring of the agreement.
- I.10.6. The beneficiaries undertake to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:
- a) prevent any unauthorised person from having access to computer systems processing personal data, and especially:
    - i) unauthorised reading, copying, alteration or removal of storage media;
    - ii) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
    - iii) unauthorised persons from using data-processing systems by means of data transmission facilities;
  - b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
  - c) record which personal data have been communicated, when and to whom;

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<sup>2</sup> Any question on the application of Regulation (EC) N° 45/2001 should be referred to the Data Protection Officer of the Agency. More information, including the privacy statement on grants and the contact details of the Data Protection Officer of the Agency, are available on the Agency's website ([http://ec.europa.eu/eahc/about/data\\_protection.html](http://ec.europa.eu/eahc/about/data_protection.html)).

- d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the contracting institution or body;
- e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;

design their organisational structure in such a way that it meets data protection requirements.

## ARTICLE I.11 – FURTHER SPECIAL CONDITIONS

The following special conditions apply to this agreement:

- I.11.1 The beneficiary shall submit the payment requests in accordance with article I.5, including the underlying financial statements, in euros. By way of derogation from Article II.16.1, any conversion of actual costs into euros shall be made by the beneficiary at the monthly accounting rate established by the Commission and published on its website for the first day of the month following the end of the reporting period<sup>3</sup>.
- I.11.2 Without prejudice to Article II.3.2, the beneficiaries grant the Executive Agency and the Commission the right to publish results and reports in hard copy or electronic form.
- I.11.3 Without prejudice to Article II.5.1, unless the Executive Agency requests or agrees otherwise, all communications or publications by the beneficiaries collectively or one of the beneficiary individually, which are related to the action, including conferences, seminars, videos, electronic communications or printed matter shall include the following statement: *“This [insert appropriate description, e.g. publication, conference, etc.] arises from the project [insert project title] which has received funding from the European Union, in the framework of the Health Programme.”*
- I.11.4 By way of derogation from Article II.14.2, the definition of ‘public officials’ shall be applied according to the following: *“An official of a public administration or body who is directly remunerated by the budget of the State or a local authority and his/her work concerns the implementation of tasks typically devolved to public institutions. By extension, it does concern all public officials who work in international organisations”.*

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<sup>3</sup> <http://ec.europa.eu/budget/inforeuro/index.cfm?fuseaction=home&Language=en>

## **II – GENERAL CONDITIONS**

### **PART A – LEGAL AND ADMINISTRATIVE PROVISIONS**

#### **ARTICLE II.1 – LIABILITY**

- II.1.1 The beneficiaries shall be responsible for complying with any legal obligations incumbent on them.
- II.1.2 The Executive Agency shall not, in any circumstances or on any grounds, be held liable in the event of a claim under the agreement relating to any damage caused during the action's execution. Consequently, the Executive Agency will not entertain any request for indemnity or reimbursement accompanying any such claim.
- II.1.3 Except in cases of force majeure, the beneficiaries shall make good any damage sustained by the Executive Agency as a result of the execution or faulty execution of the action.
- II.1.4 The beneficiaries shall bear sole liability vis-à-vis third parties, including for damage of any kind sustained by them while the action is being carried out.

#### **ARTICLE II.2 – CONFLICT OF INTERESTS**

The beneficiaries undertake to take all the necessary measures to prevent any risk of conflicts of interests which could affect the impartial and objective performance of the agreement. Such conflict of interests could arise in particular as a result of economic interest, political or national affinity, family or emotional reasons, or any other shared interest.

Any situation constituting or likely to lead to a conflict of interests during the performance of the agreement must be brought to the attention of the Executive Agency, in writing, without delay. The beneficiaries shall undertake to take whatever steps are necessary to rectify this situation at once. The Executive Agency reserves the right to check that the measures taken are appropriate and may demand that the beneficiaries take additional measures, if necessary, within a certain time.

#### **ARTICLE II.3 – OWNERSHIP/USE OF THE RESULTS**

- II.3.1 Unless stipulated otherwise in the agreement, ownership of the results of the action, including industrial and intellectual property rights, and of the reports and other documents relating to it shall be vested in the beneficiaries.
- II.3.2 Without prejudice to paragraph 1, the beneficiaries grant the Executive Agency the right to make free use of the results of the action as it deems fit, and, in particular, to display, reproduce by any technical procedure, translate or communicate the results of the action by any medium, including on the website of the Executive Agency and/or on the Europa website, provided it does not

thereby breach its confidentiality obligations or existing industrial and intellectual property rights.

- II.3.3. Where industrial and intellectual property rights, including rights of third parties, exist prior to the agreement being entered into ("pre-existing intellectual property rights"), the beneficiaries shall establish a list which shall specify all rights of ownership and use in the pre-existing intellectual property rights and disclose it to the Executive Agency at the latest prior to the commencement of implementation. The beneficiaries shall ensure that they have all rights to use any pre-existing intellectual property rights in implementation of the agreement.

#### **ARTICLE II.4 – CONFIDENTIALITY**

The Executive Agency and the beneficiaries undertake to preserve the confidentiality of any document, information or other material directly related to the subject of the agreement that is duly classed as confidential, if disclosure could cause prejudice to the other party. The parties shall remain bound by this obligation beyond the closing date of the action.

#### **ARTICLE II.5 – PUBLICITY**

- II.5.1 Unless the Executive Agency requests otherwise, any communication or publication by the beneficiaries collectively or any one of the beneficiaries individually about the action, including at a conference or seminar, shall indicate that the action has received funding from the Union.

Any communication or publication by the beneficiaries collectively or any one of the beneficiaries individually, in any form and medium, shall indicate that sole responsibility lies with the author and that the Executive Agency is not responsible for any use that may be made of the information contained therein.

- II.5.2 The beneficiaries authorise the Executive Agency to publish the following information in any form and medium, including via the Internet:

- the beneficiaries' names and addresses,
- the subject and purpose of the grant,
- the amount granted and the proportion of the action's total cost covered by the funding.

Upon a reasoned and duly substantiated request by the co-ordinator, the Executive Agency may agree to forgo such publicity if disclosure of the information indicated above would risk compromising the beneficiaries' security or prejudicing their commercial interests.

#### **ARTICLE II.6 – EVALUATION**

Whenever the Commission carries out an interim or final evaluation of the action's impact measured against the objectives of the Union programme concerned, the co-ordinator with the support of the co-beneficiaries undertake to make available to the Commission and/or persons authorised by it all such documents or information as will

allow the evaluation to be successfully completed and to give them the rights of access specified in Article II.20.

## **ARTICLE II.7 – SUSPENSION**

- II.7.1 The co-ordinator, in agreement with the co-beneficiaries, may suspend implementation of the action if exceptional circumstances make this impossible or excessively difficult, notably in the event of force majeure. The co-ordinator shall inform the Executive Agency without delay, giving all the necessary reasons and details and the foreseeable date of resumption.
- II.7.2 If the Executive Agency does not terminate the agreement under Article II.11.3, the beneficiaries shall resume implementation of the action as initially planned once circumstances allow and the co-ordinator shall inform the Executive Agency accordingly. The duration of the action might be extended by a period equivalent to the length of the suspension. In accordance with Article II.13, a supplementary written agreement shall be concluded to extend the duration of the action and to make any amendments that may be necessary to adapt the action to the new implementing conditions.

## **ARTICLE II.8 – FORCE MAJEURE**

- II.8.1 Force majeure shall mean any unforeseeable exceptional situation or event beyond the parties' control which prevents them from fulfilling any of their obligations under the agreement, was not attributable to error or negligence on their part, and proves insurmountable in spite of all due diligence. Defects in equipment or material or delays in making them available (unless due to force majeure), labour disputes, strikes or financial difficulties cannot be invoked as force majeure by the defaulting party.
- II.8.2 A party faced with force majeure shall inform the other party without delay by registered letter with advice of delivery or equivalent, stating the nature, probable duration and foreseeable effects.
- II.8.3 The party faced with force majeure shall not be held in breach of his obligations under the agreement if he's prevented from fulfilling them by force majeure. The parties shall make every effort to minimise any damage due to force majeure.
- II.8.4 The action may be suspended in accordance with Article II.7.

## **ARTICLE II.9 – AWARD OF CONTRACTS**

- II.9.1 If the beneficiaries have to conclude contracts in order to carry out the action and they constitute costs of the action under an item of eligible direct costs in the estimated budget, they shall seek competitive tenders from potential contractors and award the contract to the bid offering best value for money; in doing so they shall observe the principles of transparency and equal treatment of potential contractors and shall take care to avoid any conflict of interests.
- II.9.2 Contracts as referred to in paragraph 1 may be awarded only in the following cases:

- a) they may only cover the execution of a limited part of the action;
- b) recourse to the award of contracts must be justified having regard to the nature of the action and what is necessary for its implementation;
- c) the tasks concerned must be set out in Annex I and the corresponding estimated costs must be set out in detail in the budget in Annex II;
- d) any recourse to the award of contracts while the action is under way, if not provided for in the initial grant application, shall be subject to prior written authorisation by the Executive Agency;
- e) the beneficiaries shall retain sole responsibility for carrying out the action and for compliance with the provisions of the agreement. The beneficiaries must undertake to make the necessary arrangements to ensure that the contractor waives all rights in respect of the Executive Agency under the agreement;
- f) the beneficiaries must undertake to ensure that the conditions applicable to them under Articles II.1, II.2, II.3, II.4, II.5, II.6, II.10 and II.20 of the agreement are also applicable to the contractor.

## **ARTICLE II.10 – ASSIGNMENT**

Claims for payments to be carried out by the Executive Agency may not be transferred.

In exceptional circumstances, where the situation warrants it, the Executive Agency may authorise the assignment to a third party of the agreement and payments flowing from it, following a written request to that effect, giving reasons, from the co-ordinator in agreement with the co-beneficiaries. If the Executive Agency agrees, it must make its agreement known in writing to the co-ordinator before the proposed assignment takes place. In the absence of the above authorisation, or in the event of failure to observe the terms thereof, the assignment shall not be enforceable against and shall have no effect on the Executive Agency.

In no circumstances shall such an assignment release the beneficiaries from their obligations to the Executive Agency.

## **ARTICLE II.11 – TERMINATION OF THE AGREEMENT**

### **II.11.1 Termination by the co-ordinator**

In duly justified cases, the co-ordinator, in agreement with the co-beneficiaries, may withdraw the beneficiaries' request for a grant and terminate the agreement at any time by giving 60 days' written notice stating the reasons, without being required to furnish any indemnity on this account.

If no reasons are given or if the Executive Agency does not accept the reasons, the agreement shall be deemed to have been terminated improperly, with the consequences set out in the fifth subparagraph of paragraph 5.

### **II.11.2 Termination of the participation of a beneficiary**



In duly justified cases, the co-ordinator may request to terminate the participation of a beneficiary by giving 60 days written notice. The co-ordinator shall include with any such request to the Executive Agency the remaining beneficiaries' proposal to reallocate the tasks of that beneficiary or where relevant to nominate a replacement, the reasons for the termination of the participation and the opinion of the beneficiary whose participation is requested to be terminated.

In duly justified cases, any beneficiary may request the termination of his participation in the agreement. The request must be submitted to the Executive Agency by the co-ordinator by giving 60 days written notice stating the reasons.

If no reasons are given or if the Executive Agency does not accept the reasons, the participation shall be deemed to have been terminated improperly, with the consequences set out in the fifth subparagraph of paragraph 5.

The termination of the participation of the beneficiary concerned shall take effect on the date of the Executive Agency's approval. A written additional agreement shall be concluded to make any amendments necessary to adapt the action to the new implementing conditions resulting from the partial termination.

### **II.11.3 Termination by the Executive Agency**

The Executive Agency may decide to terminate the agreement or the participation of any one or several beneficiaries participating in the action without any indemnity on its part, in the following circumstances:

- a) in the event of a change to the beneficiary's legal, financial, technical, organisational or ownership situation that is liable to affect the agreement substantially or to call into question the decision to award the grant;
- b) if a beneficiary fails to fulfil a substantial obligation incumbent on him under the terms of the agreement, including its annexes;
- c) in the event of force majeure, notified in accordance with Article II.8, or if the action has been suspended as a result of exceptional circumstances, notified in accordance with Article II.7;
- d) if a beneficiary is declared bankrupt, is being wound up or is the subject of any other similar proceedings;
- e) if a beneficiary is found guilty of an offence involving his professional conduct by a judgment having the force of res judicata or if he is guilty of grave professional misconduct proven by any justified means;
- f) if a beneficiary is guilty of misrepresentation or submits information or reports inconsistent with reality to obtain the grant provided for in the agreement;
- g) if a beneficiary has intentionally or by negligence committed a substantial irregularity in performing the agreement or in the event of fraud, corruption or any other illegal activity on the part of a beneficiary to the detriment of the European Union's financial interests. A substantial irregularity consists of

any infringement of a provision of an agreement or regulation resulting from an act or an omission on the part of a beneficiary which causes or might cause a loss to the Union budget.

#### **II.11.4 Termination procedure**

The procedure is initiated by registered letter, with advice of delivery or equivalent. The co-ordinator shall ensure that all beneficiaries are duly informed.

In the cases referred to in points (a), (b) and (d) of paragraph 3, the co-ordinator, in consultation with the co-beneficiaries, shall have 30 days to submit observations and take any measures necessary to ensure continued fulfilment of the beneficiaries' obligations under the agreement. If the Executive Agency fails to confirm acceptance of these observations by giving written approval within 30 days of receiving them, the procedure shall continue to run.

Where notice is given, termination shall take effect at the end of the period of notice, which shall start to run from the date when notification of the Executive Agency's decision to terminate the agreement or the participation of a beneficiary is received.

Where notice is not given in the cases referred to in points (c), (e), (f) and (g) of paragraph 3, termination shall take effect from the day following the date on which notification of the Executive Agency's decision to terminate the agreement or the participation of a beneficiary is received.

#### **II.11.5 Effects of termination**

In the event of termination of the agreement, payments by the Executive Agency shall be limited to the eligible costs actually incurred by the beneficiaries up to the date when termination takes effect, in accordance with Article II.17. Costs relating to current commitments that are not due to be executed until after termination shall not be taken into account.

The co-ordinator shall have 60 days from the date when termination of the agreement takes effect, as notified by the Executive Agency, to produce a request for final payment in accordance with Article II.15.4. If no request for final payment is received within this time limit, the Executive Agency shall not reimburse the expenditure incurred by the beneficiaries up to the date of termination and it shall recover any amount if its use is not substantiated by the technical implementation reports and financial statements approved by the Executive Agency.

Where termination affects the participation of a beneficiary, only those eligible costs actually incurred by the beneficiary concerned up to the date when termination of his participation takes effect, in accordance with Article II.17 shall be considered eligible. Costs relating to current commitments that were not due to be executed until after termination shall not be taken into account. The request for payment of the eligible costs incurred up to the date when the termination of the participation of the beneficiary concerned takes effect shall be included in the following payment request due according to the schedule laid down in Article I.6.

By way of exception, at the end of the period of notice referred to in paragraph 4, where the Executive Agency is terminating the agreement on the grounds that the co-ordinator

has failed to produce the final technical implementation report and financial statement within the deadline stipulated in Article I.5 and the co-ordinator has still not complied with this obligation within two months following the written reminder sent by the Executive Agency by registered letter with advice of delivery or equivalent, the Executive Agency shall not reimburse the expenditure incurred by the beneficiaries up to the date on which the action ended and it shall recover any amount if its use is not substantiated by the technical implementation reports and financial statements approved by the Executive Agency.

By way of exception, in the event of improper termination of the agreement by the co-ordinator, or a beneficiary's participation in the action, or termination by the Executive Agency on the grounds set out in points (e), (f) or (g) of paragraph 3, the Executive Agency may require the partial or total repayment of sums already paid under the agreement on the basis of technical implementation reports and financial statements approved by the Executive Agency, in proportion to the gravity of the failings in question and after allowing the co-ordinator, and where relevant co-beneficiaries concerned, to submit their observations.

## **ARTICLE II.12 – FINANCIAL PENALTIES**

By virtue of the Financial Regulation applicable to the general budget of the European Union, any one or several of the beneficiaries declared to be in grave breach of their obligations under the agreement shall be liable to financial penalties of between 2 % and 10 % of the value of their share of the grant in question, with due regard for the principle of proportionality.

This rate may be increased to between 4 % and 20 % in the event of a repeated breach in the five years following the first. The beneficiary concerned shall be notified in writing of any decision by the Executive Agency to apply such financial penalties.

## **ARTICLE II.13 – SUPPLEMENTARY AGREEMENTS**

- II.13.1 Any amendment to the grant conditions must be the subject of a written supplementary agreement. No oral agreement may bind the parties to this effect.
- II.13.2 The supplementary agreement may not have the purpose or the effect of making changes to the agreement which might call into question the decision awarding the grant or result in unequal treatment of applicants.
- II.13.3 Where the request for amendment is made by the co-ordinator, in agreement with the co-beneficiaries, he must send the request to the Executive Agency in good time before it is due to take effect and at all events one month before the closing date of the action, except in cases duly substantiated by the co-ordinator and accepted by the Executive Agency.

## PART B – FINANCIAL PROVISIONS

### ARTICLE II.14 – ELIGIBLE COSTS

II.14.1 To be considered as eligible costs of the action, costs must satisfy the following general criteria:

- they are incurred during the duration of the action as specified in Article I.2.2 of the agreement, with the exception of costs relating to final reports and certificates on the action's financial statements and underlying accounts;
- they are connected with the subject of the agreement and they must be indicated in the estimated budget annexed to it;
- they are necessary for the implementation of the action which is the subject of the grant;
- they are identifiable and verifiable, in particular being recorded in the accounting records of a beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the usual cost-accounting practices of the beneficiary;
- they comply with the requirements of applicable tax and social legislation;
- they are reasonable, justified, and comply with the requirements of sound financial management, in particular regarding economy and efficiency.

The beneficiaries' internal accounting and auditing procedures must permit direct reconciliation of the costs and revenue declared in respect of the action with the corresponding accounting statements and supporting documents.

II.14.2 The eligible direct costs for the action are those costs which, with due regard for the conditions of eligibility set out in Article II.14.1, are identifiable as specific costs directly linked to performance of the action and which can therefore be booked to it direct. In particular, the following direct costs are eligible provided that they satisfy the criteria set out in the previous paragraph:

- the cost of staff assigned to the action, comprising actual salaries plus social security charges and other statutory costs included in the remuneration, provided that this does not exceed the average rates corresponding to the beneficiary's usual policy on remuneration;

The corresponding salary costs of personnel of national administrations are eligible to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the project concerned were not undertaken;

- travel and subsistence allowances for staff taking part in the action, provided that they are in line with the beneficiary's usual practices on travel costs or do not exceed the scales approved annually by the Commission;
- the purchase cost of equipment (new or second-hand), provided that it is written off in accordance with the tax and accounting rules applicable to the beneficiary and generally accepted for items of the same kind. Only the portion of the equipment's depreciation corresponding to the duration of the action and the rate of actual use for the purposes of the action may be taken into account by the Executive Agency, except where the nature and/or the context of its use justifies different treatment by the Executive Agency;
- costs of consumables and supplies, provided that they are identifiable and assigned to the action;
- costs entailed by other contracts awarded by a beneficiary for the purposes of carrying out the action, provided that the conditions laid down in Article II.9 are met;
- costs arising directly from requirements imposed by the agreement (dissemination of information, specific evaluation of the action, audits, translations, reproduction, etc.), including the costs of any financial services (especially the cost of financial guarantees). Such costs may also include specific costs incurred by the co-ordinator for fulfilling his responsibilities in his capability of the body responsible for the overall management of the action and the co-ordination of the beneficiaries.

II.14.3 The eligible indirect costs for the action are those costs which, with due regard for the conditions of eligibility described in Article II.14.1, are not identifiable as specific costs directly linked to performance of the action which can be booked to it direct, but which can be identified and justified by the co-ordinator or a co-beneficiary using their accounting system as having been incurred in connection with the eligible direct costs for the action. They may not include any eligible direct costs.

By way of derogation from Article II.14.1, the indirect costs incurred in carrying out the action may be eligible for flat-rate funding fixed at not more than 7 % of the total eligible direct costs. If provision is made in Article I.4.2 for flat-rate funding in respect of indirect costs, they need not be supported by accounting documents.

II.14.4 The following costs shall not be considered eligible:

- return on capital;
- debt and debt service charges;
- provisions for losses or potential future liabilities;
- interest owed;
- doubtful debts;

- exchange losses;
- VAT, unless the beneficiary can show that he is unable to recover it according to the applicable national legislation. VAT paid by public bodies is not an eligible cost;
- costs declared by a beneficiary and covered by another action or work programme receiving a Union grant;
- excessive or reckless expenditure;
- contributions in kind.

II.14.5 Not applicable.

II.14.6 By way of derogation from paragraph 3, indirect costs shall not be eligible under a grant for an action awarded to a beneficiary who already receives an operating grant from the Union budget during the period in question.

## **ARTICLE II.15 – REQUESTS FOR PAYMENT**

Payments shall be made in accordance with Article I.5 of the Special Conditions.

### **II.15.1 – PRE-FINANCING**

Pre-financing is intended to provide the beneficiaries with a float.

Where required by the provisions of Article I.5 on pre-financing, the co-ordinator shall furnish a financial guarantee from a bank or an approved financial institution established in one of the Member States of the European Union.

The guarantor shall stand as first demand guarantor and shall not require the Executive Agency to have recourse against the principal debtor (the concerned beneficiary).

The financial guarantee shall provide that it remains in force until the pre-financing is cleared against interim payment(s) or payment of the balance by the Executive Agency to the beneficiaries or, in the absence of such clearing, three months after a recovery is notified to a beneficiary by which the Executive Agency asks him to repay the pre-financing. The Executive Agency undertakes to release the guarantee within the following month.

### **II.15.2 – FURTHER PRE-FINANCING PAYMENTS**

Where pre-financing is divided into several instalments, the co-ordinator may request a further pre-financing payment once the percentage of the previous payment specified in the provisions of Article I.5 on further pre-financing has been used up. The request shall be accompanied by the following documents:

- a progress report on the technical implementation of the action;
- a detailed financial statement of the eligible costs actually incurred, including a consolidated statement and a breakdown between each beneficiary;

- where required by the above-mentioned provisions of Article I.5, a financial guarantee in accordance with paragraph 1;
- any other documents in support of his request for further pre-financing.

The documents accompanying the request for payment shall be drawn up in accordance with the relevant provisions in Article I.6 and the annexes.

### **II.15.3 – NOT APPLICABLE**

### **II.15.4 – PAYMENT OF THE BALANCE**

Payment of the balance, which may not be repeated, is made after the end of the action on the basis of the costs actually incurred by the beneficiaries in carrying out the action. It may take the form of a recovery order where the total amount of earlier payments is greater than the amount of the final grant determined in accordance with Article II.17.

By the appropriate deadline indicated in Article I.6, the co-ordinator shall submit a request for payment of the balance accompanied by the following documents:

- a final report on the technical implementation of the action;
- a final detailed financial statement of the eligible costs actually incurred, following the structure of the estimated budget, including a consolidated statement and a breakdown between each beneficiary;
- a full summary statement of the receipts and expenditure of the action including a consolidated statement and a breakdown between each beneficiary;
- any other documents in support of his request for payment of the balance.

The documents accompanying the request for payment shall be drawn up in accordance with the provisions of Article I.6 and the annexes.

If an external audit of the action's accounts is not required, the co-ordinator and the co-beneficiaries themselves shall certify that the information provided in their request for payment to the Executive Agency is full, reliable and true. They shall also certify that the costs incurred can be considered eligible in accordance with the agreement, that all receipts have been declared, and that the request for payment is substantiated by adequate supporting documents that can be checked.

On receipt of these documents, the Executive Agency shall have the period specified in Article I.5 in order to:

- approve the final report on the technical implementation of the action and the detailed financial statement;
- ask the co-ordinator for supporting documents or any additional information it deems necessary to allow the approval of the technical implementation report and the financial statement;

- reject the documents referred to in Article I.5.3. and ask for the submission of additional information or a new report.

Failing a written reply from the Executive Agency within the time limit for scrutiny indicated above, the report shall be deemed to have been approved. Approval of the report accompanying the request for payment shall not imply recognition of their regularity or of the authenticity, completeness and correctness of the declarations and information they contain.

If additional information or a new report is requested, the time limit for scrutiny shall be extended by the time it takes to obtain this information. The co-ordinator shall be informed of that request and the extension of the delay for scrutiny by means of a formal document. The co-ordinator shall have the period laid down in Article I.5 to submit the information or new documents requested.

Extension of the delay for approval of the report may delay the payment by the equivalent time.

Where a report is rejected and a new report requested, the approval procedure described in this Article shall apply.

In the event of renewed rejection, the Executive Agency reserves the right to terminate the agreement by invoking Article II.11.3(b).

#### **II.15.5 – COSTS OF TRANSFERS**

Costs of the transfers are borne in the following way:

- costs of dispatch charged by the bank of the Commission shall be borne by the Executive Agency;
- costs of receipt charged by the bank of a beneficiary shall be borne by the beneficiary;
- all costs of repeated transfers caused by one of the parties shall be borne by the party who caused repetition of the transfer.

#### **ARTICLE II.16 – GENERAL PROVISIONS ON PAYMENTS**

II.16.1 Payments shall be made by the Executive Agency in euros. Any conversion of actual costs into euros shall be made at the monthly accounting rate established by the Commission and published on its website for the first day of the month following the end of the reporting period<sup>4</sup>, unless the Special Conditions of the agreement lay down specific provisions.

Payments by the Executive Agency shall be deemed to be effected on the date when they are debited to the Executive Agency's account.

II.16.2 The Executive Agency may suspend the period for payment laid down in Article I.5 at any time by notifying the co-ordinator that his request for payment cannot be met, either because it does not comply with the provisions of the agreement, or because the appropriate supporting documents have not been produced or

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<sup>4</sup> <http://ec.europa.eu/budget/inforeuro/index.cfm?fuseaction=home&Language=en>



because there is a suspicion that some of the expenses in the financial statement are not eligible and additional checks are being conducted.

The Executive Agency may also suspend its payments at any time if a beneficiary is found or presumed to have infringed the provisions of the agreement, in particular in the wake of the audits and checks provided for in Article II.20.

The Executive Agency shall inform the co-ordinator as soon as possible of any such suspension by registered letter with advice of delivery or equivalent, setting out the reasons for suspension.

Suspension shall take effect on the date when notice is sent by the Executive Agency. The remaining payment period shall start to run again from the date when a properly constituted request for payment is registered, when the supporting documents requested are received, or at the end of the suspension period as notified by the Executive Agency.

- II.16.3 On expiry of the period for payment specified in Article I.5, and without prejudice to paragraph 2 of this Article, the beneficiaries are entitled to interest on the late payment at the rate applied by the European Central Bank for its main refinancing operations in euros, plus three and a half points; the reference rate to which the increase applies shall be the rate in force on the first day of the month of the final date for payment, as published in the C series of the Official Journal of the European Union. This provision shall not apply to recipients of a grant which are public authorities of the Member States of the European Union.

Interest on late payment shall cover the period from the final date for payment, exclusive, up to the date of payment as defined in paragraph 1, inclusive. The interest shall not be treated as a receipt for the action for the purposes of determining the final grant within the meaning of Article II.17.4. The suspension of payment by the Executive Agency may not be considered as late payment.

By way of exception, when the interest calculated in accordance with the provisions of the first and second subparagraphs is lower than or equal to EUR 200, it shall be paid to the co-ordinator only upon demand submitted within two months of receiving late payment.

- II.16.4 The Executive Agency shall deduct the interest yielded by pre-financing which exceeds EUR 50 000 as provided for in Article I.5 from the payment of the balance of the amount due to the beneficiaries. The interest shall not be treated as a receipt for the action within the meaning of Article II.17.4.

Where the pre-financing payments exceed EUR 750 000 per agreement at the end of each financial year, the interest shall be recovered for each reporting period. Taking account of the risks associated with the management environment and the nature of actions financed, the Executive Agency may recover the interest generated by pre-financing lower than EUR 750 000 at least once a year.

Where the interest yielded exceeds the balance of the amount due to the beneficiaries as indicated in Article II.15.4, or is generated by pre-financing referred to in the previous subparagraph, the Executive Agency shall recover it in accordance with Article II.19.

Interest yielded by pre-financing paid to Member States is not due to the Executive Agency.

- II.16.5 The co-ordinator shall have two months from the date of notification by the Executive Agency of the final amount of the grant determining the amount of the payment of the balance or the recovery order pursuant to Article II.17, or failing that of the date on which the payment of the balance was received, to request information in writing on the determination of the final grant, giving reasons for any disagreement. After this time such requests will no longer be considered. The Executive Agency undertakes to reply in writing within two months following the date on which the request for information is received, giving reasons for its reply. This procedure is without prejudice to the beneficiaries' right to appeal against the Executive Agency's decision pursuant to Article I.9. Under the terms of Union law in this matter, such appeals must be lodged within two months following the notification of the decision to the applicant or, failing that, following the date on which the applicant learned of the decision.

#### **ARTICLE II.17 – DETERMINING THE FINAL GRANT**

- II.17.1 Without prejudice to information obtained subsequently pursuant to Article II.20, the Executive Agency shall adopt the amount of the final payment to be granted to the beneficiaries on the basis of the documents referred to in Article II.15.4 which it has approved.
- II.17.2 The total amount paid by the Executive Agency may not in any circumstances exceed the maximum amount of the grant laid down in Article I.4.3, even if the total actual costs eligible exceed the estimated total eligible costs specified in Article I.4.2.
- II.17.3 If the actual eligible costs when the action ends are lower than the estimated eligible costs, the Executive Agency's contribution shall be limited to the amount obtained by applying the grant percentage of Union co-funding per beneficiary - specified in the table 'Budget by beneficiary' of Annex II, 'Estimated budget of the action' -, to the respective actual eligible costs approved by the Executive Agency per beneficiary.
- II.17.4 The beneficiaries hereby agree that the grant shall be limited to the amount necessary to balance the action's receipts and expenditure and that it may not in any circumstances produce a profit for them.

Profit shall mean any surplus of total actual receipts attributable to the action over the total actual costs of the action. The actual receipts to be taken into account shall be those which have been established, generated or confirmed on the date on which the request for payment of the balance is drawn up by the co-ordinator for financing other than the Union grant, to which shall be added the amount of the grant determined by applying the principles laid down in

paragraphs 2 and 3 of this article. For the purposes of this article, only actual costs falling within the categories set out in the estimated budget referred to in Article I.4.1 and contained in Annex II shall be taken into account; non-eligible costs shall always be covered by non-Union resources.

Any surplus determined in this way shall result in a corresponding reduction in the amount of the grant.

- II.17.5 Without prejudice to the right to terminate the agreement under Article II.11, and without prejudice to the right of the Executive Agency to apply the penalties referred to in Article II.12, if the action is not implemented or is implemented poorly, partially or late, the Executive Agency may reduce the grant initially provided for in line with the actual implementation of the action on the terms laid down in the agreement.
- II.17.6 On the basis of the amount of the final payment determined in this way and of the aggregate amount of the payments already made under the terms of the agreement, the Executive Agency shall set the amount of the payment of the balance as being the amount still owing to the beneficiaries. Where the aggregate amount of the payments already made exceeds the amount of the final grant, the Executive Agency shall issue a recovery order for the surplus.

#### **ARTICLE II.18 – FINANCIAL JOINT RESPONSIBILITY**

The beneficiaries agree to be irrevocably and unconditionally, jointly and severally responsible for any amount due to the Executive Agency by one of them which could not be honoured by the latter. The amount due to the Executive Agency will not exceed the maximum value of the contribution that could be granted to the beneficiaries in accordance with Article I.4.3, increased where applicable by interest on late payment.

The beneficiaries are not jointly responsible for financial penalties which could be imposed on any defaulting beneficiary in accordance with Article II.12.

#### **ARTICLE II.19 – RECOVERY**

- II.19.1 Where an amount, paid by the Executive Agency to the co-ordinator in his capacity of recipient of all payments, is to be recovered under the terms of the agreement, the co-ordinator undertakes to repay the Executive Agency the sum in question, on whatever terms and by whatever date it may specify, even if he has not been the final recipient of the amount due. In the latter case, if payment has not been made by the due date, the Executive Agency reserves the right to recover directly the amount due from the final recipient.

Where such an amount to be recovered under the terms of the agreement was directly paid by the Executive Agency to a beneficiary, or if recovery is justified under Article II.12 of the agreement, the beneficiary concerned undertakes to pay the Executive Agency the sum in question, on whatever terms and by whatever date it may specify.

- II.19.2 If the obligation to pay the amount due is not honoured by the date set by the Executive Agency, the amount due shall bear interest at the rate indicated in Article II.16.3. Interest on late payment shall cover the period between the date

set for payment, exclusive, and the date when the Executive Agency receives full payment of the amount owed, inclusive.

Any partial payment shall first be entered against charges and interest on late payment and then against the principal.

- II.19.3 If payment has not been made by the due date, sums owed to the Executive Agency may be recovered by offsetting them against any sums owed to the concerned beneficiary, in cases where the beneficiary also has a claim on the Union or the European Atomic Energy Community, after informing him accordingly by registered letter with acknowledgment of receipt or equivalent, or, depending on the terms of the Special Conditions, by calling in the financial guarantee provided in accordance with Article II.15.1. In exceptional circumstances, justified by the necessity to safeguard the financial interests of the Union, the Executive Agency and/or the Commission may recover by offsetting before the due date of the payment. The beneficiary's prior consent shall not be required. If the recovery remains unsuccessful under the provisions above, the Executive Agency shall hold all the beneficiaries collectively jointly responsible for the amount due in accordance with Article II.18.
- II.19.4 Bank charges occasioned by the recovery of the sums owed to the Executive Agency shall be borne by the concerned beneficiary.
- II.19.5 The beneficiaries understand that under Article 299 of the Treaty on the functioning of the European Union, the Commission may adopt an enforceable decision formally establishing an amount as receivable from persons other than States. An action may be brought against such decision before the General Court of the European Union.

## **ARTICLE II.20 – CHECKS AND AUDITS**

- II.20.1 The co-ordinator undertakes to provide any detailed information requested by the Executive Agency and/or the Commission or by any other outside body authorised by the Executive Agency and/or the Commission to check that the action and the provisions of the agreement are being properly implemented. Where the Executive Agency and/or the Commission so wishes, it may request such information to be provided directly by a co-beneficiary.
- II.20.2 The beneficiaries shall keep at the Executive Agency's disposal all original documents, especially accounting and tax records, or, in exceptional and duly justified cases, certified copies of original documents relating to the agreement, stored on any appropriate medium that ensures their integrity in accordance with the applicable national legislation, for a period of five years from the date of payment of the balance specified in Article I.5.
- II.20.3 The beneficiaries agree that the Executive Agency may have an audit of the use made of the grant carried out either directly by its own staff or by any other outside body authorised to do so on its behalf. Such audits may be carried out throughout the period of implementation of the agreement until the balance is paid and for a period of five years from the date of payment of the balance. Where appropriate, the audit findings may lead to recovery decisions by the Executive Agency and/or the Commission.

- II.20.4 The beneficiaries undertake to allow Executive Agency staff and outside personnel authorised by the Executive Agency and/or the Commission the appropriate right of access to sites and premises where the action is carried out and to all the information, including information in electronic format, needed in order to conduct such audits.
- II.20.5 By virtue of Council Regulation (Euratom, EC) No 2185/96 and Regulation (EC) No 1073/1999 of the European Parliament and the Council, the European Anti-Fraud Office (OLAF) may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the European Union against fraud and other irregularities. Where appropriate, the inspection findings may lead to recovery decisions by the Executive Agency and/or the Commission.
- II.20.6 The Court of Auditors shall have the same rights as the Executive Agency and the Commission, notably right of access, as regards checks and audits.

## SIGNATURES

For the co-ordinator

**Prof Enrico GARACI**  
President

*Recd and approved,*

  
Signature

Done at Roma, on 18.03.2013

For the Executive Agency

**Mr. Luc BRIOL**  
Director

  
Signature

Done at Luxembourg, on 22/3/2013

In duplicate in English

**ANNEX I**  
**DESCRIPTION OF THE ACTION**



# ANNEX I a

## (Technical annex)

|                              |  |
|------------------------------|--|
| <b>Title:</b>                | Facilitating exchange of organs donated in EU member states(FOEDUS)  |
| <b>Duration (in months):</b> | 36   |
| <b>Sub-action:</b>           | 3.1.4.2. Facilitating collaboration between national authorities in the EU organising optimal allocation and use/transplantation of donated organs |

### Executive Summary

Organ donation and transplantation is a successful therapy that provides cure to some categories of patients suffering from serious organ failures(kidney,heart,liver,lung,pancreas,and bowel).As it is well known,the number of organ donors is still insufficient in all European MS,but another value that should be also considered is the number of organs that are used per donor.Since not all tx programs are running in all EU countries yet,and it is more difficult to find the correct compatibility for some patient categories,it may happen that some organs are not allocated at national level,mainly because there is no suitable recipient on the national WL.These organs although suitable are unfortunately wasted although they could be used in another country.First outcomes of COORENORproject show that the present number of exchanges could grow substantially.The main aim of this action is therefore to better practice of exchange of organs with the end objective of increasing bilateral agreements,and an overall approach that includes raising awareness and preventing wrong communication attitude.

### Strategic relevance & contribution to the programme

This Action is meant to complement Member State policies in this field through reaching consensus on essential tools for increasing organ exchange (guidelines, consensus on necessary clinical data, common IT platform, tools for proper communication to general public) and bringing to general attention the possible obstacle and barriers to this form of cooperation, in full accordance with the art 2 of the Public Health Programme 2008-2013. This action also fits very well with the implementation of some priorities of the Action Plan 2009-2015 set by the EU Commission [Com(2008) 818 final] to strengthen cooperation between MS, namely Priority Action 8 aiming to have a system or a structure for the exchange of organs for urgent patients and difficult to treat patients and Priority action 4 (improving the knowledge and communication skills of health professionals and patient support groups on organ transplantation).For these reasons, sustainability of IT portal should prospectively be ensured directly by EU commission services for which reason system compatibility has been ensured.

### Methods and means

Taking advantage of COORENOR project outcomes, the consortium will first perform an overview and analysis of contents of existing bilateral and multilateral agreements between national or international organizations aimed at cross-border organ exchanges. At the same time a common form to be used for international cross-border exchanges will be developed with necessary medical information for speeding up the evaluation procedures of donors and organs. Such form will be tested during a pilot performed

through the IT tool developed and adapted under a dedicated work-package. Finally a strategy for tackling communication issues on cross-border exchanges as a part of a general approach to increasing public awareness for organ donation will be defined.

### Expected outcomes

The expected outcome is a EU-wide common approach to the issue of organ exchanges, along with a better knowledge of present barriers and obstacles (financial, logistic, legal), that are presently hindering this practice. This would also give the EU Commission correct inputs for addressing these issues at their level, if the case.

### General objective of the project

The focus of this action is on facilitating collaboration on organ donation between national authorities in the EU as prescribed by art 3.1.4.2. of Community Action Health Programme 2012. This focus will have a twofold approach: 1. supplying the MSs with a concrete theoretical support for organizing optimal allocation and use/transplantation of donated organs through bi-multilateral arrangements between the different tx systems and analyzing all the existing barriers. As a result the action is expected to stimulate the exchange of organs because this is an important way of increasing the number of organs available and meeting the needs of patients in all European MS.

2. developing a tested methodology to inform general public about organ donation in general and international exchange in particular, teaching experts to avoid wrong communication attitudes

The final expected outcome of the action is the increasing of bilateral agreement between MS and a better approach to communication issues in this field.

### Specific objective(s) of the project

| # | Title  | Description  |
|---|--|--|
| 1 | Reduction of logistical and organizational issues arising in cross border organ exchanges  | A better knowledge of existing logistical and organizational barriers would allow MS willing to develop such activity to implement measures to overcome such hindrance. Medium-term objective  |
| 2 | Identification of financial pathways for coverage of cross border organ exchanges in different EU countries and patient mobility for organ transplantation | A clear identification of existing financial mechanisms regulating cross border transplantation will allow tx organizations to tackle this issues at institutional level and provide for solutions. Medium term objective.   |
| 3 | Development of common donor forms (organ specific) to be used for international cross-border exchanges   | Create a list of common agreed definitions and selected items that are necessary for donor evaluation will facilitate the collection and transmission of all the essential information necessary for the organ acceptance in other MS, hence speeding-up exchanges by avoiding the loss of time consequent to the request of complementary tests. Short term objective |



| # | Title  | Description  |
|---|--|--|
| 4 | Increase in number of bilateral/multilateral agreements for cross border organ exchanges       | Providing a model for agreements will assist the MS in concluding bi/multilateral agreements and could facilitate patient mobility under well defined terms. The overall value would include providing better access to care for patients. Long term object  |
| 5 | Increase in number of exchanged organs   | Use of IT portal is expected to bring an increase in exchange organs over a short term, since this contributes to speed up communication and provides agreed tools to overcome existing barriers as far as already available organs are concerned. Long term |
| 6 | Optimization of public awareness initiatives towards organ donation and cross border exchanges | The manual for the media on how to communicate about organ donation and cross border exchange and the adoption of the methodology on how to measure the effectiveness of the campaigns will help in optimizing initiatives to increase public awareness      |

### Deliverables

**Deliverables identified in the following table shall be submitted to EAHC, within two months of the delivery month for the technical and final reports and within one month of the delivery month for all other deliverables**

| # | Title   | Description   | Confidential level | Month of delivery |
|---|---|---|--------------------|-------------------|
| 1 | Interim technical and financial report        | Interim technical and financial reports will be delivered at months 18 + 2 unless differently specified in the grant agreement.                                     | Confidential       | 18                |
| 2 | Final technical and financial report          | Final technical and financial reports will be delivered at months 36 + 2 unless differently specified in the grant agreement.                                       | Confidential       | 36                |
| 3 | Final dissemination report                    | Project website and Layman brochure will be ready at month 2 and draft dissemination plan at month 4 and intermediate dissemination analysis will done at month 15. | Public             | 29                |
| 4 | Final evaluation report on Quality and Impact | Evaluation report will include strategy and tools developed for the task, also the formative analysis with an interim   | Confidential       | 30                |

| #  | Title   | Description   | Confidential level       | Month of delivery |
|----|---|---|--------------------------|-------------------|
|    |   | estimation but most of all the Final evaluation with the External Advisory Board's review   |                          |                   |
| 5  | Report on current practice regarding crossborder organ exchanges                                      | Report on current practice regarding crossborder handling of surplus organs and obstacles to international exchange;  | Confidential             | 18                |
| 6  | Recommendations for international organ exchange  | recommendations regarding basic principles and general guidelines for international organ exchanges and suggestions to overcome barriers  | Public                   | 27                |
| 7  | Report on use of common forms for international organ exchanges                                       | Report containing all organs forms + recommendations + conclusion of simulations/test of forms on the platform  | Scientif. community only | 29                |
| 8  | Terms of use of IT portal   | User Guide for the portal that will include description of the software, user profiles, FAQ and other relevant information  | Confidential             | 14                |
| 9  | Results of pilot testing  | After the pilot testing in different working modes and schemes there will be a statistical report with quantitative data and qualitative information on weak points that need to be improved but also the users' experience                         | Confidential             | 29                |
| 10 | Manual of guidelines on how to communicate efficiently about organ donation and cross border exchange | Document containing a set of guidelines/recommendations on how to develop an effective communication strategy and raise public awareness based on studies and experience. Will also include tools for measuring the effectiveness of such measures. | Public                   | 26                |

## OVERVIEW - Work Packages and deliverables

| # | Title   | Leader  | Start | End | Deliverables   | Global Cost | Staff |
|---|---|---------|-------|-----|--|-------------|-------|
| 1 | Coordination of the joint action  | CNT-ISS | 1     | 36  | Interim technical and financial report<br>Final technical and financial report                                       | 253 124€    | 618   |
| 2 | Dissemination of the joint action   | OVSZ    | 1     | 36  | Final dissemination report   | 153 745€    | 631   |
| 3 | Evaluation of the joint action  | EOM     | 2     | 36  | Final evaluation report on Quality and Impact  | 114 505€    | 402   |
| 4 | Definition of guidelines for cooperation in cross-border organ exchanges and analysis of barriers/obstacles | ETI     | 1     | 27  | Report on current practice regarding crossborder organ exchanges<br>Recommendations for international organ exchange | 245 657€    | 536   |
| 5 | Consensus on donor medical information recommended for international organ                                  | ABM     | 1     | 29  | Report on use of common forms for international organ exchanges  | 271 463€    | 761   |
| 6 | Upgrading IT Platform for International Exchange of Organs for Transplantation                              | KST     | 12    | 30  | Terms of use of IT portal<br>Results of pilot testing  | 348 019€    | 813   |
| 7 | Communication and public awareness  | ST      | 1     | 26  | Manual of guidelines on how to communicate efficiently about organ donation and cross border exchange                | 321 343€    | 814   |
|   |   |         |       |     |  | 1 707 856€  | 4 575 |

**Horizontal Work Packages****Work package #1****Work package title:** Coordination of the joint action**Work package description:** Actions undertaken to manage the project and to make sure that it is implemented as planned**Work package leader:** CNT-ISS**List of the partners involved**

ALL PARTNERS

**List of deliverable(s) linked to this work package**

| <b>Deliverable #</b> | <b>Deliverable title</b>               |
|----------------------|--|
| 1                    | Interim technical and financial report |
| 2                    | Final technical and financial report   |

**Milestones reached by this work package**

| <b>#</b> | <b>Milestone title</b>   | <b>Month of achievement</b> |
|----------|--|-----------------------------|
| 1        | kickoff meeting  | 2                           |
| 2        | Manual with internal procedures (Consortium agreement)                         | 4                           |
| 3        | intermediate general meeting   | 14                          |
| 4        | Final general meeting  | 28                          |
| 5        | Sustainability plan (in collaboration with all partners and WP6 in particular) | 30                          |



**Work package #2****Work package title:** Dissemination of the joint action**Work package description:** Actions undertaken to ensure that the results and deliverables of the project will be made available to the target groups.**Work package leader:** OVSZ**List of the partners involved**

ALL PARTNERS

**Overview table showing the distribution and target for all project deliverables**

| #  | Title   | Distribution channel   | Target audience   |
|----|---|--|---|
| 1  | Interim technical and financial report  | internal   | project committee + EAHC                                      |
| 2  | Final technical and financial report  | internal   | project committee + EAHC                                      |
| 3  | Final dissemination report  | internal   | project committee + EAHC                                      |
| 4  | Final evaluation report on Quality and Impact   | internal   | project committee + EAHC                                      |
| 5  | Report on current practice regarding crossborder organ exchanges                                      | internal   | project committee.collaborating partner, EAHC                 |
| 6  | Recommendations for international organ exchange  | external (internet) + paper copies to be spread among EU Member States | project committee.collaborating partners, EAHC, target groups |
| 7  | Report on use of common forms for international organ exchanges                                       | external (internet) + paper copies to be spread among EU Member States | project committee.collaborating partners, EAHC, target groups |
| 8  | Terms of use of IT portal   | internal   | project committee + EAHC                                      |
| 9  | Results of pilot testing  | internal   | project committee + EAHC                                      |
| 10 | Manual of guidelines on how to communicate efficiently about organ donation and cross border exchange | external (internet) + paper copies to be spread among EU Member States | project committee.collaborating partners, EAHC, target groups |

**List of deliverable(s) linked to this work package**

| Deliverable # | Deliverable title          |
|---------------|----------------------------|
| 3             | Final dissemination report |

**Milestones reached by this work package**

| # | Milestone title                             | Month of achievement |
|---|---|----------------------|
| 1 | Layman's brochure and project website setup | 2                    |
| 2 | Draft dissemination plan                    | 4                    |
| 3 | Interim dissemination report                | 12                   |
| 4 | newsletter                                  | 18                   |
| 5 | Layman's final report                       | 30                   |



**Work package#3****Work package title:** Evaluation of the joint action**Work package description:** Actions undertaken to verify if the project is being implemented as planned and reaches the objectives.**Work package leader:** EOM**List of the partners involved**

ALL ASSOCIATED PARTNERS and ALL COLLABORATING PARTNERS

**List of specific objectives**

**Specific objective 1**      Reduction of logistical and organizational issues arising in cross border organ exchanges

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| <b>Process Indicators</b>                          | <b>Output Indicators</b>   | <b>Outcomes Indicators</b>                                 |
|--|--|--|
| Information on barriers gathered from 80% partners | Identification of at least 1 proposed solution for solving logistics/organizational issues | 100% Implementation of proposed solution at national level |

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**Specific objective 2**      Identification of financial pathways for coverage of cross border organ exchanges in different EU countries and patient mobility for organ transplantation

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| <b>Process Indicators</b>  | <b>Output Indicators</b>   | <b>Outcomes Indicators</b>  |
|--|--|---|
| Degree of completeness of infos on financial pathways equal to 80% partner countries | 80% degree of knowledge by partners concerning the financial coverage mechanisms for crossborder organ exchanges and patient mobility in their own country | 80% identification of pathway to cover all expenses incurred during crossborder organ exchanges or patient mobility |

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**Specific objective 3**      Development of common donor forms (organ specific) to be used for international cross-border exchanges

| <b>Process Indicators</b>   | <b>Output Indicators</b>   | <b>Outcomes Indicators</b>  |
|---|--|---|
| Number of analyzed national donor forms $\geq 10$   | 60% agreement on common form   | Number of exchanges for which common donor form has been used $\geq 4$  |
| <b>Specific objective 4</b>   | Increase in number of bilateral/multilateral agreements for cross border organ exchanges       |   |
| <b>Process Indicators</b>   | <b>Output Indicators</b>   | <b>Outcomes Indicators</b>  |
| 100% mapping of existing agreements   | 100% identification of success elements of existing agreements                                 | 10% increase in number of bi-multilateral agreement between EU member states as to previous situation (COORENOR data) |
| <b>Specific objective 5</b>   | Increase in number of exchanged organs   |   |
| <b>Process Indicators</b>   | <b>Output Indicators</b>   | <b>Outcomes Indicators</b>  |
| 100% of all CAs and EOEOs in MSs have to be listed on IT platform by month 15 and have access to the system | 50% partners must use the IT platform during action duration                                   | 10% increase of exchanged organs through IT portal as to previous situation (COORENOR data)                           |
| <b>Specific objective 6</b>   | Optimization of public awareness initiatives towards organ donation and cross border exchanges |   |



**Process Indicators**

Number of studied awareness campaigns and bad communication examples  $\geq 10$

**Output Indicators**

Development of at least 3 strategies to increase public awareness and reduce communication mistakes

**Outcomes Indicators**

Rate of effectiveness of developed methodologies  $\geq 70\%$

**List of deliverable(s) linked to this work package**

| <b>Deliverable #</b> | <b>Deliverable title</b>                      |
|----------------------|---|
| 4                    | Final evaluation report on Quality and Impact |

**Milestones reached by this work package**

| <b>#</b> | <b>Milestone title</b>   | <b>Month of achievement</b> |
|----------|--|-----------------------------|
| 1        | Developing a Project Evaluation System                             | 6                           |
| 2        | Setting up of Advisory Board                                       | 2                           |
| 3        | Interim progress analysis and assessment                           | 16                          |
| 4        | Final Advisory Board evaluation focused on impact and reached aims | 28                          |

**Work package# 4**

**Work package title:** Definition of guidelines for cooperation in cross-border organ exchanges and analysis of barriers/obstacles

**Work package description:** Definition of guidelines for cooperation in cross-border organ exchanges and analysis of barriers/obstacles

**Work package leader:** ETI

**List of the partners involved**

ALL PARTNERS except PFSPH, MoHRC, SMU, MDH, NHSBT

**List of deliverable(s) linked to this work package**

| Deliverable # | Deliverable title  |
|---------------|--|
| 5             | Report on current practice regarding crossborder organ exchanges |
| 6             | Recommendations for international organ exchange                 |

**Milestones reached by this work package**

| # | Milestone title  | Month of achievement |
|---|--|----------------------|
| 1 | Development of questionnaire to identify barriers for international organ exchange and collect existing agreements                     | 6                    |
| 2 | Report on the current practice and obstacles regarding the handling of non-allocatable organs existing across Europe                   | 12                   |
| 3 | Report on international agreements regarding the international exchange of donor organs across Europe                                  | 18                   |
| 4 | Recommendations regarding basic principles and general guidelines for overcoming identified obstacles for international organ exchange | 24                   |
| 5 | Recommendations regarding standards for bi- or multilateral contracts as template for new or updating existing contracts               | 27                   |

**Work package# 5****Work package title:** Consensus on donor medical information recommended for international organ**Work package description:** Consensus on donor medical information recommended for international organ**Work package leader:** ABM**List of the partners involved**

ALL PARTNERS + ONT except MoHRC, SMU

**List of deliverable(s) linked to this work package**

| <b>Deliverable #</b> | <b>Deliverable title</b>  |
|----------------------|---|
| 7                    | Report on use of common forms for international organ exchanges |

**Milestones reached by this work package**

| <b>#</b> | <b>Milestone title</b>  | <b>Month of achievement</b> |
|----------|---|-----------------------------|
| 1        | organ-specific offer form   | 13                          |
| 2        | testing phase of the forms on the IT platform with fakes organ proposals                      | 14                          |
| 3        | guideline: forms + recommendation on donor evaluation + donor maintenance                     | 24                          |
| 4        | all the organs form + recommendation + conclusion of simulation/test of forms on the platform | 29                          |

**Work package# 6****Work package title:** Upgrading IT Platform for International Exchange of Organs for Transplantation**Work package description:** Upgrading IT Platform for International Exchange of Organs for Transplantation**Work package leader:** KST**List of the partners involved**

ALL PARTNERS except PFSPH, MoHRC, SMU, DGS, FCI

**List of deliverable(s) linked to this work package**

| <b>Deliverable #</b> | <b>Deliverable title</b>  |
|----------------------|---------------------------|
| 8                    | Terms of use of IT portal |
| 9                    | Results of pilot testing  |

**Milestones reached by this work package**

| <b>#</b> | <b>Milestone title</b>   | <b>Month of achievement</b> |
|----------|--|-----------------------------|
| 1        | Uploading of organ offer forms on the platform                         | 13                          |
| 2        | Implement tools for assisting in transport/logistic/finance management | 20                          |

**Work package# 7****Work package title:** Communication and public awareness**Work package description:** Communication and public awareness**Work package leader:** ST**List of the partners involved**

ALL PARTNERS except ETI, ABM, MDH, NHSBT, DGS, FCI

**List of deliverable(s) linked to this work package**

| <b>Deliverable #</b> | <b>Deliverable title</b>  |
|----------------------|---|
| 10                   | Manual of guidelines on how to communicate efficiently about organ donation and cross border exchange |

**Milestones reached by this work package**

| <b>#</b> | <b>Milestone title</b>  | <b>Month of achievement</b> |
|----------|---|-----------------------------|
| 1        | Analysis of studies and positive/negative experiences in communication (ST/DSO)       | 4                           |
| 2        | Survey within consortium good/bad experience of communication+analysis                | 8                           |
| 3        | Workshops with experts M10 ST - M16 DSO   | 16                          |
| 4        | Elaboration of messages for traditional/print media (ST) and new media/internet (DSO) | 14                          |
| 5        | Survey on effectiveness of messages in 5 countries to be selected                     | 20                          |

## Timetable specification

|     | WP 1 | WP 2 | WP 3 | WP 4 | WP 5 | WP 6 | WP 7 |
|-----|------|------|------|------|------|------|------|
| M1  | X    | X    |      | X    | X    |      | X    |
| M2  | M    | M    | M    | X    | X    |      | X    |
| M3  | X    | X    | X    | X    | X    |      | X    |
| M4  | M    | M    | X    | X    | X    |      | M    |
| M5  | D    | X    | X    | X    | X    |      | X    |
| M6  | X    | X    | M    | M    | X    |      | X    |
| M7  | X    | X    | X    | X    | X    |      | X    |
| M8  | X    | X    | X    | X    | X    |      | M    |
| M9  | X    | X    | X    | X    | X    |      | X    |
| M10 | X    | X    | X    | X    | X    |      | X    |
| M11 | X    | X    | X    | X    | X    |      | X    |
| M12 | X    | M    | X    | M    | X    | X    | X    |
| M13 | X    | X    | X    | X    | M    | M    | X    |
| M14 | M    | X    | X    | X    | M    | D    | M    |
| M15 | X    | X    | X    | X    | X    | X    | X    |
| M16 | X    | X    | M    | X    | X    | X    | M    |
| M17 | X    | X    | X    | X    | X    | X    | X    |
| M18 | D    | M    | X    | MD   | X    | X    | X    |
| M19 | X    | X    | X    | X    | X    | X    | X    |
| M20 | X    | X    | X    | X    | X    | M    | M    |
| M21 | X    | X    | X    | X    | X    | X    | X    |
| M22 | X    | X    | X    | X    | X    | X    | X    |
| M23 | X    | X    | X    | X    | X    | X    | X    |
| M24 | X    | X    | X    | M    | M    | X    | X    |
| M25 | X    | X    | X    | X    | X    | X    | X    |
| M26 | X    | X    | X    | X    | X    | X    | D    |
| M27 | X    | X    | X    | MD   | X    | X    |      |
| M28 | M    | X    | M    |      | X    | X    |      |
| M29 | X    | D    | X    |      | MD   | D    |      |
| M30 | M    | M    | D    |      |      | X    |      |
| M31 | X    | X    | X    |      |      |      |      |
| M32 | X    | X    | X    |      |      |      |      |
| M33 | X    | X    | X    |      |      |      |      |
| M34 | X    | X    | X    |      |      |      |      |
| M35 | X    | X    | X    |      |      |      |      |
| M36 | D    | X    | X    |      |      |      |      |

**Associated partners**

| #  | Institution  | Legal Representative (First name and Last name) | Address (City, Country)                |
|----|--|---|--|
| 1  | Országos Vérellátó Szolgálat   | Eszter,Miskovits                                | Budapest,Hungary                       |
| 2  | Hellenic Transplant Organization   | Hatzis,Anastasios                               | Athens,Greece                          |
| 3  | Eurotransplant International Foundation  | Arie,Oosterlee                                  | Leiden,Netherlands                     |
| 4  | Agence de la Biomedecine   | Emmanuelle,Pradabordenave                       | Saint Denis La Plaine Cedex ,France    |
| 5  | Koordinacni stredisko transplantaci  | Pavel,Brezovský                                 | Praha 10,Czech Republic                |
| 6  | Institute for Transplantation of organs and tissues of the Republic of Slovenia - Slovenija Transplant | Danica ,Avsec-Letonja                           | Ljubljana,Slovenia                     |
| 7  | Deutsche Stiftung Organtransplantation   | Guenter,Kirste                                  | Frankfurt,Germany                      |
| 8  | Public Federal Service – Health, Food Chain control and Environment                                    | Dirk,CUYPERS                                    | Brussels,Belgium                       |
| 9  | MINISTRY OF HEALTH OF THE REPUBLIC OF CROATIA  | RAJKO,OSTOJIĆ                                   | ZAGREB,Croatia                         |
| 10 | Bulgarian Executive Agency for Transplant  | Silvi,Kirilov                                   | Sofia,Bulgaria                         |
| 11 | NATIONAL TRANSPLANT BUREAU UNDER THE MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA                   | AUDRONE,BŪZIUVIENE                              | Vilnius,Lithuania                      |
| 12 | Mater Dei Hospital, Malta Ministry of Health   | KENNETH,GRECH                                   | Valletta,Malta                         |
| 13 | Instituto Portugues do Sangue e da Transplantação  | Helder,Trindade                                 | Lisboa,Portugal                        |
| 14 | Slovak Medical University  | Dana,Farkašová                                  | Bratislava,Slovakia                    |
| 15 | NHS Blood and Transplant Department of Health  | Sally,Johnson                                   | Watford, Hertfordshire, United Kingdom |
| 16 | CENTRUM ORGANIZACYJNO-KOORDYNACYJNE DS. TRANSPLANTACJI "POLTRANSPLANT"                                 | ROMAN,DANIELEWICZ                               | WARSZAWA,Poland                        |
| 17 | INSTITUTUL CLINIC FUNDENI  | Carmen,Orban                                    | Bucarest,Romania                       |

**Collaborating partners**

| # | Institution  | Contact person (First name and Last name) | Address (City, Country)                          |
|---|--|---|--|
| 1 | Helsedirektoratet  | Jorunn Svendsen                           | Universitetsgata 2, St Olavs plass, Oslo, Norway |
| 2 | Sotsiaalministeerium (Ministry of Social Affairs of Estonia)     | Ingrid Ots-Vaik                           | Gonsiori 29, 15027 Tallinn, Estonia              |
| 3 | Nicosia Gen. Hospital  | Panayiotis Hadjicostas                    | Nechrou Abe, 1102 South Eastern Nicosia, Cyprus  |
| 4 | The Directorate of Health(Embætti landlæknis)                    | Anna Björg Aradóttir                      | Barónsstígur 47 101 Reykjavík Iceland            |
| 5 | Dutch Transplant Foundation/Nederlandse Transplantatie Stichting | Bernardette Haase                         | Postbus 2304, 2301 CH Leiden The Netherland      |
| 6 | Organisation Nacionál de Transplante                             | Rafael Matesanz                           | Sinesio Delgado c/6 Madrid, Spain                |



**Acronym: FOEDUS****Title: Facilitating exchange of organs donated in EU member states****Problem analysis including evidence base**

Organ shortage is the common problem all European countries have to face. Some Member States (MS) (such as newly acceded or smaller ones) may face greater health problems than the rest of the Union in this field. Exchange of organs between Member States could be of great help for recipients that need an infrequent match and will have very low prospects of finding an organ, while at the same time some donors will not be considered because of lack of such a program or of any compatible recipients on the waiting lists. The number of such exchanges is far below the potential according to the deliverable 7.2 of COORENOR project in 2009, only 39 organs were requested abroad and only 25 organs were transplanted whereas 88 were offered out of 18 countries and only 60 out of 75 organs accepted were transplanted. On the other side, since all countries have at least a kidney transplantation program running, but this is not the case for other life-saving organs such as liver, heart and lung, it often happens that kidneys alone are retrieved while other organs are wasted. Causes are multiple: legal, organizational, logistical, administrative, communication. In particular we already know from COORENOR that cross-border organ exchanges is not prohibited in the European Union countries, despite many of them are not presently exchanging organs with others. The lack of a common set of information collected for donor selections lengthens ischemia times or sometimes makes exchanges impossible for safety reasons. Another important issue to be clarified under this action concerns the coverage of costs entailed by cross-border donations. National organ exchange organizations have often difficulties in identifying proper interlocutors that are in charge of additional expenses that may arise in cross border exchanges (such as local ambulance transport to airport, retrieval costs). Eventually from COORENOR again we have now lists of “clearance centres” in different countries that are in charge of cross-border health care cost reimbursements, but a procedure to approach these and allow reimbursements for expenses not directly done on patients in other countries should be explored. These issues are highly prioritized by Directive 2010/53/EU, by its Action Plan and by the Commission implementing Directive 2012/25/EU and need thorough investigation. Since some topics indicated in

Joint Action call text have already been explored in all EU MS by the still ongoing COORENOR project (expiring Dec 2012), namely the overview of consent systems to organ donation, overview of brain death diagnosis criteria and overview of activity data for organ exchanges, such evidence will be thoroughly passed on to FOEDUS JA to avoid duplication of work. To address call requests, FOEDUS will therefore concentrate on the development of a common clinical form with medical infos on organ donors (WP5), the overview of contents of existing cross-border agreements and analysis of barriers as well as overview of patient mobility patterns under such agreements (WP4), bearing in mind EU Directive 2011/24/EU does not apply to organ transplantation and therefore such mobility follows different pathways that will be however highlighted. Methods for mutual understanding of existing consent systems will be addressed by WP7. Underlying ethical principles will also need and be given due attention, considering existing literature and experiences such as the very recent report from British Medical Association on organ donation.

### **Target groups**

Target groups for this kind of action will be mainly identified at two levels, institutional and professional, both within the participating countries and at the European level: - EU/non EU institutions - Competent Authorities/Health Ministries - Organ Exchange Organizations - Transplantation Centres - Procurement Organizations - Intensive Care Professionals - Transplant Professionals - Hospital Administrations - Organ Donor Associations - Mass Media/Journalists - Patients Associations - General Public. The consortium will ensure that suitable information and links are included on the action website so that interested members of the public can be informed of the project's aims, methods and progress. To this end WP2 and 7 will closely collaborate. At the end of the project, dissemination material will be produced to highlight the main findings of the project, ensuring that this information is properly distributed to defined target groups.

## Methods and means

Taking advantage of COORENOR project outcomes, the consortium will first perform an overview and analysis of contents of existing bilateral and multilateral agreements between national or international organizations aimed at cross-border organ exchanges in 4 steps. Exchanges with third countries will be however excluded. The overview will be performed through questionnaire and review of documents made available by partners and collaborating partners. WP4 will:

1) describe the current practice regarding the handling of surplus organs existing across Europe, with special attention to number of organs that cannot be allocated within donor's Organ Organization (EOEO) area; number of organs exchanged/ discarded; allocation of non-allocable organs from donor EOEO to other EOEOs; allocation of donor organs within receiving EOEO.

2) identify obstacles and barriers that hinder transborder exchange of these organs, Legal: e.g. legal provisions regarding the exchange of donor organs, access of the procurement teams to the donor country, liability in case of disease transmission or other donor organ quality related issues, legal provisions regarding the use of selected donor types like non heart-beating donors; Logistical: e.g. transport related problems resulting (availability of airfields for charter flights, timetable of commercial flights); accessibility of EOEO duty desk for organ offers; Financial: coverage of costs related to donor pre-treatment, procurement and shipping of the organ. Medical aspects that may arise will be dealt in collaboration with WP5.

3) inventory of current bi- and multilateral agreements between MS and/or EOEO's. Member states will be requested to send in contractual agreements translated to the English language, related to cross border exchange of donor organs. Based on the analysis of stage 1, it will be decided whether or not to ask additional information to the member states. Medical aspects raising from such inventory will be dealt in collaboration with WP5.

4) Standards for International Organ exchange within Europe will be developed. At the same time a common form, to be adopted on a voluntary basis, to be used for international cross-border exchanges will be developed with necessary medical information for speeding up the evaluation procedures of donors and organs. A guideline - containing a list of common agreed definitions and justification for the selected items that were recommended to adopt for donor evaluation - will also be drafted. Implementation of these forms will also be tested on the platform developed and updated under WP6. All such documents will be made available through the IT platform that will be accessible for EOEOs through authentication by user-id and password.

Finally under WP7 a strategy for tackling communication issues on organ donation and on cross-border

exchanges will be developed as a part of a general approach to increasing public awareness for organ donation.

### **Expected Outcomes**

Expected outcomes include a possible increase of bilateral agreements and the adoption of a common communication strategy to raise awareness regarding organ donation and international cross-border exchanges, but most of all this is an opportunity to agree on some common general rules, that would set up a transparency framework, helping preventing illicit practices in a very sensitive field. FOEDUS wants to show policy makers and general public how the Competent Authorities and EOEOs try to handle the problem of unallocated organs. The basis for reaching this result is the development of a EU-wide common approach to the issue of organ exchanges, along with a better knowledge of present barriers and obstacles (financial, logistic, legal), that are presently hindering this practice. This would also give the EU Commission correct inputs for addressing these issues at their level, if the case. Creating the tools for cross-border organ exchange will bring the EU one step closer to having a common policy at least for the special cases such as pediatric, urgencies and hypersensitized. Increasing the availability of organs is also expected to stimulate some Member States to invest resources to develop their own lacking transplant programs for achieving self-efficiency and meet their own patient requirements. The common communication strategy will help raising awareness and tackling issues such as explaining different national consent systems and addressing mistrust or major differences in public opinion among EU countries with clear consequences on donation rates.

### **External and internal risk analysis and contingency planning**

From an internal point of view the major risks that might interfere with the project work-plan concern the size of the Consortium (namely 18 associated partners and 6 collaborating partners). In order to cope with internal risks, a special effort will be made on coordination and management activities as CNT has a consolidate experience with coordinating large-partnership projects and joint action (EUROCET, EUSTITE, SOHOV&S, COORENOR and MODE) and a devoted staff for these tasks both at technical and administrative level. Since CNT is leading two projects under 2009 Public Health program (COORENOR and SOHOV&S) and another Join Action under 2010 Public Health program (MODE) finishing between 2012-2013, a proper number of skilled staff units will be available to

manage both scientific and administrative issues. In particular, the management team is made of three full-time assistants, to work along with the project leader. Should there be the need, additional personnel will be assigned to these tasks. Other internal risks are related to a delay in the return of the filled in questionnaires, collecting data and information, lack of active participation and collaboration of main target groups involved, difficulties on reaching consensus at the different WP and, consequently, a delay in the submission of the related deliverables. In order to avoid such a risk, a proper timetable will be shared among the partners with apt deadlines scheduled for the completion of the tasks, each WP leader will be responsible for the partner involved in the WP and they will refer to the coordinator any problem they may face.

As far as external risks are concerned, changes in political and economic situation may lead to staff changes, but these situation are normally rapidly coped with, thanks to the fact that most Consortium partners represent long-standing official organizations or national Ministries of Health. National public health plans and policies in the organ donation and transplantation field are aligned with the JA aims, particularly all the Member States have a mandate to transpose the Directive 2010/53/EU and the new Commission implementing Directive 2012/25/EU of 9 October 2012 “laying down information procedures for the exchange, between Member States, of human organs intended for transplantation”, but still the JA implementation could be slow down due to different political priorities at Member States level. Moreover some activities could not be performed in all the European Member States due to the lack of national regulation for the cross border organ exchange. Another possible external risk is the possibility that stakeholders of the field and other national organizations not involved in the project won't cooperate with the project activities as external experts. In order to actively involve the key stakeholders to the pivotal project activities and take their suggestions in due consideration, the set-up of an Advisory Board has been foreseen under WP3.

Such board will be consulted and invited to initial, intermediate and final plenary meetings.

## Horizontal Work package - Description of the work

### Work package number 1

The Project Manager (PM) will monitor the activity of all partners involved in the project and of outputs from the project. It will control quality and timing of activities, to avoid any major gap between what has been planned and work done. The PM will give an active support to dissemination, control the financial and administrative parts of the project and will carry out the main secretarial duties. Effective internal communication will be ensured by prompt front office and organization of 1 plenary meeting per year where associated partners will review and discuss progress in all areas of the project. The PM will produce the interim and final implementation and financial reports, ensuring that all partners provide information and documentation, as required. The work-package leaders will form a steering committee that will meet regularly by teleconference indicatively each six months to make most of the planning decisions and have a continuous update on the project activities. By month 4 a manual in the form of a consortium agreement (with internal procedure for voting, publishing and reaching consensus within the consortium) will be produced, with specification of roles of associated and collaborating partners. Since the consortium size is rather large, the consortium agreement will also specify the roles of associated partners in different WPs. The involvement of main partners in most activities is on the other side a prerequisite for this joint action, the main goal of which is incentivating all partners to cooperate in the fields of crossborder organ exchanges and public awareness raising as to organ donation. E-mail will be the primary mode of internal communication between the coordination group and both associated and collaborating partners, as well teleconference when the number of involved partners allows for this. Collaborating partners will be involved in all plenary meetings in Rome. The PM will organize the venue, develop the agenda, invite the participants, chair the meetings, write and circulate the minutes of the general meeting. The key purpose of the plenary meetings will be to share the plans and work of the workpackage groups with the entire partnership so that the experience and expertise of all partners will be used in all workpackages. Regular contacts with EAHC will be held,

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*PM*      *EU*

5. Production and printing of dissemination material, including a layman's brochure at month 2, one newsletter to be disseminated among stakeholders M16 and a final layman report at month 30;
6. Identification of national /international events where dissemination can take place.

The dissemination leader will be also responsible together with the project coordinator to check that all the final products (article, deliverable, layman brochure, final report) contain references to the EU funding. Sustainability of dissemination action will be ensured by prolonged maintenance of developed website and creation of wiki pages where the major project outcomes will be made available, tailored for public target group. The same will be applied for tools like videos posted on YouTube, for which a link will be added on action website and on single national websites and published during workshop events organized by WP7 and in general during the action duration.

### Work package number 3

Evaluation is measuring success in a systematic and objective way. The aim of this WP is to evaluate action effectiveness, objectives achievement and outcomes impact. Topics for evaluation: Partnership (Planning & management, Composition, Commitment, Co-ordination and leadership, Communication);

communicating any variations to the project timetable or plan. PM will also liaise routinely with the relevant team at SANCO to ensure that outputs of the project are presented and discussed at regulatory forum at EU level. WP 1 will also define a sustainability plan with all partners and EU commission. Such plan will take into account the possibility that in the future the portal for organ exchanges could be hosted on the EU Commission servers or such exchanges could be handled by another supranational body.

## **Work package number 2**

WP2 is dedicated to the dissemination of the project and external communication, its aim is to ensure that all the JA results, products, deliverables are known and made available to the different stakeholders: general public, health care officials, scientific societies, national and international policy makers, European Institution, National/International Organ Exchange Organizations. It will be led by the Hungarian partner that will draft a dissemination strategy and plan for its implementation during the project execution and beyond. However each partner will be responsible for dissemination of the action in their own country, by attending local and national conferences in order to present the project and its results to experts in the field and communicating the findings to the Competent Authority responsible for organ donation and transplantation activities, making link of project website available on national pages and publishing articles on project activities. Consistency of disseminated information will be ensured by providing single partners with model presentations of general and specific activities upon request. These national dissemination activities will be notified by all partners to the WP leader, so that a complete record of national project dissemination activities can be constructed. Dissemination will also be managed internationally, via the website, and attendance by partners at international conferences. In addition the following joint activities will be carried out:

1. Building up of a dedicated website platform devoted to external communication; under such website a private area (access through user-id and password) will grant access to all action documents by associated and collaborating partners;
2. Definition of targeted groups for communication (citizens of the participating countries, international stakeholders such as EOEO, CoE, EC, WHO, transplant professionals, health-care officials, national and European institutions etc.
3. Identification of tools (including wikipages, google sites, shooting videos to be posted on you tube) and strategies for diffusion and the information to a wider audience

with Internal stakeholders and EAHC, mainly project managers. Evaluation: Assessment of Outcomes will take place annually at general meetings on the basis of longer-term changes occurring as a result of completion of all project activities. Method: combination of document review (i.e., review of tracking reports), key informant interviews, focus groups, survey. Will produce an in-depth mid-term and end of project report, with executive summary shared with internal and external stakeholders. The final Advisory Board evaluation report will be focused on the impact of the action and the reached aims. The impact of the portal on the organ exchanged as well as the number of new bi-multilateral agreement eventually signed between European Member States during the joint action will be evaluated.

## **Core Work Package - Description of the work**

### **Work package number 4**

The general aim of this WP is to stimulate the exchange of organs because this is an important way of increasing the number of organs available. This is one of the aims of the DIRECTIVE 2010/45/EU

**Work package number 5**

This WP will focus on the development of common organ specific donor forms to be used for international cross-border exchanges. Such forms, to be adopted on a voluntary basis, will contain the necessary medical/units measurement information for speeding-up the evaluation procedures of donors and organs. In order to reach this goal, as a first step, all MS participating to this joint action will be invited to provide an English copy of the forms they currently use for international organ exchanges. Previous work from ALLIANCE-O/EOEOs will be taken in. Consensus will be reached through questionnaires and experts discussions. Agreed forms will be supplied in English but also translated by each partner in local language to avoid mistakes filling in at national levels or in organ acceptance at local level. Implementation of these forms will also be tested on the WP6 platform. Secondly, from the dedicated WP meetings and participants' discussions, on the top of consensual items selected to design the forms, a guideline -containing a list of common agreed definitions and justification for the selected items that were recommended to adopt for donor evaluation- will also be drafted. Such medical advises, based on best practices on sites and long term experience, will not only be a valuable support for countries where specific transplant programs are not in place by facilitating evaluation of potential donors for organs that are not usually retrieved, but will also allow to gather all the essential information necessary for the organ acceptance in other MS, hence speeding-up exchanges by avoiding the loss of time consequent to the request of complementary test.

Additionally, recommendations on donor maintenance could be provided as well. Sharing knowledge and experience of transplantation practices internationally shall directly impact organ exchanges and shall in the long term, bring support to MS developing their transplantation system and activities.

ONT, as collaborating partner, will cooperate with the Agence de la biomédecine and will be actively involved in the activities of this workpackage.

**Work package number 6**

The work will be based on the results of COORENOR organ exchange IT platform, and will implement and make available the results of other FOEDUS core work-packages. The platform and applications will be developed on the basis of technologies widely used by IT departments such as JAVA JEE, in order to facilitate future possible running and sustainability. The platform will be accessible to



registered users (namely EOEOs). Individual working issues will include:

- test of IT platform in different working modes and schemes
- analysing weak points of the platform, improving its characteristics
- analysing feedback with regards to user's experience, operation
- creating statistical reports for the EC
- access for new users proposed by the EC
- offering platform for info and work of Competent Authorities
- offering templates of bi/multilateral international cooperation agreements (input by WP4)
- solutions for transport and logistics in international exchange(input by WP4)
- solutions for financing of international exchange(input by WP4)
- publishing best-practices and recommended procedures in international exchange (input by WP4)
- piloting of common forms for international exchange (input by WP5)
- availability of newsletters for professional users, spots and articles to improve public awareness, FAQ (inputs by WP7 During the last two months of work.

WP6 will also actively cooperate to the drafting of a sustainability plan (see WP1)

## **Work package number 7**

The aim of WP 7, co-led by ST and DSO on equal basis, is to develop a specific approach in communication about organ donation to general public with special focus on cross border organ exchange. Final target group is general public, yet specific target groups will also be identified to use them as info multipliers.

Activities:

- 1.Studies/campaigns with previous efficient communication and positive experience(European Donation Day, workshop for journalists) will be analyzed (ST).
- 2.DSO will analyze negative communication and survey inside the consortium for good/bad experience with gen pub.
- 3.Workshop with communication experts (ST).
- 4.Several types of messages proven to be necessary when communicating with general public (brain death, general aspects of organ donation, possibilities of declaration) will be developed (ST). Messages will be transferred to test their effectiveness in reaching general public with the goal to increase

information and trust in organ donation procedures. DSO will perform activity on new media (social networks)+ organize workshop to revise messages with experts.

5.A methodology to find out the effectiveness of taken measures will be developed (ST). Message effectiveness will be tested using appropriate methodology in a valid, objective and reliable study done on a sample of general public of 5 participating countries. Included countries will differ in geographical area, development of transplantation medicine, level and quantity of communication with general public, legislative system and other variables as well as differentiation in communication approach if needed. The dynamic nature of general public, sensitive to different information will be taken into account when interpreting the results. The final output will be a manual of guidelines on "how to communicate efficiently about organ donation and cross border exchange". Detailed instruction on most effective approaches when communicating with media and general public will be included.

Contract no. : 20122101

Acronym : FOEDUS

ARES(2012) 300710

Instrument/Strand : ACTION / (HS-2012)

**ANNEX II****A. GLOBAL BUDGET (in EUR)**

| <b>Expenditures</b>   |                     |
|---|---------------------|
| <u>Direct eligible costs</u>                                |                     |
| E1. Staff   | 1 019 519,00        |
| <i>a. Costs pertaining to public officials</i>              | 428 954,00          |
| <i>b. Costs not pertaining to public officials</i>          | 590 565,00          |
| E2. Travel costs and subsistence allowances                 | 232 120,00          |
| E3. Equipment   | 0,00                |
| E4. Consumables and supplies directly linked to the project | 0,00                |
| E5. Subcontracting costs                                    | 265 550,00          |
| E6. Other costs   | 83 100,00           |
| <b>Total direct eligible costs</b>                          | <b>1 600 289,00</b> |
| <u>Indirect eligible costs</u>                              |                     |
| E7. Overheads   | 107 567,30          |
| <b>Total indirect eligible costs</b>                        | <b>107 567,30</b>   |
| <b>Total - Expenditures</b>                                 | <b>1 707 856,30</b> |

| <b>Incomes</b>                                  |                     |
|---|---------------------|
| I1. Commission funding                          | 1 149 902,30        |
| I2. Contribution pertaining to public officials | 428 954,00          |
| I3. Applicant's financial contribution          | 129 000,00          |
| I4. Income generated by the project             | 0,00                |
| I5. Other external resources                    | 0,00                |
| <b>Total - Incomes</b>                          | <b>1 707 856,30</b> |

|                                 |               |
|---------------------------------|---------------|
| <b>I1. Commission funding %</b> | <b>67,33%</b> |
|---------------------------------|---------------|

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## ANNEX II

### B. DETAILED BUDGET (in EUR)

| <b>E1. Staff</b>                               |                                |                                     |                                |                        |                  |
|--|--------------------------------|-------------------------------------|--------------------------------|------------------------|------------------|
| <b>a. Costs pertaining to public officials</b> |                                |                                     |                                |                        |                  |
| Partner reference                              | Function                       | Name                                | Number of person days          | Daily cost (€/per day) | Cost (€)         |
| 01 - ISS-CNT - IT                              | Project leader                 | Alessandro Nanni Costa              | 40                             | 764,00                 | 30 560,00        |
| 01 - ISS-CNT - IT                              | management responsible         | Paola Di Ciaccio                    | 35                             | 371,00                 | 12 985,00        |
| 01 - ISS-CNT - IT                              | technical coworker             | Claudia Carella                     | 60                             | 176,00                 | 10 560,00        |
| 01 - ISS-CNT - IT                              | transplant sys responsible     | Andrea Ricci                        | 20                             | 382,00                 | 7 640,00         |
| 01 - ISS-CNT - IT                              | communication expert           | Manuela Trerorola/Marzia Filippetti | 15                             | 206,00                 | 3 090,00         |
| 01 - ISS-CNT - IT                              | biologist, technical expert    | Francesca Puoti                     | 15                             | 206,00                 | 3 090,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>01 - ISS-CNT - IT</b>       | <b>185</b>             | <b>67 925,00</b> |
| 02 - OVSZ - HU                                 | director/chief nat coord       | Sandor Mihaly                       | 150                            | 115,00                 | 17 250,00        |
| 02 - OVSZ - HU                                 | national coordinator           | Orsolya Deme                        | 70                             | 73,00                  | 5 110,00         |
| 02 - OVSZ - HU                                 | national coordinator           | Anikó Szucs                         | 80                             | 73,00                  | 5 840,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>02 - OVSZ - HU</b>          | <b>300</b>             | <b>28 200,00</b> |
| 03 - EOM - EL                                  | psychologist                   | Georgia Menoudaku                   | 150                            | 130,00                 | 19 500,00        |
| 03 - EOM - EL                                  | nurse                          | Efthalia Nikolau                    | 100                            | 137,00                 | 13 700,00        |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>03 - EOM - EL</b>           | <b>250</b>             | <b>33 200,00</b> |
| 05 - ABM - FR                                  | head allocation platform       | Olivier Hout                        | 20                             | 722,00                 | 14 440,00        |
| 05 - ABM - FR                                  | allocation expert              | Géraldine MALAQUIN                  | 50                             | 295,00                 | 14 750,00        |
| 05 - ABM - FR                                  | transplant expert              | Christian LAMOTTE;                  | 14                             | 704,00                 | 9 856,00         |
| 05 - ABM - FR                                  | transplant expert              | Marie Thoung                        | 14                             | 547,00                 | 7 658,00         |
| 05 - ABM - FR                                  | scientific expert              | Arnaud de Guerra                    | 37                             | 374,00                 | 13 838,00        |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>05 - ABM - FR</b>           | <b>135</b>             | <b>60 542,00</b> |
| 06 - KST - CZ                                  | wp leader/director             | Pavel Brezovsky                     | 300                            | 208,00                 | 62 400,00        |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>06 - KST - CZ</b>           | <b>300</b>             | <b>62 400,00</b> |
| 07 - ST - SI                                   | director/wp manager            | Danica Avsec                        | 92                             | 276,00                 | 25 392,00        |
| 07 - ST - SI                                   | medical advisor                | ...                                 | 64                             | 185,00                 | 11 840,00        |
| 07 - ST - SI                                   | financial advisor              | ...                                 | 20                             | 185,00                 | 3 700,00         |
| 07 - ST - SI                                   | 2 project assistant            | ...                                 | 90                             | 126,00                 | 11 340,00        |
| 07 - ST - SI                                   | expert for donation program    | ...                                 | 44                             | 185,00                 | 8 140,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>07 - ST - SI</b>            | <b>310</b>             | <b>60 412,00</b> |
| 09 - PFS PH - BE                               | transplant coordinator         | Isabelle Senepart                   | 30                             | 226,00                 | 6 780,00         |
| 09 - PFS PH - BE                               | nurse                          | Luc Colenbe                         | 25                             | 255,00                 | 5 875,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>09 - PFS PH - BE</b>        | <b>55</b>              | <b>12 655,00</b> |
| 10 - MOH RC - HR                               | head of institute              | Mirela Basic                        | 20                             | 135,00                 | 2 700,00         |
| 10 - MOH RC - HR                               | head of tx department          | Martina Anusic Juricic              | 30                             | 58,00                  | 1 740,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>10 - MOH RC - HR</b>        | <b>50</b>              | <b>4 440,00</b>  |
| 11 - BEAT - BG                                 | director                       | Silvi Kirilov                       | 60                             | 38,00                  | 2 280,00         |
| 11 - BEAT - BG                                 | medical doctor                 | Toni Stoykova                       | 40                             | 21,00                  | 840,00           |
| 11 - BEAT - BG                                 | medical doctor                 | Evelina Tsvetkova                   | 10                             | 10,00                  | 100,00           |
| 11 - BEAT - BG                                 | assistant                      | Violetta Marinikova                 | 20                             | 13,00                  | 260,00           |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>11 - BEAT - BG</b>          | <b>130</b>             | <b>3 480,00</b>  |
| 12 - NTB - LT                                  | specialist for transplantation | Asta Kubiliene                      | 60                             | 81,00                  | 4 860,00         |
| 12 - NTB - LT                                  | transplant coordinator         | Audrone Buziuviene                  | 50                             | 82,00                  | 4 100,00         |
| 12 - NTB - LT                                  | assistant                      | Vytautas Zekonis                    | 35                             | 55,00                  | 1 925,00         |
| 12 - NTB - LT                                  | transplant coordinator 2       | Rasa Pekarskiene                    | 30                             | 84,00                  | 2 520,00         |
| 12 - NTB - LT                                  | donation campaign expert       | Janina Radaviene                    | 40                             | 72,00                  | 2 880,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>12 - NTB - LT</b>           | <b>215</b>             | <b>16 285,00</b> |
| 13 - MDH - MT                                  | director of Unit               | Joseph Zarb Adamu                   | 15                             | 405,00                 | 6 075,00         |
| 13 - MDH - MT                                  | intensivist                    | to be assigned                      | 10                             | 244,00                 | 2 440,00         |
| 13 - MDH - MT                                  | IT nurse                       | to be assigned                      | 15                             | 79,00                  | 1 185,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>13 - MDH - MT</b>           | <b>40</b>              | <b>9 700,00</b>  |
| 14 - IPST - PT                                 | medical doctor                 | Gerardo Oliveira                    | 50                             | 135,00                 | 6 750,00         |
| 14 - IPST - PT                                 | staff assistant                | Rita Piteira                        | 30                             | 104,00                 | 3 120,00         |
| 14 - IPST - PT                                 | administrative assistant       | Eunice Aleixo                       | 20                             | 104,00                 | 2 080,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>14 - IPST - PT</b>          | <b>100</b>             | <b>11 950,00</b> |
| 15 - SMUSCOT - SK                              | medical doctor                 | Luboslav Bena                       | 70                             | 98,00                  | 6 860,00         |
| 15 - SMUSCOT - SK                              | transplant coordinator         | Daniel Kuba                         | 45                             | 97,00                  | 4 365,00         |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>15 - SMUSCOT - SK</b>       | <b>115</b>             | <b>11 225,00</b> |
| 16 - NHSBT - UK                                | head nurse                     | Sue Falvey                          | 40                             | 419,00                 | 16 760,00        |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>16 - NHSBT - UK</b>         | <b>40</b>              | <b>16 760,00</b> |
| 17 - POLTRANSPLANT - PL                        | general director               | Roman Danielewicz                   | 50                             | 111,00                 | 5 550,00         |
| 17 - POLTRANSPLANT - PL                        | medical director               | Jaroslav Czerwinski                 | 50                             | 82,00                  | 4 100,00         |
| 17 - POLTRANSPLANT - PL                        | medical doctor                 | Piotr Malanowski                    | 20                             | 31,00                  | 620,00           |
| 17 - POLTRANSPLANT - PL                        | public relation expert         | Anna Pzenny                         | 20                             | 30,00                  | 600,00           |
|  |                                | <i>Sub-Total Staff a.</i>           | <b>17 - POLTRANSPLANT - PL</b> | <b>140</b>             | <b>10 870,00</b> |
| 18 - FCI - RO                                  | head liver surgeon             | Irinel Popescu                      | 50                             | 191,00                 | 9 550,00         |
| 18 - FCI - RO                                  | general surgeon                | Bogdan Dorobantu                    | 10                             | 136,00                 | 1 360,00         |
| 18 - FCI - RO                                  | medical doctor                 | Victor Zota                         | 20                             | 200,00                 | 4 000,00         |
| 18 - FCI - RO                                  | assistant                      | Rosanna Turcu                       | 20                             | 200,00                 | 4 000,00         |

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## ANNEX II

### B. DETAILED BUDGET (in EUR)

| <i>Sub-Total Staff a.</i>                                  |                               | <i>18 - FCI - RO</i>       | <i>100</i>                   | <i>18 910,00</i>              |                   |
|--|-------------------------------|----------------------------|------------------------------|-------------------------------|-------------------|
| <b>Sub-Total: Costs pertaining to public officials</b>     |                               | <b>2 465</b>               |                              | <b>428 954,00</b>             |                   |
| <b>b. Costs not pertaining to public officials</b>         |                               |                            |                              |                               |                   |
| <i>Partner reference</i>                                   | <i>Function</i>               | <i>Name</i>                | <i>Number of person days</i> | <i>Daily cost (€ per day)</i> | <i>Cost (€)</i>   |
| 01 - ISS-CNT - IT  | medical doctor/head nurse     | ...                        | 328                          | 220,00                        | 72 160,00         |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>01 - ISS-CNT - IT</i>     | <i>328</i>                    | <i>72 160,00</i>  |
| 04 - ETI - NL  | medical doctor+admin manager  | Axel Rahmel/Arie Oosterlee | 106                          | 800,00                        | 84 800,00         |
| 04 - ETI - NL  | 2 IT experts                  | to be assigned             | 39                           | 450,00                        | 17 550,00         |
| 04 - ETI - NL  | 2 technical coworker          | to be assigned             | 96                           | 270,00                        | 25 920,00         |
| 04 - ETI - NL  | 3 various professionals       | to be assigned             | 135                          | 345,00                        | 46 575,00         |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>04 - ETI - NL</i>         | <i>376</i>                    | <i>174 845,00</i> |
| 05 - ABM - FR  | scientific expert/project man | Candide Font-Sala          | 340                          | 283,00                        | 96 220,00         |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>05 - ABM - FR</i>         | <i>340</i>                    | <i>96 220,00</i>  |
| 06 - KST - CZ  | legal expert                  | Presmyl Fryda              | 220                          | 135,00                        | 29 700,00         |
| 06 - KST - CZ  | IT specialist                 | Mirka Langrova             | 110                          | 133,00                        | 14 630,00         |
| 06 - KST - CZ  | transplant coordinator        | Lucie Baudysova            | 170                          | 89,00                         | 15 130,00         |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>06 - KST - CZ</i>         | <i>500</i>                    | <i>59 460,00</i>  |
| 07 - ST - SI   | technical manager             | ...                        | 167                          | 220,00                        | 36 740,00         |
| 07 - ST - SI   | lector                        | ...                        | 6                            | 170,00                        | 1 020,00          |
| 07 - ST - SI   | PR professional               | ...                        | 18                           | 220,00                        | 3 960,00          |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>07 - ST - SI</i>          | <i>191</i>                    | <i>41 720,00</i>  |
| 08 - DSO - DE  | medical director              | Guenter Kirste             | 30                           | 608,00                        | 18 240,00         |
| 08 - DSO - DE  | communication expert          | Alexandra Hesse            | 195                          | 304,00                        | 59 280,00         |
| 08 - DSO - DE  | medical expert                | Thomas Breidembach         | 90                           | 592,00                        | 53 280,00         |
| 08 - DSO - DE  | assistant                     | to be assigned             | 60                           | 256,00                        | 15 360,00         |
|  |                               | <i>Sub-Total Staff b.</i>  | <i>08 - DSO - DE</i>         | <i>375</i>                    | <i>146 160,00</i> |
| <b>Sub-Total: Costs not pertaining to public officials</b> |                               | <b>2 110</b>               |                              | <b>590 565,00</b>             |                   |
| <b>TOTAL STAFF COSTS</b>                                   |                               | <b>4 575</b>               |                              | <b>1 019 519,00</b>           |                   |

| <b>Travel costs including Subsistence allowances</b> |                           |                                   |                                       |
|--|---------------------------|-----------------------------------|---------------------------------------|
| <i>Partner reference</i>                             | <i>Number of meetings</i> | <i>Number of persons foreseen</i> | <i>Average total cost of meetings</i> |
| 01 - ISS-CNT - IT                                    | 19                        | 1                                 | 15 323,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>01 - ISS-CNT - IT</i>              |
| 02 - OVVSZ - HU                                      | 17                        | 1                                 | 16 398,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>02 - OVVSZ - HU</i>                |
| 03 - EOM - EL  | 17                        | 1                                 | 16 398,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>03 - EOM - EL</i>                  |
| 04 - ETI - NL  | 11                        | 1                                 | 11 166,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>04 - ETI - NL</i>                  |
| 05 - ABM - FR  | 15                        | 1                                 | 13 183,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>05 - ABM - FR</i>                  |
| 06 - KST - CZ  | 14                        | 1                                 | 13 963,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>06 - KST - CZ</i>                  |
| 07 - ST - SI   | 15                        | 1                                 | 14 678,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>07 - ST - SI</i>                   |
| 08 - DSO - DE  | 17                        | 1                                 | 16 398,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>08 - DSO - DE</i>                  |
| 09 - PFS PH - BE                                     | 10                        | 1                                 | 10 911,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>09 - PFS PH - BE</i>               |
| 10 - MOH RC - HR                                     | 6                         | 1                                 | 7 931,00                              |
|  |                           | <i>Sub-Total Travels</i>          | <i>10 - MOH RC - HR</i>               |
| 11 - BEAT - BG                                       | 6                         | 1                                 | 7 931,00                              |
|  |                           | <i>Sub-Total Travels</i>          | <i>11 - BEAT - BG</i>                 |
| 12 - NTB - LT  | 17                        | 1                                 | 16 398,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>12 - NTB - LT</i>                  |
| 13 - MDH - MT  | 11                        | 1                                 | 11 166,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>13 - MDH - MT</i>                  |
| 14 - IPST - PT                                       | 15                        | 1                                 | 11 783,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>14 - IPST - PT</i>                 |
| 15 - SMUSCOT - SK                                    | 9                         | 1                                 | 9 146,00                              |
|  |                           | <i>Sub-Total Travels</i>          | <i>15 - SMUSCOT - SK</i>              |
| 16 - NHSBT - UK                                      | 11                        | 1                                 | 11 166,00                             |
|  |                           | <i>Sub-Total Travels</i>          | <i>16 - NHSBT - UK</i>                |

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## ANNEX II

### B. DETAILED BUDGET (in EUR)

|   |                          |                                |                   |
|---|--------------------------|--------------------------------|-------------------|
| 17 - POLTRANSPLANT - PL                 | 17                       | 1                              | 16 398,00         |
|   | <i>Sub-Total Travels</i> | <i>17 - POLTRANSPLANT - PL</i> | <i>16 398,00</i>  |
| 18 - FCI - RO                           | 15                       | 1                              | 11 783,00         |
|   | <i>Sub-Total Travels</i> | <i>18 - FCI - RO</i>           | <i>11 783,00</i>  |
| <b>Sub-Total: Travels costs</b>         |                          |                                | <b>232 120,00</b> |
| <b>TOTAL TRAVELS &amp; SUBSISTENCES</b> |                          |                                | <b>232 120,00</b> |

| <b>E3. Equipment</b>     |                    |             |             |
|--------------------------|--------------------|-------------|-------------|
| <i>Partner reference</i> | <i>Description</i> | <i>Cost</i> |             |
| <b>TOTAL EQUIPMENT</b>   |                    |             | <b>0,00</b> |

| <b>E4. Consumables and supplies directly linked to the project</b> |                    |             |             |
|--|--------------------|-------------|-------------|
| <i>Partner reference</i>   | <i>Description</i> | <i>Cost</i> |             |
| <b>TOTAL CONSUMABLES &amp; SUPPLIES</b>                            |                    |             | <b>0,00</b> |

| <b>E5. Subcontracting costs</b>    |  |  |                          |
|------------------------------------|--|--|--------------------------|
| <i>Partner reference</i>           | <i>Description</i>   |  | <i>Cost</i>              |
| 01 - ISS-CNT - IT                  | teleconference service for 4 Steering Committees                       |  | 4 550,00                 |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>01 - ISS-CNT - IT</i> |
|                                    |  |  | <b>4 550,00</b>          |
| 02 - OVSZ - HU                     | project wesite development   |  | 15 000,00                |
| 02 - OVSZ - HU                     | web dissemination expert   |  | 15 000,00                |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>02 - OVSZ - HU</i>    |
|                                    |  |  | <b>30 000,00</b>         |
| 03 - EOM - EL                      | quality assurance expertise from greek transplant centre               |  | 20 000,00                |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>03 - EOM - EL</i>     |
|                                    |  |  | <b>20 000,00</b>         |
| 06 - KST - CZ                      | IT portal development and maintenance                                  |  | 141 000,00               |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>06 - KST - CZ</i>     |
|                                    |  |  | <b>141 000,00</b>        |
| 07 - ST - SI                       | survey about the effectiveness of the message in 5 countries throu CAW |  | 40 000,00                |
| 07 - ST - SI                       | public awareness raising material development                          |  | 10 000,00                |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>07 - ST - SI</i>      |
|                                    |  |  | <b>50 000,00</b>         |
| 08 - DSO - DE                      | public awareness video shooting  |  | 20 000,00                |
|                                    |  | <i>Sub-Total Sub-Contracting Costs</i> | <i>08 - DSO - DE</i>     |
|                                    |  |  | <b>20 000,00</b>         |
| <b>TOTAL SUB-CONTRACTING COSTS</b> |  |  | <b>265 550,00</b>        |

| <b>E6. Other costs</b>   |  |                              |                          |
|--------------------------|--|------------------------------|--------------------------|
| <i>Partner reference</i> | <i>Description</i>   |                              | <i>Cost</i>              |
| 01 - ISS-CNT - IT        | catering for 3 WP1/2/3 meetings (3days each)   |                              | 1 500,00                 |
| 01 - ISS-CNT - IT        | trav/sub cost WP3 3 meetings 2 days Advisory board 7-9 people (collaborating partners) |                              | 26 500,00                |
|                          |  | <i>Sub-Total Other Costs</i> | <i>01 - ISS-CNT - IT</i> |
|                          |  |                              | <b>28 000,00</b>         |
| 02 - OVSZ - HU           | production electronic version layman brochure  |                              | 1 000,00                 |
| 02 - OVSZ - HU           | printing layman brochure 500 copies  |                              | 1 000,00                 |
| 02 - OVSZ - HU           | printing final layman report 1000 copies   |                              | 2 500,00                 |
|                          |  | <i>Sub-Total Other Costs</i> | <i>02 - OVSZ - HU</i>    |
|                          |  |                              | <b>4 500,00</b>          |
| 04 - ETI - NL            | catering for 4 WP4 meetings  |                              | 1 300,00                 |
| 04 - ETI - NL            | printing of WP4 recommendations 500 copies   |                              | 8 000,00                 |
| 04 - ETI - NL            | travel/sub WP1/2/3, 4 WP4 meetings legal advisor German Health Ministry                |                              | 7 000,00                 |
|                          |  | <i>Sub-Total Other Costs</i> | <i>04 - ETI - NL</i>     |
|                          |  |                              | <b>16 300,00</b>         |
| 05 - ABM - FR            | printing WP5 guidelines on medical issues fro organ exchanges (500 copies)             |                              | 8 000,00                 |
| 05 - ABM - FR            | catering for 3 WP5 meetings and 1 WP5 and WP6 meeting                                  |                              | 1 300,00                 |
|                          |  | <i>Sub-Total Other Costs</i> | <i>05 - ABM - FR</i>     |
|                          |  |                              | <b>9 300,00</b>          |
| 06 - KST - CZ            | catering for 3 WP6 meetings  |                              | 1 000,00                 |
|                          |  | <i>Sub-Total Other Costs</i> | <i>06 - KST - CZ</i>     |
|                          |  |                              | <b>1 000,00</b>          |
| 07 - ST - SI             | catering for 1 WP7 meeting   |                              | 500,00                   |
| 07 - ST - SI             | workshop with communication experts  |                              | 20 000,00                |
|                          |  | <i>Sub-Total Other Costs</i> | <i>07 - ST - SI</i>      |
|                          |  |                              | <b>20 500,00</b>         |
| 08 - DSO - DE            | printing manual on awareness-raising communication 1500 copies                         |                              | 3 500,00                 |
|                          |  | <i>Sub-Total Other Costs</i> | <i>08 - DSO - DE</i>     |
|                          |  |                              | <b>3 500,00</b>          |
| <b>TOTAL OTHER COSTS</b> |  |                              | <b>83 100,00</b>         |

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**ANNEXE II**  
**C. BUDGET BY BENEFICIARY (in EUR)**

|   |                             | 01 - ISS-CNT - IT | 02 - OVSZ - HU   | 03 - EOM - EL    | 04 - ETI - NL     |
|---|-----------------------------|-------------------|------------------|------------------|-------------------|
|   |                             | Public<br>IT      | Public<br>HU     | Public<br>EL     | Private<br>NL     |
| <i>Legal Entity Code (EAHC use only)</i>                  |                             |                   |                  |                  |                   |
| <i>Bank Account Code (EAHC use only)</i>                  |                             |                   |                  |                  |                   |
| <i>Legal Status in ABAC<br/>Country</i>                   |                             |                   |                  |                  |                   |
| <b>Expenditures</b>                                       |                             |                   |                  |                  |                   |
| <b>Direct eligible costs</b>                              |                             |                   |                  |                  |                   |
|   | <b>TOTAL</b>                |                   |                  |                  |                   |
| E1. Staff   | 1.019.519,00                | 140.085,00        | 28.200,00        | 33.200,00        | 174.845,00        |
| a. Costs pertaining to public officials                   | 428.954,00                  | 67.925,00         | 28.200,00        | 33.200,00        | 0,00              |
| b. Costs not pertaining to public officials               | 590.565,00                  | 72.160,00         | 0,00             | 0,00             | 174.845,00        |
| E2. Travel costs and subsistence allowances               | 232.120,00                  | 15.323,00         | 16.398,00        | 16.398,00        | 11.166,00         |
| E3. Equipment   | 0,00                        | 0,00              | 0,00             | 0,00             | 0,00              |
| E4. Consumables & supplies directly linked to the project | 0,00                        | 0,00              | 0,00             | 0,00             | 0,00              |
| E5. Subcontracting costs                                  | 265.550,00                  | 4.550,00          | 30.000,00        | 20.000,00        | 0,00              |
| E6. Other costs   | 83.100,00                   | 28.000,00         | 4.500,00         | 0,00             | 16.300,00         |
| <b>Total direct eligible costs</b>                        | <b>1.600.289,00</b>         | <b>187.958,00</b> | <b>79.098,00</b> | <b>69.598,00</b> | <b>202.311,00</b> |
| <b>Indirect eligible costs</b>                            |                             |                   |                  |                  |                   |
| E7. Overheads   | 107.567,30                  | 13.157,00         | 5.536,00         | 4.871,00         | 14.161,00         |
|   | <i>% of Overheads</i> 6,72% | 7,00%             | 7,00%            | 7,00%            | 7,00%             |
| <b>Total - Expenditures</b>                               | <b>1.707.856,30</b>         | <b>201.115,00</b> | <b>84.634,00</b> | <b>74.469,00</b> | <b>216.472,00</b> |
| <b>Incomes</b>  |                             |                   |                  |                  |                   |
|   | <b>TOTAL</b>                |                   |                  |                  |                   |
| I1. Commission funding                                    | 1.149.902,30                | 133.190,00        | 56.434,00        | 41.269,00        | 147.472,00        |
| I2. Contribution pertaining to public officials           | 428.954,00                  | 67.925,00         | 28.200,00        | 33.200,00        | 0,00              |
| I3. Applicant's financial contribution                    | 129.000,00                  | 0,00              | 0,00             | 0,00             | 69.000,00         |
| I4. Income generated by the project                       | 0,00                        | 0,00              | 0,00             | 0,00             | 0,00              |
| I5. Other external resources                              | 0,00                        | 0,00              | 0,00             | 0,00             | 0,00              |
| <b>Total - Incomes</b>                                    | <b>1.707.856,30</b>         | <b>201.115,00</b> | <b>84.634,00</b> | <b>74.469,00</b> | <b>216.472,00</b> |
| <b>% of Commission funding</b>                            | <b>67,33%</b>               | 66,23%            | 66,68%           | 55,42%           | 68,13%            |

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**ANNEXE II**  
**C. BUDGET BY BENEFICIARY (in EUR)**

|   |  | 05 - ABM - FR     | 06 - KST - CZ     | 07 - ST - SI      | 08 - DSO - DE     |
|---|--|-------------------|-------------------|-------------------|-------------------|
|   | <i>Legal Entity Code (EABC use only)</i> |                   |                   |                   |                   |
|   | <i>Bank Account Code (EABC use only)</i> |                   |                   |                   |                   |
|   | <i>Legal Status in ABAC</i>              | Public            | Public            | Public            | Private           |
|   | <i>Country</i>                           | FR                | CZ                | SI                | DE                |
| <b>Expenditures</b>                                       |  |                   |                   |                   |                   |
|   | <b>TOTAL</b>                             |                   |                   |                   |                   |
| <u>Direct eligible costs</u>                              |  |                   |                   |                   |                   |
| E1. Staff   | 1.019.519,00                             | 156.762,00        | 121.860,00        | 102.132,00        | 146.160,00        |
| a. Costs pertaining to public officials                   | 428.954,00                               | 60.542,00         | 62.400,00         | 60.412,00         | 0,00              |
| b. Costs not pertaining to public officials               | 590.565,00                               | 96.220,00         | 59.460,00         | 41.720,00         | 146.160,00        |
| E2. Travel costs and subsistence allowances               | 232.120,00                               | 13.183,00         | 13.963,00         | 14.678,00         | 16.398,00         |
| E3. Equipment   | 0,00                                     | 0,00              | 0,00              | 0,00              | 0,00              |
| E4. Consumables & supplies directly linked to the project | 0,00                                     | 0,00              | 0,00              | 0,00              | 0,00              |
| E5. Subcontracting costs                                  | 265.550,00                               | 0,00              | 141.000,00        | 50.000,00         | 20.000,00         |
| E6. Other costs   | 83.100,00                                | 9.300,00          | 1.000,00          | 20.500,00         | 3.500,00          |
| <b>Total direct eligible costs</b>                        | <b>1.600.289,00</b>                      | <b>179.245,00</b> | <b>277.823,00</b> | <b>187.310,00</b> | <b>186.058,00</b> |
| <u>Indirect eligible costs</u>                            |  |                   |                   |                   |                   |
| E7. Overheads   | 107.567,30                               | 12.547,00         | 15.000,00         | 13.111,00         | 13.024,00         |
|   | <i>% of Overheads</i>                    | 7,00%             | 5,40%             | 7,00%             | 7,00%             |
| <b>Total - Expenditures</b>                               | <b>1.707.856,30</b>                      | <b>191.792,00</b> | <b>292.823,00</b> | <b>200.421,00</b> | <b>199.082,00</b> |
| <b>Incomes</b>  |  |                   |                   |                   |                   |
|   | <b>TOTAL</b>                             |                   |                   |                   |                   |
| I1. Commission funding                                    | 1.149.902,30                             | 131.250,00        | 230.423,00        | 140.009,00        | 139.082,00        |
| I2. Contribution pertaining to public officials           | 428.954,00                               | 60.542,00         | 62.400,00         | 60.412,00         | 0,00              |
| I3. Applicant's financial contribution                    | 129.000,00                               | 0,00              | 0,00              | 0,00              | 60.000,00         |
| I4. Income generated by the project                       | 0,00                                     | 0,00              | 0,00              | 0,00              | 0,00              |
| I5. Other external resources                              | 0,00                                     | 0,00              | 0,00              | 0,00              | 0,00              |
| <b>Total - Incomes</b>                                    | <b>1.707.856,30</b>                      | <b>191.792,00</b> | <b>292.823,00</b> | <b>200.421,00</b> | <b>199.082,00</b> |
|   | <b>% of Commission funding</b>           | 68,43%            | 78,69%            | 69,86%            | 69,86%            |



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**ANNEXE II**  
**C. BUDGET BY BENEFICIARY (in EUR)**

|   |  | 09 - PFS PH - BE | 10 - MOH RC - HR | 11 - BEAT - BG   | 12 - NTB - LT    |
|---|--|------------------|------------------|------------------|------------------|
|   | <i>Legal Entity Code (EAHC use only)</i> |                  |                  |                  |                  |
|   | <i>Bank Account Code (EAHC use only)</i> |                  |                  |                  |                  |
|   | <i>Legal Status in ABAC</i>              |                  |                  |                  |                  |
|   | <i>Country</i>                           | Public<br>BE     | Public<br>HR     | Public<br>BG     | Public<br>LT     |
| <b>Expenditures</b>                                       |  |                  |                  |                  |                  |
|   | <b>TOTAL</b>                             |                  |                  |                  |                  |
| <b>Direct eligible costs</b>                              |  |                  |                  |                  |                  |
| E1. Staff   | 1.019.519,00                             | 12.655,00        | 4.440,00         | 3.480,00         | 16.285,00        |
| a. Costs pertaining to public officials                   | 428.954,00                               | 12.655,00        | 4.440,00         | 3.480,00         | 16.285,00        |
| b. Costs not pertaining to public officials               | 590.565,00                               | 0,00             | 0,00             | 0,00             | 0,00             |
| E2. Travel costs and subsistence allowances               | 232.120,00                               | 10.911,00        | 7.931,00         | 7.931,00         | 16.398,00        |
| E3. Equipment   | 0,00                                     | 0,00             | 0,00             | 0,00             | 0,00             |
| E4. Consumables & supplies directly linked to the project | 0,00                                     | 0,00             | 0,00             | 0,00             | 0,00             |
| E5. Subcontracting costs                                  | 265.550,00                               | 0,00             | 0,00             | 0,00             | 0,00             |
| E6. Other costs   | 83.100,00                                | 0,00             | 0,00             | 0,00             | 0,00             |
| <b>Total direct eligible costs</b>                        | <b>1.600.289,00</b>                      | <b>23.566,00</b> | <b>12.371,00</b> | <b>11.411,00</b> | <b>32.683,00</b> |
| <b>Indirect eligible costs</b>                            |  |                  |                  |                  |                  |
| E7. Overheads   | 107.567,30                               | 1.649,00         | 865,90           | 798,70           | 2.287,80         |
|   | <i>% of Overheads</i> 6,72%              | 7,00%            | 7,00%            | 7,00%            | 7,00%            |
| <b>Total - Expenditures</b>                               | <b>1.707.856,30</b>                      | <b>25.215,00</b> | <b>13.236,90</b> | <b>12.209,70</b> | <b>34.970,80</b> |
| <b>Incomes</b>  |  |                  |                  |                  |                  |
|   | <b>TOTAL</b>                             |                  |                  |                  |                  |
| I1. Commission funding                                    | 1.149.902,30                             | 12.560,00        | 8.796,90         | 8.729,70         | 18.685,80        |
| I2. Contribution pertaining to public officials           | 428.954,00                               | 12.655,00        | 4.440,00         | 3.480,00         | 16.285,00        |
| I3. Applicant's financial contribution                    | 129.000,00                               | 0,00             | 0,00             | 0,00             | 0,00             |
| I4. Income generated by the project                       | 0,00                                     | 0,00             | 0,00             | 0,00             | 0,00             |
| I5. Other external resources                              | 0,00                                     | 0,00             | 0,00             | 0,00             | 0,00             |
| <b>Total - Incomes</b>                                    | <b>1.707.856,30</b>                      | <b>25.215,00</b> | <b>13.236,90</b> | <b>12.209,70</b> | <b>34.970,80</b> |
| <b>% of Commission funding</b>                            | <b>67,33%</b>                            | <b>49,81%</b>    | <b>66,46%</b>    | <b>71,50%</b>    | <b>53,43%</b>    |

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Contract no. : 20122101  
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**ANNEXE II**  
**C. BUDGET BY BENEFICIARY (in EUR)**

13 - MDH - MT      14 - IPST - PT      15 - SMUSCOT - SK      16 - NHSBT - UK

*Legal Entity Code (E.AHC use only)*  
*Bank Account Code (E.AHC use only)*  
*Legal Status in ABAO*  
*Country*

Public  
MT

Public  
PT

Public  
SK

Public  
UK

| <b>Expenditures</b>                                       | <b>TOTAL</b>                |                  |                  |                  |                  |
|---|-----------------------------|------------------|------------------|------------------|------------------|
| <b>Direct eligible costs</b>                              |                             |                  |                  |                  |                  |
| E1. Staff   | 1.019.519,00                | 9.700,00         | 11.950,00        | 11.225,00        | 16.760,00        |
| a. Costs pertaining to public officials                   | 428.954,00                  | 9.700,00         | 11.950,00        | 11.225,00        | 16.760,00        |
| b. Costs not pertaining to public officials               | 590.565,00                  | 0,00             | 0,00             | 0,00             | 0,00             |
| E2. Travel costs and subsistence allowances               | 232.120,00                  | 11.166,00        | 11.783,00        | 9.146,00         | 11.166,00        |
| E3. Equipment   | 0,00                        | 0,00             | 0,00             | 0,00             | 0,00             |
| E4. Consumables & supplies directly linked to the project | 0,00                        | 0,00             | 0,00             | 0,00             | 0,00             |
| E5. Subcontracting costs                                  | 265.550,00                  | 0,00             | 0,00             | 0,00             | 0,00             |
| E6. Other costs   | 83.100,00                   | 0,00             | 0,00             | 0,00             | 0,00             |
| <b>Total direct eligible costs</b>                        | <b>1.600.289,00</b>         | <b>20.866,00</b> | <b>23.733,00</b> | <b>20.371,00</b> | <b>27.926,00</b> |
| <b>Indirect eligible costs</b>                            |                             |                  |                  |                  |                  |
| E7. Overheads   | 107.567,30                  | 1.460,60         | 1.661,30         | 1.425,00         | 1.954,80         |
|   | <i>% of Overheads</i> 6,72% | 7,00%            | 7,00%            | 7,00%            | 7,00%            |
| <b>Total - Expenditures</b>                               | <b>1.707.856,30</b>         | <b>22.326,60</b> | <b>25.394,30</b> | <b>21.796,00</b> | <b>29.880,80</b> |
| <b>Incomes</b>  |                             |                  |                  |                  |                  |
| I1. Commission funding                                    | 1.149.902,30                | 12.626,60        | 13.444,30        | 10.571,00        | 13.120,80        |
| I2. Contribution pertaining to public officials           | 428.954,00                  | 9.700,00         | 11.950,00        | 11.225,00        | 16.760,00        |
| I3. Applicant's financial contribution                    | 129.000,00                  | 0,00             | 0,00             | 0,00             | 0,00             |
| I4. Income generated by the project                       | 0,00                        | 0,00             | 0,00             | 0,00             | 0,00             |
| I5. Other external resources                              | 0,00                        | 0,00             | 0,00             | 0,00             | 0,00             |
| <b>Total - Incomes</b>                                    | <b>1.707.856,30</b>         | <b>22.326,60</b> | <b>25.394,30</b> | <b>21.796,00</b> | <b>29.880,80</b> |
| <b>% of Commission funding</b>                            | <b>67,33%</b>               | 56,55%           | 52,94%           | 48,50%           | 43,91%           |

Contract no. : 20122101  
 Acronym : FOEDUS  
 ARES(2012) 300710  
 Instrument/Strand : ACTION / (HS-2012)

**ANNEXE II**  
**C. BUDGET BY BENEFICIARY (in EUR)**

|   |                             | 17 -<br>POLTRANSPLANT -<br>PL | 18 - FCI - RO    |
|---|-----------------------------|-------------------------------|------------------|
|   |                             | Public<br>PL                  | Public<br>RO     |
| <i>Legal Entity Code (EAHC use only)</i>                  |                             |                               |                  |
| <i>Bank Account Code (EAHC use only)</i>                  |                             |                               |                  |
| <i>Legal Status in ABAC<br/>Country</i>                   |                             |                               |                  |
| <b>Expenditures</b>                                       |                             |                               |                  |
|   | <b>TOTAL</b>                |                               |                  |
| <b>Direct eligible costs</b>                              |                             |                               |                  |
| E1. Staff   | 1.019.519,00                | 10.870,00                     | 18.910,00        |
| a. Costs pertaining to public officials                   | 428.954,00                  | 10.870,00                     | 18.910,00        |
| b. Costs not pertaining to public officials               | 590.565,00                  | 0,00                          | 0,00             |
| E2. Travel costs and subsistence allowances               | 232.120,00                  | 16.398,00                     | 11.783,00        |
| E3. Equipment   | 0,00                        | 0,00                          | 0,00             |
| E4. Consumables & supplies directly linked to the project | 0,00                        | 0,00                          | 0,00             |
| E5. Subcontracting costs                                  | 265.550,00                  | 0,00                          | 0,00             |
| E6. Other costs   | 83.100,00                   | 0,00                          | 0,00             |
| <b>Total direct eligible costs</b>                        | <b>1.600.289,00</b>         | <b>27.268,00</b>              | <b>30.693,00</b> |
| <b>Indirect eligible costs</b>                            |                             |                               |                  |
| E7. Overheads   | 107.567,30                  | 1.908,70                      | 2.148,50         |
|   | <i>% of Overheads</i> 6,72% | 7,00%                         | 7,00%            |
| <b>Total - Expenditures</b>                               | <b>1.707.856,30</b>         | <b>29.176,70</b>              | <b>32.841,50</b> |
| <b>Incomes</b>  |                             |                               |                  |
|   | <b>TOTAL</b>                |                               |                  |
| I1. Commission funding                                    | 1.149.902,30                | 18.306,70                     | 13.931,50        |
| I2. Contribution pertaining to public officials           | 428.954,00                  | 10.870,00                     | 18.910,00        |
| I3. Applicant's financial contribution                    | 129.000,00                  | 0,00                          | 0,00             |
| I4. Income generated by the project                       | 0,00                        | 0,00                          | 0,00             |
| I5. Other external resources                              | 0,00                        | 0,00                          | 0,00             |
| <b>Total - Incomes</b>                                    | <b>1.707.856,30</b>         | <b>29.176,70</b>              | <b>32.841,50</b> |
| <b>% of Commission funding</b>                            | <b>67,33%</b>               | <b>62,74%</b>                 | <b>42,42%</b>    |

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## ANNEX III REPORTING REQUIREMENTS

### 1. INTERIM IMPLEMENTATION REPORT(S)

The interim technical implementation report(s) will describe the work carried out and the results obtained during the period indicated in Article I.6 of this grant agreement and state in particular:

- the results obtained to date and an indication of any deviation from the initial work programme set out in Annex I to the grant agreement that has occurred or is likely to occur<sup>1</sup>;
- the work programme planned for the following period;
- copies of any publications, products or other relevant outputs or deliverables of the project to date.

The interim financial implementation report(s) will compare the expenditure incurred during the reporting period with the foreseen budget stated in Annex II of this grant agreement. The budget implemented in the interim financial report should follow the same structure as the estimated budget in Annex II.

The interim implementation report(s) and any other documents referred to, must be sent to the Executive Agency before the date indicated in Article I.6.

### 2. FINAL IMPLEMENTATION REPORT

The final implementation report referred to in Article I.6 should include in particular a final technical implementation report and a final financial report<sup>2</sup>:

#### 2.1. Technical implementation report

##### *2.1.1. Detailed description of all the activities conducted*

The description should relate to the activities specifically foreseen in Annex I. This section of the report should summarise the activities specifically foreseen and those directly related to the objectives of the project and present and explain the activity actually done, their correspondence to the foreseen programme and objectives, and show how each activity has contributed to the stated objectives.

Copies of any publications, products or other relevant outputs or deliverables of the project to date shall be annexed.

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<sup>1</sup> Without prejudice to Art. II.13.

<sup>2</sup> N.B. : The description of the required content of the activity report is not exhaustive

Any difference between the programme and objectives foreseen and those actually conducted and achieved must be highlighted and explained.

### ***2.1.2. Manpower for the execution of the activities***

This section of the report should present a complete list of all the persons who have participated in the execution of the project and, for each of them, the man/days of work, the professional level or category and the corresponding unit and total cost. In order to conciliate the man/days of work with the expenditure, the portion of time of each individual carrying out the action must be recorded.

In the case of partner organisations or external bodies, the organisation to which each person belongs should be clearly identified. The activities conducted by each person involved will be described and it will be explained how they relate to the various activities and objectives of the project.

It must be shown how the data requested for Annex II compares with the corresponding information provided with the proposal. It should naturally also correspond to the details provided in the financial report.

### ***2.1.3. Partners involved***

This section should present how the work has been distributed among the various partners. It will explain which activities the various partners have conducted, how they have been co-ordinated and how they have contributed to the set objectives.

### ***2.1.4. Countries involved***

This section should explain what activities have been conducted in each of the countries involved and how the results have been made available in each country.

### ***2.1.5. Achievement of the objectives***

This section should explain how the objectives have been achieved. It should present an evaluation of the results achieved and explain on what monitoring, assessment or relevant evidence the conclusions presented on the results achieved are based. Any problem in achieving the objectives must be highlighted and explained.

## **2.2. Financial report**

The beneficiaries should respect the following rules<sup>3</sup>:

- Their final financial report must follow the same structure as the estimated budget in Annex II.
- The financial report must be certified according to the provisions of Article 180, paragraph 1a of the Implementing Rules<sup>4</sup> and signed.

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<sup>3</sup> Templates of the documents are available in the "Guidelines for the balance payment" published on EAHC website.

- The payment request (dated and signed) must be jointed to this report.

**The (co-)beneficiary who has the status of non-governmental body** should submit additionally:

- Copy of the balance sheet and a full summary statement of the receipts and expenditure for the period of eligibility covered by the grant agreement (i.e. up to 3 years);
- The final detailed financial statement must be accompanied by an external audit report on the beneficiary's accounts for the duration of the action (one copy) if the share in the grant for an action for the beneficiary is EUR 750 000<sup>5</sup> or more, when the cumulative amounts of requests for payment is at least EUR 325 000. The thresholds shall apply to each beneficiary
- In line with Annex VI of the Commission Decision concerning the adoption of the financing decision for 2011 in the framework of the second programme of Community action in the field of health (2008-13) and on the selection, award and other criteria for financial contributions to the actions to this programme (Work Plan 2011), the (co-)beneficiary who has the status of non-governmental body should submit additionally:
  - The Financial independence form filled in according to the template attached in Annex VII of the grant agreement and certified by an independent auditor. Information provided in this form should cover the period of the grant agreement.

At the time of the final report, the financial independence will be assessed based on the financial information for the financial year for which the grant was attributed. If the information provided shows that during the financial years covered by the agreement, the (co-)beneficiary received more than 20 % of its core funding from private sector organisations representing a conflicting interest, or from other sources representing a conflicting interest, the entire amount of the grant shall be recovered.

Any beneficiary (public or non-governmental body), whose accountancy is established in another currency than euros, shall convert actual costs as registered in his accounts into euros at the monthly accounting rate established by the Commission, published on its website<sup>6</sup> for the first day of the month the final report is to be submitted by the beneficiary.

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<sup>4</sup> The beneficiary shall certify on his honour that information contained in requests for payments is full, reliable and true. He shall also certify that the costs incurred can be considered eligible in accordance with the grant agreement and that requests for payment are substantiated by adequate supporting documents that can be checked.

<sup>5</sup> The audit certificate shall certify that the costs declared by the beneficiary in the financial statements on which the request for payment is based are real, accurately recorded and eligible in accordance with the grant agreement)

<sup>6</sup> <http://ec.europa.eu/budget/inforeuro/index.cfm?fuseaction=home&Language=en>

**IMPORTANT: The absence of complete, clear and structured information and data as described in this annex will be a reason for non acceptance of the activity report.**

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**ANNEX IV**  
**LETTERS OF MANDATE<sup>1</sup>**

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<sup>1</sup> Please use the headed paper on national language of the organisation who gives mandate.