



MINISTERO DELLA SALUTE

Istituto Superiore di Sanità
Centro Nazionale Trapianti

Roma.



WHO Collaborating Centre
On Vigilance and Surveillance for
Human Cells, Tissues and Organs

ACCESSION
to the
FOEDUS COOPERATION AGREEMENT

The Party:

Italian National Transplant Centre

with its registered seat at:

Viale Regina Elena n. 299 – 00161 Rome, Italy

represented by:

Dr Alessandro Nanni Costa

in the position of:

Director General

hereby declares its accession to the FOEDUS Cooperation Agreement

given in:

Rome, 30/05/2016

The signature:

Viale Regina Elena, 299 - 00161 Roma
Tel +39 06/4990.4040 - 4041 - 4045
Fax. +39 06/4990.4101
e-mail: cnt@iss.it - PEC: cnt-corrispondenza-certificata@mailcert.iss.it

www.trapianti.salute.gov.it



FOEDUS Cooperation Agreement

1. The Parties

Koordinální středisko transplantací (hereinafter as KST),
with its registered seat at Ruská 85, Praha 10, Czech Republic,
represented by prof. MUDr. Miloš Adamec, CSc., Director

and

Bulgaria – Bulgaria Executive Agency for Transplant, BEAT
With its registered seat at
Represented by

and

France - Agence de la biomédecine (ABM)
with its registered seat at 1 avenue du Stade de France, 93212 SAINT-DENIS LA PLAINE,
Cedex, France
represented by Ms Anne COURREGES, Director General

and

Italy - Italian National Transplant Centre (CNT)
With its registered seat at Viale Regina Elena n. 299 – 00161 Rome, Italy
Represented by Dr. Alessandro Nanni Costa, Director-General

and

Lithuania - National Transplant Bureau under the Ministry of Health of the Republic of
Lithuania – (NTB)

and

Poland – Polish Transplant Coordinating Center – Poltransplant
with its registered seat at AL. Jerozolimskie 87, 02-001 Warsaw, Poland
represented by Prof. Roman Danielewicz, Director

and

Romania
With its registered seat at
Represented by

and

Slovakia - Národná transplantáčna organizácia (NTO)

with its registered seat at Limbova street 14, 83303, Bratislava, Slovakia

represented by Dr Daniel Kuba, Director

and

Spain - Organización Nacional de Trasplante (ONT)

With its registered seat at C/ Sinesio Delgado 6, pabellón 3, 28029, Madrid, Spain

Represented by Dr Rafael Matesanz, Director

and

Swisstransplant

With its registered seat at Effingerstrasse 1, Postfach, 3011 Bern, Switzerland

Represented by PD Dr. med. Franz F. Immer, CEO

and

United Kingdom –NHSBT

With its registered seat at

Represented by

HAVE AGREED to the following terms established in this cooperation agreement
("the Agreement")

2. The Preamble

- (a) Considering that organ shortage is a common problem for all European Member States and the exchange of organs is an important way of increasing the number of available organs, ensuring a better match between donor and recipient and therefore improving the quality of transplantation;
- (b) Whereas, the "Action Plan of on organ donation and transplantation (2009-2015)" as adopted by the European Commission, stresses the importance of facilitating collaboration on organ donation between national authorities in the EU;
- (c) That the FOEDUS Joint Action was started in May 2013, is focused on facilitating collaboration on organ donation between national authorities in the European Union as described in the Directive 2010/53/EU and in the Action Plan 2009-2015 by the European Commission;
- (d) Considering that it is within the common interest of the Parties to strengthen and implement the collaboration among their authorities in an effort to facilitate the allocation and transplantation from deceased donors while optimizing and conspiring the needs of specific types of patients, such as pediatric and highly sensitized patients;

- (e) Considering that International exchange of organs requires quick and efficient exchange of information and that the Joint Action FOEDUS (G.A. 20122101) funded by the European Union in the framework of the Health Programme had initiated notably the creation of the FOEDUS-EOEO IT Portal tool for international organ exchanges.

3. The Purpose

- (a) The purpose of this Agreement is to establish a framework for cooperation of the Parties using the FOEDUS-EOEO IT Portal for organ exchanges in order to facilitate international organ exchange.
- (b) Furthermore, the Purpose of this Agreement is to specify conditions, rights and responsibilities of the Parties in bi-and multilateral cooperation in international organ exchanges.
- (c) The Parties shall use the FOEDUS-EOEO Portal to (i) offer surplus organs and/or to (ii) place request for organs for patients in life threatening condition.
- (d) In the framework of this Agreement the Parties define the financial contribution to the maintenance of the FOEDUS-EOEO Portal.

4. The FOEDUS-EOEO Portal

- (a) The Parties shall carry out international organ exchange solely through FOEDUS-EOEO Portal , unless otherwise specified in a bilateral agreement or due to emergency situations.
- (b) The address of the FOEDUS-EOEO Portal remains “www.foedus-oeo.eu”.
- (c) The owner of the address as well as of the source codes of the FOEDUS-EOEO Portal is KST.
- (d) KST is authorized to appoint experts to provide maintenance, servicing and/or further developments of the FOEDUS-EOEO Portal upon the FOEDUS board approval (see section 6).
- (e) The FOEDUS-EOEO Portal is open to any European country upon willingness to participate in international organ exchanges, to follow the principles laid in this Agreement, and upon budget availability to contribute financially to support the costs of the FOEDUS-EOEO Portal.

5. Safety and Quality

- (a) International organ exchanges may not give rise to financial gain or comparable advantages; trading and trafficking of organs is strictly prohibited.
- (b) No patient may appear simultaneously on more than one waiting list for organ transplantation maintained by Parties.
- (c) The Parties may send offers to any Party or to group of Parties or to all Parties as per their sole discretion. Likewise, selecting among accepting countries is the sole decision of the offering country (having notably to decide in accordance of bilateral agreements).
- (d) The Parties shall allocate available organs to patients who are on their waiting list in accordance with applicable National legislation; the donating Party has no right to interfere whatsoever in the allocation process to the receiving country.
- (e) Screening, examination and laboratory testing shall be performed as agreed by both Parties.
- (f) The Parties mutually guarantee quality control of their Health Facilities, education and experience of the personnel, as well as the origin and traceability of organs exchanged.
- (g) Upon request the Parties shall provide each other with relevant follow-up data of the recipient.
- (h) The Parties shall ensure compliance with all relevant privacy regulations and the rules applicable to protection of personal data and confidentiality of patients records.
- (i) The Parties shall report serious adverse events and reactions to the competent authorities in writing and with no delay.

6. The FOEDUS Board

- (a) A FOEDUS Board (hereinafter as FB) will be nominated in order to provide guidance and support, and take decision about any issue related to the FOEDUS-EOEO IT portal.
- (b) Each Party has a right to nominate one or two representatives to FB for the term of five years.
- (c) FB elects from its members the President for the term of two years. The presidency shall rotate. The President shall convene and preside the meetings of FB.
- (d) FB shall hold annual meetings. The first meeting will be held in Prague, Czech Republic, in the last quarter of 2016 (date and place to be agreed upon).
- (e) Each FB country has one vote. In the event of equal vote the will of the President prevails. Vote *per-rollam* is accepted in case no objection is raised by any Party within two weeks of a vote proposal transmission by the President. FB may adopt its own by-laws.

- (f) FB will specify the contribution of each Party in the agreement and redefine the amount of contribution in the event of one partner resigning from the agreement.

7. The Funds

- (a) The Parties have expressed their will to contribute to the work of the Portal in the “FOEDUS Joint Action Sustainability & Implementation Plan” of December 2015.

- (b) The initial voluntary contributions of individual Parties shall be for the first year (2016) as follow:

• Koordinační středisko transplantací, Czech Republic	€ 1.000
• Agence de la biomédecine, France	€ 2.000
• Centro Nazionale Trapianti, Italy	€ 2.000
• Poltransplant, Poland	€ 1.000
• Fundeni Clinical Institute, Romania	€ 1.000
• NHS Blood and Transplant, United Kingdom	€
• Organización Nacional de Trasplantes, Spain	€ 2.000
• National Transplant Bureau, Lithuania	€
• Swisstransplant, Switzerland	€ 1.000
• Bulgarian Executive Agency for Transplantation, Bulgaria	€ 1.000
• Národná transplantáčná organizácia, Slovakia	€ 1000

- (c) The contributions for the year 2016 shall be sent to the official account of Koordinační středisko transplantací, Czech Republic,. The account number is: 4229101/0710 at Ceska narodni banka, Na Prikope 28, Prague 1, BIC (SWIFT): CNBACZPP - IBAN: CZ37 0710 0000 0000 0422 9101.

- (d) The contributions for the following years shall be sent in the amount and in the manner as agreed upon by the FOEDUS Board.

- (e) New Parties may be relieved of the duty to pay the annual contribution in part/in full, as FB may decide.

- (f) There is no charge for organs that are exchanged between the Parties based on this Agreement. Costs of transportation of the organ and/or the procurement team as well as possible material costs are covered by the respective authority in the country of destination.

8. Miscellaneous

- (a) This Agreement shall enter into force on the first day after its signature by the two Parties and shall continue for an indefinite period of time.

- (b) A newly acceding Party shall duly sign the ACCESSION to the FOEDUS COOPERATION AGREEMENT and send it to the FB. FB shall agree with the new party upon financial and other conditions and shall inform all other Parties accordingly.

- (c) Any Party can withdraw from this Agreement at any time and for any reason upon written notice to FB.
- (d) In the event of a Party resign from the agreement the costs will be redistributed according to the decision of the FB.
- (e) A revision of this agreement should be foreseen after two years according to the decisions of the FB.