

Allegato B. en

Exploratory notice for interest declaration in the service of acquisition of gametes to be used in the techniques of heterologous medically assisted conception (MAC) at Azienda per l'Assistenza Sanitaria n. 5 "Friuli occidentale", via Vecchia ceramica 1, 33170 Pordenone, ITALIA. ID 15SER006

The EGAS, in the name of, and on behalf of The Azienda per l'Assistenza Sanitaria n. 5 "Friuli Occidentale" (A.A.S.5) intends to know which Institutes, in possession of the necessary requirements are interested in collaborating with thereof to provide, if needed, a service of acquisition of gametes to be used in the techniques of heterologous medically assisted conception (MAC).

It is specified that the notice is reserved to

- the Italian Institutes authorized and periodically inspected in accordance with the current legislation
- to foreign Institutes belonging to the European Union, approved by the competent national authorities in accordance with the quality and safety standards referred to in the Directives 2004/23/EC, 2006/17/EC 2006/86/EC
- as well as to non-EU Institutes authorized by the competent national authorities in accordance with the aforementioned European legislation in force.

Given the initial phase of MAC with heterologous technique, and the need to provide the most extensive assistance, it intends to verify the most appropriate methods for choosing the Institutes with whom to collaborate.

Whereas the specifications of the service are indicated in the form enclosed as attachment sub A1), an eventual agreement that with foreign Institutes will be operational after the approval of the Regional Reference Centre for Transplantation subject to the approval of the National Transplant Centre (CNT) - will include separate charges according to the type of tissue, in addition to the reimbursement of transportation expenses.

The choice of the Institute to turn to, if necessary, will be made on a basis of economic convenience, technical and operational, functional to the satisfaction of concrete and actual needs.

The mandatory requirements that the Institutions must meet in order to collaborate with A.A.S. 5 are listed below:

- a) the Institution must have obtained the certification / authorization specifying which activities can perform and under what conditions, pursuant to and by effect of Directive 2004/23/EC 2006/17/C and 2006/86/EC if in the EU and, if Italian, also pursuant to and by effect of Legislative Decree no. 191/2007, of Legislative Decree no. 16/2010 and of Law 40 of 19 February 2004. If the Institute is located in a non-EU country, it must have been authorized by the competent authority, in accordance with the aforementioned European legislation in force. If any part of the processing was entrusted to a third party, the institution must indicate which and provide a copy of the agreement with the latter;
- b) the Institute must have designated an administrator in charge of the bank with adequate training and experience;
- c) the Institute must have stipulated an appropriate insurance policy to cover the risks and eventual damages during the supply of gametes to MAC Centres.

ENTE PER LA GESTIONE ACCENTRATA DEI SERVIZI CONDIVISI

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
SERVIZIO SANITARIO REGIONALE

The full notice, as well as the form for interest declaration and the information sheet with the specifications of the service, are published on the website.

The interested Institutes are therefore invited to submit a written interest declaration, exclusively by filling in the facsimile form provided, to the following address: EGAS Via Colugna 50 33100 UDINE ITALY www.egas.sanita.fvg.it or www.aopn.sanita.fvg.it, indicating in subject line: "interest to collaborate with A.A.S.5 for heterologous fertilization ID 15SER006".

It is recommended to submit the interest declaration no later than 22 May 2015.

Please note: Photocopies of valid identity documents of the Legal Representative of the Institute and of the Executive Medical Director of the bank are to be attached.

All statements documents must be written in Italian.