Establishment of institutional control on the safety and quality of human tissues and cells used for transplantation - Development of a National Centre for Tissue and Cell Banking.

1. Basic Information
   1.1 CRIS Number: 2004/016-829.01.05 Twinning No PL2004/IB/SO/02
   1.2 Title: Establishment of institutional control on the safety and quality of human tissues and cells used for transplantation - Development of a National Centre for Tissue and Cell Banking.
   1.3 Sector: Poland
   1.4 Location: Poland

2. Objectives:
   2.1 Overall Objective(s):
      1. Implementation of EU standards on the safety and quality of tissues and cells used for transplantation.
      2. Development of the National Centre for Tissue and Cell Banking.

   2.2 Project purpose:
      2. Developing and strengthening the competence, capabilities and capacities of the National Centre for Tissue and Cell Banking.
      3. Enhancement the knowledge of the parties involved in the issue of the safety and quality of tissues and cell used for transplantation.
      4. Creation of software programme to serve in tissue banking practice.

2.3 Justification
Tissue and cell transplantation is a field in which intensive exchange is taking place, and thus there is an urgent need for a unified framework to ensure high standards of quality and safety with respect to donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells across the Community.
The Directive 2004/23/EC of the European Parliament and of a Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells in order to ensure a high level of health protection in the Community should be implemented during the next two years in all Member States.

3. Description

3.1 Background and justification:
Currently, there are 8 tissue banks active in Poland: 3 multi-tissue banks and 5 mono-tissue banks.
Three multi-tissue banks: the Central Tissue Bank in Warsaw established in the Medical University in 1963 and two banks created at Blood Transfusion Centers in Katowice in 1969 and Kielce in 1978, provide tissue allografts such as bone, cartilage, tendons, ligaments, sclera, skin and amnion. The main methods of tissue preservation used in these tissue banks
are deep freezing and/or lyophilization with subsequent radiation-sterilization with a dose of 35 kGy with gamma rays of $^{60}$Co source or with a beam of accelerated electrons (10 MeV linear accelerator). These banks prepare approximately 15 000 tissue allografts per year. Three of the mono-tissue banks (in Warsaw, Krakow and Zabrze) prepare approximately 350 heart valve allografts per year and two oculair tissue banks (in Warsaw and Lublin) provide approximately 700 cornea allografts per year.

Since 1963, over 250 000 radiation-sterilized tissue grafts have been prepared and used in 250 hospitals throughout Poland: 150 000 allografts (of which 75% constitute bone allografts) and some 100 000 xenografts and animal collagen-derived membranes and sponges. Due to possible contamination of animal tissues with prions (bovine origin) or with PERV viruses (porcine origin), we ceased preparing xenografts to avoid transmission of zoonotic diseases to the human population. We have also ceased preparing human dura mater grafts, which may be infected with prions.

Tissue banking is a highly specialized procedure requiring appropriate professional qualifications and specialized supervision. Therefore, in January 2004, the Polish Minister of Health established a National Centre for Tissue and Cell Banking using the expertise, manpower and infrastructure of the Central Tissue Bank in Warsaw, which has been the leading institution for tissue banking in Poland.

As mentioned above, the purpose of the project is to strengthen the competence, capabilities and capacities of this Centre which will be responsible for setting and updating national standards on quality and safety of donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells according to Directive 2004/23/EC and standards of the European Association of Tissue Banks (EATB). Due to the fact that personnel directly involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be appropriately qualified and provided with timely and relevant training, this Centre will elaborate training programmes for various groups of health professionals engaged in tissue banking practice, e.g.: pathologists, forensic medicine specialists and other medical doctors responsible for donor screening and classification; medical directors of tissue establishments; technical staff; tissue graft users (e.g. orthopaedic surgeons, neurosurgeons, cardiosurgeons, ophtalmologists, etc.)

This newly created Centre as a training unit for health professionals from all tissue establishments in Poland prepare various types of tissue allografts such as bone, rib cartilage, skin, acellular dermis, amnion and carry out research in order to optimise preservation and sterilization procedures of various tissue allografts.

Moreover, in order to fulfil the obligations of the Directive 2004/23/EC some technical requirements of tissue and cell processing, storage and distribution should be ensured. However, the current infrastructure of the Centre (room for tissue reception, registration and quarantine, tissue processing rooms, tissue storage room, and tissue culture laboratory) is rather old, insufficient and does not meet the EU standards. Therefore, further upgrading of tissue bank and cell culture facilities is required to reach sanitary and epidemiological protection conditions according to EU standards included in the Directive 2004/23/EC and to receive an accreditation. The Polish party is obliged by this Directive to ensure that the Centre where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited. In particular, it is necessary to design and upgrade tissue processing and cell culture rooms with a standard of cleanrooms in which the air filtration, supply and distribution is required on each step of processing according to GLP and EU standards. It is also required to design a central air conditions system for all laboratories. That will guarantee the desired continuous
quality of the final product – tissue grafts. The Transition Facility project could help the Centre in implementation of the *acquis* by improving the technical standards of tissue and cell processing, storage and distribution. Thanks to this project the Centre could receive the accreditation for activities connected with tissue banking.

Other *acquis* requirement is to create a special software programme, which will hold databases of donor screening and selection, tissue procurement, processing, preservation and storage as well as databases of tissue allograft distribution to recipients and short (up to 1 year) and long-term follow-up after surgical treatment with tissue grafts (graft traceability). This software programme will allow the tracking of the tissue from its procurement till clinical application by storing all data as long as it is necessary according to the requirements included in the Directive 2004/23/EC. This will also allow for an exchange of information between tissue banks in an easy and secure way. At present the Centre does not possess computerized databases of donors, tissue procurement, processing, preservation, storage and distribution procedures. All the mentioned above data are kept on a flow chart. Other tissue banks, which operates in Poland, also does not possess computerized systems for tissue banking procedures.

### 3.2 Linked activities

At present, no projects in the field of tissue banking are being implemented in Poland.

### 3.3 Results

1. Development of tissue banking surveillance system at the national level.
2. Creation and updating national standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells according to Directive 2004/23/EC and EATB standards.
3. Creation of training programmes for various groups of health professionals engaged in tissue banking practice to increase their qualifications.
4. Upgrading tissue bank facilities to reach sanitary and epidemiological protection conditions according to EU standards.
5. Creation of special software programme to hold several databases allowing traceability from tissue procurement via donor screening and selection, tissue processing, preservation and storage up to clinical application and long-term follow up post surgical treatment with tissue allografts.
6. Optimization of preservation and sterilization procedures for various types of tissue allografts.

### 3.4 Activities

**Twinning** focused on:

1. Interpretation and assistance in implementing Directive 2004/23/EC.
2. Preparing and updating national standards concerning proper classification of donors, tissue procurement, testing, processing, preservation, storage and distribution of human allografts.
3. Consultations for tissue bank professionals to disseminate current knowledge in this field as well as improve qualifications and maintain them at the appropriate level.
4. Training courses and seminars for various groups of health professionals engaged in tissue banking practice to increase their qualifications:
   a. pathologists, forensic medicine specialists and other medical doctors
responsible for donor screening and classification (approx. 30 persons), 
b. medical directors of tissue establishments (approx. 8 persons), 
c. technical staff (approx. 30 persons), 
d. tissue graft users (e.g. orthopedic surgeons, neurosurgeons, cardiologists, ophthalmologists, etc., approx. 80 persons).

5. Consultations in upgrading tissue bank facilities to reach sanitary and epidemiological protection conditions according to EU standards.

6. Strengthening cooperation among institutions involved in tissue banking both at national and EU level.

7. Advisory in creating a special software programme to hold several databases: donor screening and selection, tissue procurement, processing, preservation, sterilization and storage, tissue allograft distribution to recipients and short (up to 1 year) and long-term follow-up post surgical treatment, allowing for tissue traceability at each stage.

To support activities foreseen in the programme, the Twinning component should include:
- A 1,5 year Resident Twinning Adviser (RTA) to be located in the National Centre for Tissue and Cell Banking in Warsaw.

The RTA should provide consultations, advice and expertise to implement Directive 2004/23/EC at the national level between 2005-2007. The RTA should also be responsible for the overall coordination of project activities.

The RTA should meet the following requirements:
- be experienced in tissue banking practice and be familiar with EU regulations relevant to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, particularly Directive 2004/23/EC; knowledge on the application of ionizing radiation for end-sterilization of tissue allografts would be an advantage.
- have strategic management skills
- be fluent in both written and spoken English

The participation of short-term experts (STEs) will also be required: one particularly familiar in evaluating tissue bioburden (initial contamination), tissue sampling for microbiological studies, resistance of pathogens to ionizing radiation, setting of sterilization dose, etc., and second, an IT specialist, familiar with creation of databases and computer programmes.

Experts will be responsible for developing training curricula.

The project cost is 1.04 MEUR (Transition Facility – 1.0 MEUR and 0.04 MEUR of Polish co-financing).

**Investment – works, focused on:**

Upgrading tissue bank facilities to reach sanitary and epidemiological protection conditions during tissue processing, that would guarantee the desired continuous quality of the final product – tissue allografts:

1. Designing and upgrading of tissue processing rooms with a standard of cleanrooms.
2. Designing and upgrading of air condition system for processing rooms.
A Cleanroom - specially designed and constructed room in which the air supply, air distribution, filtration of air supply is required on each step of tissue allograft processing according to GMP and EU standards.

There were no applications for Phare funds or other funds for this project in the past.

The project cost is 0.305 MEUR (Transition Facility – 0.2287 MEUR and 0.0763 MEUR of Polish co-financing).

**Technical Assistance focused on:**
Creation and testing of the specialised software programme holding several databases: donor screening and selection, tissue procurement, processing, preservation, sterilization and storage, tissue allograft distribution to recipients and short (up to 1 year) and long-term follow-up post surgical treatment, allowing for tissue graft traceability of each stage.

The project cost is 0.244 MEUR (Transition Facility – 0.244 MEUR).

**3.5 Lessons learned**
N/A

**4. Institutional Framework**
The Ministry of Health, as the main beneficiary of the National Centre for Tissue and Cell Banking will coordinate the project as activities are planned to be on a national level.

The Unit responsible for the realization and coordination of the project:
National Centre for Tissue and Cell Banking, ul. Chalubinskiego 5, 02-004 Warsaw, Phone/Fax +48 (22) 621 75 43, Phone: +48 (22) 696 13 36
email:agoclaw@ib.amwaw.edu.pl

Implementation of the project does not change the above institutional framework.

**5. Detailed Budget**

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6. Implementation Arrangements

6.1 Implementing Agency

PAO: Tadeusz Kozek, Under-secretary of State at the Office of the Committee for European Integration, Aleje Ujazdowskie 9, 00-918 Warsaw, Phone: +(4822) 455 52 41

Finance and Contacts Unit, Foundation “Co-operation Found”, CFCU Director, ul. Górnośląska 4a, 00-444 Warsaw, Phone: +(4822) 622 88 20

6.2 Twinning

SPO: has to be established by the Polish Ministry of Health.
Project Leader: Anna Dziedzic-Goclawwska, Director, National Centre for Tissue and Cell Banking, ul. Chalubinskiiego 5, 02-004 Warsaw, Phone/Fax +48(22) 621 75 43, Phone: +48 (22) 696 13 36, email: agoclaw@ib.amwaw.edu.pl

6.3 Non-standards aspects

Tender procedures and contracts will be conducted according to the Law on Public Procurement.
The IB part of the project shall be implemented according to the Twinning Manual.

6.4 Contracts

Twinning Covenant: Transition Facility - 1.0 MEUR + National co-financing - 0.04 MEUR –
In Twinning the co-financing covers direct and indirect costs of the beneficiary administration
in compliance with Twinning Manual.
Investment - works contract 0.305 MEUR – gross value (Transition facility – 0.2287 MEUR
+ National co-financing – 0.0763 MEUR) - joint co-financing
Technical Assistance - Transition Facility - 0.244 MEUR - gross value

7. Implementation Schedule

7.1. Preparation of TORs - 4th quarter of year 2004
7.2. Start of project implementation - 2nd quarter of year 2005
7.3. Start of Twinning - 2nd quarter of year 2005
7.4. Project Completion - 4th quarter of year 2007

8. Sustainability

The National Centre for Tissue and Cell Banking has been established using the expertise,
manpower and infrastructure of the Central Tissue Bank in Warsaw, which is a Department of
the Warsaw Medical University. The annual budget for the activities of the National Centre
for Tissue and Cell Banking will be included in the budget of Poland’s Ministry of Health.

9. Conditionality and Sequencing

1. Estimation of expert selection.
2. Twinning Covenant.
3. Setting and updating national standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells according to Directive 2004/23/EC and EATB standards.

4. Creation of training programmes for various groups of health professionals engaged in tissue banking practice to increase their qualifications.

5. Training courses and seminars for various groups of health professionals engaged in tissue banking practise.

6. Creation of a special software programme to hold several databases that will allow for traceability from tissue procurement, via donor screening and selection, tissue processing, preservation and storage up to clinical application and long-term follow-up post surgical treatment with tissue allografts.

7. Testing of software programme.
### Annex 1: LOGFRAME PLANNING MATRIX FOR THE PROJECT

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<th>LOGFRAME PLANNING MATRIX FOR</th>
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<td><strong>Project purpose (Immediate Objectives)</strong></td>
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Development of tissue banking surveillance system at the national level.
Creation and updating national standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells according to Directive 2004/23/EC and EATB standards.
Creation of training programmes for various groups of health professionals engaged in tissue banking practice to increase their qualifications.
Upgrading of tissue bank facilities to reach sanitary and epidemiological protection conditions according to EU standards.
Creation of special software programme to hold several databases allowing traceability from tissue procurement via donor screening and selection, tissue processing, preservation and storage up to clinical application and long-term follow up post surgical treatment with tissue allografts.
Optimization of preservation and sterilization procedures for various types of tissue allografts.

<table>
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<th>Activities</th>
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Interpretation and assistance in implementation of Directive 2004/23/EC.
Preparing and updating standards concerning the proper classification of donors, tissue procurement testing, processing, preservation, storage and distribution of human allografts. Consultations for tissue banks in order to disseminate the current knowledge in this field as well as to improve qualifications and maintain them at the appropriate level.
Training courses and seminars for various groups of health professionals engaged in tissue banking practise to increase their qualifications.
Consultations in upgrading of tissue bank facilities to reach sanitary and epidemiological protection conditions according to EU standards.
Setting up a quality control & management system for tissue allografts.
Strengthening co-operation among institutions involved in tissue banking both at national and EU level.
Advisory on the special software programme to hold several databases (donor screening and selection, tissue procurement, processing, preservation, sterilization and storage, tissue allograft distribution and short (up to 1 year) and long term follow-up post surgical treatment allowing for traceability of each stage.
Upgrading of tissue bank facilities to reach sanitary and epidemiological protection conditions.
Creation and testing of software programme.

Pre-Accession Adviser (RTA) to provide consultations, advisory and expertise with respect to implementing Directive 2004/23/EC.
Translated and interpreted documents.
Upgraded tissue bank facilities.
Created and tested software programme.

Estimation of expert selection.
Project realization reports.
Estimation of training.

Implemented Directive 2004/23/EC.
Professional people involved in the project.
Valuable training programmes.
Provision of adequate funding by the Polish government to ensure proper, effective and continuous training of personnel from the National Centre for Tissue and Cell Banking.
Providing appropriate software for data collection.

Preconditions
Annex 2-3. Implementation, contracting and disbursement schedules

Establishment of institutional control of the safety and quality of human tissues and cells used for transplantation - Creation of a National Centre for Tissue and Cell Banking

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Legend:
D = design of sub-projects
C = tendering and contracting
I = contract implementation and payment