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### ***Chernobyl Tissue Bank (CTB) Fact Sheet***

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#### **1. What is the CTB?**

The CTB is an international cooperation to establish banks of material from and information on patients who were exposed as children or adolescents to fallout from the Chernobyl nuclear accident. The project is supported by the governments of 2 of the 3 countries which were exposed to the heaviest contamination from the accident: the Russian Federation and Ukraine. Belarus, which was also contaminated and was initially part of the CTB, is currently suspended because of political issues. Funds to support the bank are currently provided by the European Commission, the National Cancer Institute of the USA and the Sasakawa Memorial Health Foundation of Japan. The Coordinating Centre for the project is based at Imperial College, London, UK.

The project commenced collection of material on 1<sup>st</sup> October 1998. It is designed to promote collaboration and avoid wasteful competition in the use of limited and very scientifically important resources. The project is overseen by a Steering Committee, which includes the Ministers of Health or their representatives from the Russian Federation and Ukraine and senior representatives of each of the funding organisations.

The objectives of the project are to provide an internationally supported research resource for both ongoing and future studies of the health consequences of the Chernobyl accident. It aims to:

- 1 Ensure that specimens of thyroid cancer operated on or after 1<sup>st</sup> October 1998 (the start date of the project) are consistently described and sampled, and that the materials (extracted tumour and normal DNA/RNA and blood samples and in some cases fixed tissue sections) together with the relevant information, are available for appropriate research studies.
- 2 Provide a diagnosis agreed by an international committee of pathologists for all cases in the CTB. The diagnosis will be made available to research groups carrying out molecular biological, therapeutic, epidemiological and other studies as well as to the countries concerned.
- 3 Ensure that knowledge pertaining to the consequences of this accident that may benefit the patients involved, or mankind in general, and be of value in responding to future nuclear accidents is not lost.

#### **2. What types of material and information is available from the CTB?**

The bank includes material and information from patients with thyroid carcinomas and cellular adenomas from the contaminated oblasts of the Russian Federation and Ukraine who were born after 26<sup>th</sup> April 1967 (i.e. aged under 19 at the time of the Chernobyl accident) and operated on or after 1<sup>st</sup> October 1998. The tissue banks which comprise the CTB are held in the Institute of Endocrinology and Metabolism in Kiev, Ukraine and the Medical Radiological Research Centre in Obninsk, Russia. Detailed standard operating procedures for the collection, documentation and storage of specimens and blood samples have been agreed with professional staff involved in the collection of material. Ethical standards, conforming to the requirements of the country involved, including those of the funding organisations have been agreed with the relevant authorities.

Standard operating procedures for the collection of information and material have been approved by the relevant Institutional Review Boards. Each specimen is given a code authorised by the appropriate person responsible for the management of the bank in each of the three countries. The age, sex, date of birth, date of operation, oblast and country of residence is recorded for each specimen stored in the bank and made available to researchers with

approved projects receiving material from the bank, together with the review diagnosis agreed by the international panel of pathologists.

Frozen aliquots of DNA and RNA extracted from normal and neoplastic thyroid tissue and DNA extracted from blood, are available. A frozen section is taken from each portion of tissue before extraction to verify its nature. DNA and RNA are extracted to an internationally agreed protocol. Quality control is performed on nucleic acid extracted from all tissues and blood samples. In addition, sections from paraffin sections and from sections of tissue microarrays are available.

### **3. Who can obtain material and/or information from the CTB?**

Samples of extracted DNA and RNA from tissue, DNA from blood, samples of serum, paraffin embedded sections and tissue microarrays are available to the international scientific community. Researchers must apply to the CTB on the forms provided (available through the web site) for use of the resources. It is not the aim of the project to restrict supply of material to researchers, but to coordinate and monitor the use of this unique resource in order to ensure that the maximum possible information can be obtained from a limited supply of material.

### **4. How do researchers apply?**

Researchers who are interested in using material or information from the CTB for research must complete a brief, but detailed, proposal that includes information on the study design and requirements for materials or data.

Applicants whose projects are approved are encouraged to cooperate with the Institutes in Ukraine and Russia depending on which Institute's material is most suitable and is available. For major collaborative studies, a period of training for a member of the relevant Institute's staff may be recommended, and allowance in the application to funding bodies for financial support may need to take account of this and other costs.

No charge is made for samples of nucleic acid, but researchers must be prepared to pay appropriate expenses for shipment of specimens. Any request which may involve the relevant Eastern European Institute in work additional to the collection of samples for nucleic acid extraction and the minimal data set, will also attract an additional charge. Prospective applicants who are not yet in receipt of funding, or who are in the process of obtaining funds, are strongly encouraged to contact the CTB Secretariat to obtain information on resource availability. The CTB does not provide funding for research projects.

### **5. How are requests evaluated?**

Requests are evaluated for scientific merit and appropriate use of CTB resources by the External Review Panel (ERP), which is an independent, multi-disciplinary panel of senior researchers in the fields of thyroid cancer and radiobiological research. The External Review Panel awards scores for various aspects of an application, which are then averaged. Based on the score, an application will be assigned to one of three categories: (i) approve for access, (ii) the PI to be invited to respond to the ERP's comments, or (iii) reject. The Chairman of the SAB will be advised, for information, of applications scoring in categories (i) or (iii), but will review applications about which questions have been raised and/or for which the PI's response requires further consideration. The Chairman may seek views from other members of the SAB. The CTB Steering Committee will be the final arbiter in cases where the Chairman of the SAB is unable to reach a decision. Projects may be submitted at any time and the review procedures are, in most cases, completed by e-mail.

### **6. What are the criteria for evaluation and review of applications?**

Criteria have been established to ensure that valid, productive and equitable scientific use is made of the CTB resources for multidisciplinary and international studies on post Chernobyl thyroid cancer. Approval for a project may be subject to the development of appropriate collaborative links. Collaborative publications between Eastern European Institute personnel and researchers using material provided by that Institute are anticipated.

Researchers applying for CTB resources must provide evidence that the following criteria are satisfied:

1. The question being addressed is of considerable scientific and/or medical interest.
2. The study design is appropriate to address the question.
3. The sample size is sufficient to provide a good chance of answering the question.
4. The researcher and his/her research team have appropriate qualifications and experience to conduct the study.
5. The researchers are familiar with the relevant literature.
6. The proposed work cannot be undertaken without the data and/or materials of the type collected by the CTB.
7. The researchers have provided sufficient evidence to the External Review Panel that they can perform to accepted standards and quality control, the relevant laboratory analytical procedures.
8. If data other than the standard data set (date of birth, date of operation, sex, oblast of residence and international pathology panel review diagnosis) are required, the costs of obtaining this data and ethical and consent issues should be adequately addressed.
9. The researchers are able to obtain sufficient funds to pay for the shipping of Material. Cost estimates will be provided by the Secretariat, based on Steering Committee guidelines.

10. The researchers, or their collaborators, can perform and interpret properly the appropriate statistical methods required for the study.
11. The researchers identify suitably qualified and trained persons to perform the work, and agree that only these persons will have access to the data and material.
12. The amounts of material requested by the researchers are appropriate for the specified study, and are not excessive, given the limited availability of material.
13. The research can be undertaken within the time consistent with the researcher's funding and the availability of the necessary data and materials.
14. Any potentially clinically relevant data uncovered during the course of the study will be passed to the CTB Secretariat immediately who will pass the information on to the appropriate centre, through the channels agreed by the Steering Committee.
15. The researchers agree to provide within 3 months of the completion of their research project, a brief report on their work, including the results of their investigations on each sample studied, identified by the CTB sample code number. This information will be sent to the CTB Secretariat for use within the CTB. It will not be otherwise disseminated without the agreement of the Principal Investigator.
16. The researchers will inform the CTB Secretariat if any material has not been used in the performance of their designated study and will return this material, if requested, to the Secretariat for transmission to the appropriate Eastern European Institute.
17. The researchers agree not to use the material for any use other than that explicitly proposed in their approved project, or to pass any material supplied by the CTB to third parties without the explicit permission of the Scientific Advisory Board.

#### **7. How do I get an answer to any other queries?**

If you have any questions that are not covered in this fact sheet, please contact the CTB secretariat and we will do our best to help you:

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