The Establishment of Human Research Tissue Banking in the UK and Several Western European Countries

The Report and Recommendations of ECVAM Workshop 44¹,²


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¹ECVAM — The European Centre for the Validation of Alternative Methods. ²This document represents the agreed report of the participants as individual scientists.
This is the report of the forty-fourth of a series of workshops organised by the European Centre for the Validation of Alternative Methods (ECVAM). ECVAM’s main goal, as defined in 1993 by its Scientific Advisory Committee, is to promote the scientific and regulatory acceptance of alternative methods which are of importance to the biosciences and which reduce, refine or replace the use of laboratory animals. One of the first priorities set by ECVAM was the implementation of procedures that would enable it to become well-informed about the state-of-the-art of non-animal test development and validation, and the potential for the possible incorporation of alternative tests into regulatory procedures. It was decided that this would be best achieved by the organisation of ECVAM workshops on specific topics, at which small groups of invited experts would review the current status of in vitro tests and their potential uses, and make recommendations about the best ways forward (1). In addition, other topics relevant to the Three Rs concept of alternatives to animal experiments have been considered in several ECVAM workshops.

A workshop on the establishment of human research tissue banking in the UK and several western European countries was held at The Belfry, Birmingham, UK, on 8–10 September 2000, under the chairmanship of Robert Anderson (UK Human Tissue Bank [UK HTB]). There were 22 participants from six western European countries.

The principal aim of the workshop was to explore the feasibility of setting up a research tissue banking service in the UK and several western European countries was held at The Belfry, Birmingham, UK, on 8–10 September 2000, under the chairmanship of Robert Anderson (UK Human Tissue Bank [UK HTB]). There were 22 participants from six western European countries.

The problems and solutions involved in setting up a research tissue banking service in the UK are included in this report for information only: it is not intended that particular emphasis should be placed upon the situation existing in Great Britain. It is hoped that the views of all the participants concerned with the provision of research tissue banking services in their own countries are given balanced treatment in this respect. The establishment of a human research tissue banking service to academia and industry is a multi-faceted process. It is reasonable to assume that some aspects of the problems involved in creating a service of this kind will be different in each country in Europe.

The European Network of Research Tissue Banks

The participants attending the workshop agreed that an ad hoc ENRTB should be formed, consisting of a group of national networks of not-for-profit human RTBs established to collect, process, characterise, store and distribute non-transplantable and surgical-residue human organs and tissues, in order to facilitate academic and pharmaco-
toxicological research at ethically approved institutions in each member country. The members of the ENRTB will operate RTBs in their own countries to an agreed set of standards and guidelines for the optimal use of donated human material and its equitable distribution to accredited recipient institutions. The Network will be constituted to further the aims and objectives of human research tissue banking and to share agreed best-practice protocols. It will appoint a representative from each participating RTB to provide input to a nominated ad hoc steering group, charged with providing a framework for discussion, leading to agreement on common ethical and operational standards. The steering group will subsequently be superseded by a management board that will, inter alia, arrange to have published an annual report for distribution to members, public institutions, government departments and others.

The network will welcome RTBs from other countries prepared to meet the agreed standards set by the ENRTB. Individual RTBs will be able to consult members of other tissue banks taking part in the ENRTB with regard to the availability of specific categories of human cells and tissues. A common database cataloguing the availability of fresh or cryopreserved cells and tissues will be established after the publication of the ENRTB’s aims, objectives and ethical standards. It is hoped that the legal and ethical situation with regard to the movement of samples of human material will permit the international distribution of research material. To certify compatibility between research tissue banks in Europe, a standard coding system, perhaps based on that currently used by the UK HTB, will be established.

The network will facilitate communication concerning the importance of organ and tissue donation for transplantation programmes in each country, and the option of using human material found to be unsuitable for transplantation to facilitate biomedical research. RTBs must operate without detriment to existing programmes for organ and tissue donation for transplantation, but should seek collaboration with transplantation/tissue co-ordinators in order to facilitate the use of non-transplantable tissues from cadaveric donors for biomedical research.

The Appointment of an Ad Hoc Steering Group

The ENRTB will be able to provide a strong collective voice when approaching government departments on behalf of its membership. National departments of health throughout the member countries will be informed of the need for an operationally transparent, not-for-profit, research tissue-banking service for the benefit of academia and industry. Government departments in all member countries should be made aware of the need to avoid the risk of scandals of the type recently publicised in the UK press, concerning the removal of organs from deceased individuals without the consent of their next-of-kin.

The agreed high ethical and scientific standards supported by the ENRTB must be clearly and efficiently communicated to government departments. The existence of a research tissue-banking service of the kind advocated by members of the ENRTB will remove the risk of access to human organs and tissues by researchers who have not obtained ethical approval for their programmes of research.

A service of this kind will, by facilitating ethically approved biomedical research, be in the long-term interests of any national health programme. The membership of the ENRTB will work together to promote this service to academia and industry throughout Europe. All governments should be encouraged to regulate such services appropriately, and to work to achieve clarification and harmonisation of laws concerning the use of the non-transplantable and surgical-residue human tissue used to support a wide range of ethically approved programmes of medical and pharmacotoxicological research.

The participants in this workshop have taken the decision to set up an ad hoc steering group to take the first formal steps toward creating the ENRTB, including the appointment of a management board, which will consist of one representative from each RTB. Each bank will be encouraged to include a transplantation/tissue coordinator and a lay representative. The board will be charged with the responsibility for communicating the wishes of the membership to government health departments. It will also be responsible for seeking funding from the following organisations:
— the European Commission
— national governments
— scientific societies
— industrial associations
— journals (medical and scientific)
— media contacts

Funding obtained in this way will be used to support an annual conference on the progress made by members in their individual countries toward providing a comprehensive, safe and ethical research tissue-banking service to the benefit of their own biomedical research institutions.

Guidelines for the Steering Group of the ENRTB

Ethical standards

The network will seek the specialist advice of clinical tissue-banking associations that have already published guidelines on several relevant ethical and safety issues. Following consultation with members in the various countries represented, the network will produce ethical guidelines for member RTBs, with a view to developing “best practice” protocols covering the following areas:

— confidentiality and anonymity
— consent issues
— recording/tracking procedures
— not-for-profit status
— monitoring end-use of tissue
— auditing arrangements within the RTB
— safety issues

The network will strive to achieve a standardised approach to ethical and safety issues, and will ensure that member RTBs are confident that they are conforming to the best practice standards available.

The ENRTB will ensure that it is aware of any laws or changes in laws in member countries that could affect research tissue banking in general.

The Donation of Human Tissue to RTBs

Anonymity

It has been established in the UK, by various means, that the donor’s identity and right to privacy must be protected. Laws also exist in most European countries to protect the anonymity of organ and tissue donors (4). It is important that the RTBs make human tissue anonymous to researchers using the tissue, so that no direct contact can be established between researchers and donors or their families.

A unified European system needs to be established to ensure that appropriate information regarding details of the past medical and social history of the donor can be made available to researchers, to optimise the interpretation of any experimental results obtained.

Consent from donors for human tissue to be used for research

Evidence that the living donor or, in the case of a cadaveric donor, the donor’s family, has consented to the donation of organs/tissue for research must be provided to the RTB. This can be in the form of a pre-printed form outlining that consent has been given, which is sent with the tissue to the laboratory. Ethical committees in the UK and elsewhere in Europe insist that an approved form of wording is adhered to, and that information concerning the type of research undertaken with donated human material should be made available to the donor or the donor’s family. Literature will be provided by the ENRTB as guidance for all RTBs involved in the Network. Staff operating RTBs in each country will then be able to consider adapting this information to their own particular cultural situation.

A trained person must make contact with the donor or donor’s family to establish consent. This is best done through the existing network of transplantation/tissue coordinators or research nurses working in hospitals. The ENRTB could offer advice on establishing best-practice throughout the network.

Donors or donors’ families must be informed that tissue could be used by commercial companies that may take out patents or, albeit indirectly, gain commercially from the donation. The RTB involved will be a not-for-profit organisation and, as such, will only charge end-users the fees necessary to recover the costs of processing. It has been mentioned elsewhere in this report that coordinators counselling living patients or next-of-kin of cadaveric
donors should be provided with written information provided by the RTB, that can be communicated to donors or donor families.

The Use of Human Tissues for Research

Research undertaken by RTBs

The ENRTB should seek advice from organisations within each country in order to establish a data bank of existing guidelines concerning the safe handling and processing of human tissue. In time, the ENRTB will accumulate sufficient expertise, become an organisation of professionals with an interest in human research tissue banking, and act as a centre for advice on this type of service to academia and industry.

Quality issues

The ENRTB is charged with providing quality-control criteria to enable individual RTBs to:

1. ensure that materials of a high standard are produced by all the participating tissue banks;
2. ensure that reproducibility of results is achievable with respect to issues of viability and characterisation;
3. promote the validation of alternative methods of experimentation involving in vitro human-tissue models;
4. ensure that a uniform standard is achieved by all members of the network. A code of practice should also be published to promote harmonisation of practice within member RTBs; this will promote consistency as well as high levels of confidence among donors, donor families and bioscientists in academia and industry.

International availability of tissues and their distribution

The ENRTB could ensure that:

1. an inventory is made of all tissues requested;
2. standardised distribution techniques/methods are employed;
3. all available tissue from participating RTBs is catalogued and made available to potential recipient organisations; and
4. maximum use is made of human tissue donated through RTBs.

Audit and Review Procedures

Audit/Review

The auditing of all aspects of the receipt, storage, distribution and use of donated human tissue is extremely important as a means of ensuring operational transparency and honesty. Individual RTBs participating in the ENRTB must follow its guidelines and accept responsibility for auditing their own inventory of donated human tissue, and for monitoring the agreed research protocols of end-users.

Individual RTBs must also be open to audit by an independent mechanism. A review mechanism could be set up by the ENRTB to ensure that all participating member RTBs consistently meet the agreed standards. This should be undertaken regularly, to encourage confidence and promote transparency within the whole system.

Tracking and disposal of human tissue

The ENRTB should provide guidelines on the following points:

1. installation of an adequate framework for tracking tissue from donation to end-use in all participating RTBs;
2. establishment of high standards of practice for all participating RTBs for tracking human tissues; and
3. participation by all RTBs and research institutions receiving donations of human material in mutual tracing and appropriate human tissue disposal procedures.

Distribution of Information

The ENRTB should compile a directory of its members, to be made available to all interested parties in the public and private sectors, as well as to the media and government organisations. The temporary ad hoc steering group will take the initial responsibility for seeking funding to support an annual
meeting of the members of the network and for the publication of an annual report of the ENRTB.

A Web-site should be constructed, to provide information about the membership of the ENRTB and to promote its aims and objectives.

**End Users of Human Tissue Supplied by Members of the ENRTB**

RTBs participating in the ENRTB should agree a standard protocol for the accreditation of recipients of human tissue for research purposes.

Clear definitions will need to be agreed with respect to the following areas of research tissue banking:

1. what constitutes ethically acceptable and unacceptable research on donated human tissue;
2. types of human tissue that will and will not be supplied by RTBs operating within the network;
3. the agreed format of a legally binding tissue-transfer agreement for researchers who receive human material from an RTB within the ENRTB; and
4. minimum standards to be met by any end user of human tissue supplied by a member RTB of the ENRTB.

**The Consent Process**

The process of gaining consent for tissues to be used to facilitate biomedical research from brain-dead or asystolic cadaveric donors varies from country to country throughout Europe. In the UK, The Human Tissue Act 1961 (5) permits organs and tissues to be removed from the dead for therapeutic purposes or for research, either where the deceased has given expressed permission or where, even though there is no such expressed permission, there is no evidence following the pursuit of reasonable enquiries, that either the deceased or existing relatives would have objected to the procedure. In practice, of course, expressed consent is obtained from relatives in cases where the deceased made no such expressed request prior to their death.

The Human Organ Transplant Act 1989 (6) prohibits payments, or the offer thereof, in connection with the removal of organs or tissues intended for transplantation into another individual. In The Netherlands and Germany, the law permits non-transplantable organs and tissues to be used only for purposes of research related to transplantation. Both Finland and The Netherlands are currently enacting legislation to make donated human material available for research not related to transplantation.

Recent publicity in the UK regarding the removal at post mortem examinations of organs and tissues from children who had died following a surgical procedure, without the knowledge of their next-of-kin, has led to an outcry in the media against such practices. Some families came forward to explain that, had they been asked for their permission for the removal of organs and tissues from the deceased to be used for research, they would have given their consent. Therefore, the barrier to the ethical and acceptable donation of tissues for research was the absence of a request for consent from the donor's family.

It should be emphasised that the issue concerning the amount of information made available to donors and to the relatives of cadaveric donors is a matter of law, ethics and national policy. The bereaved relatives of a patient diagnosed as being brain-stem dead can have very little time to consider whether or not to consent to organ donation for transplantation or research. If consent is given, the patient must be removed from the intensive-care unit to an operating theatre within a very short time. Non-heart beating (asystolic) patients, who have died in hospital accident-and-emergency units, may also be considered as potential donors. The relatives of these patients also can have very little time to make a decision concerning the donation of kidneys for transplantation, and the donation of other non-transplantable organs (for example, the liver) to support biomedical research. However, it is now possible to transplant livers from some non-heart-beating cadaveric donors, when the physiological conditions are suitable. Competent living adult patients electing to undergo a therapeutic surgical operation can consider information from a surgeon or research nurse, and can read written material provided by the RTBs at least one week before undergoing surgery.
The choice of the health professional responsible for communicating this important information to the deceased patient’s next-of-kin or to the living patient is as important as the choice of the most appropriate time to make the approach. Organ and tissue coordinators are trained to work with the bereaved families of recently deceased patients who could become organ or tissue donors. These health professionals have the responsibility for deciding how information concerning the use of non-transplantable human material in biomedical research should be imparted to the donor families of brain-stem-dead organ or tissue donors. Therefore, it is suggested that the existing network of transplantation or tissue coordinators should be trained to approach the families of brain-stem-dead organ or tissue donors to raise the question of consent for non-transplantable tissue to be used for research purposes. It should be emphasised that the first concern of transplantation and tissue coordinators is to explore the question of organ donation for transplantation with the relatives of the deceased. The question of non-transplantable human material being used to support biomedical research must be a secondary consideration. Health professionals are well placed to make the approach, but require access to information from RTBs on the type of tissues needed by researchers and the intended uses of such tissues, in order to be able to give adequate information to families.

It must be made clear to all involved that donors and donors’ families are generally not perceived to have legal property rights in relation to removed organs and tissues. Donors and donors’ families should also be informed that organs and tissues may be used by commercial companies that exist to make profits and which may take out patents based on the information gained from the use of the donated tissues. Living donors, the families of cadaveric donors, transplantation professionals, or staff operating the RTBs can have no claim of any kind on intellectual property or profits resulting from any research activity conducted by commercial companies with donated human material. It should also be made clear to all concerned with the donation process that RTBs do not deal with tissues supplied for therapeutic use or for clinical research, where the donated tissue is to be incorporated into products or medical devices.

Tissue banks must provide adequate and up-to-date information to transplantation/tissue coordinators concerning tissues required by biomedical researchers, and the type of research programmes that may be undertaken with donated human tissue. A letter can be sent out by the coordinator, and this is often a further opportunity to provide more information to the family about the type of research undertaken on the tissues donated by their deceased relative. Prior to the donation, however, the family must be told about what organs or tissues from the body can be donated for research (without detriment to the transplantation-procurement programme), and for what broadly defined research projects they may be used. Donor families must be given the opportunity to refuse to donate certain organs or tissues, as well as to object to supporting certain types of biomedical research. They must also be given the opportunity of reversing their decision to donate at any stage of the process, although, in practice, it would be difficult to retrieve tissue donated for research once that research project had begun within an end-user institution. Consent for the donation of non-transplantable tissues must be documented in the patient’s medical records by means of a pre-printed consent form or other appropriate form of words agreed by government-appointed research-ethics committees or the existing law of the country, as appropriate. In the UK, the donor’s next-of-kin signs the patient’s medical notes to give consent to the donation of organs and tissues for transplantation and research. In the system that has been established by the UK HTB, a copy of an anonymised form of consent accompanies tissues for research to the UK HTB laboratory. This has been achieved through the use of a donor information form, giving a limited anonymised medical and drug treatment history of the donor. The transplantation/tissue co-ordinator signs the form to state that the family has consented to this type of donation. The protocols described above have gained government-appointed research-ethics committee approval in the UK. They are offered in this report as an example only. Tissue banks in other countries, working within different legal and ethical systems, will undoubtedly have different procedures for obtaining consent.
In the UK, a similar system is used to gain the consent of the living patient, who is approached to consider the donation of any tissue necessarily removed during a therapeutic surgical procedure and which is surplus to diagnostic requirements. In this case, research nurses or similar hospital-employed health professionals should be trained to request consent from patients in this category. When the competent adult patient consents to undergoing a therapeutic surgical procedure, consent for the operation is kept separate from any signed consent permitting excess tissue to be used for research purposes. Information documents should include a full explanation of how donated human tissue is to be used to support programmes of biomedical research. The patient should read the information brochure in advance of being asked to make a decision concerning donation. For such patients, time is not a crucial factor; preparation for surgery usually takes place over a matter of weeks or days, allowing patients sufficient time for careful consideration before coming to a decision concerning the donation of tissue surplus to diagnostic requirements for use for biomedical research purposes. This information would be accompanied by the name of an appropriate health-care professional who could be contacted to answer questions and explain any matter in more detail. Patients must be assured that refusing donation for research is totally acceptable, and that any future treatment that they may need will not be influenced in any way, whatever they decide. Once again, while this system has been found to be acceptable to all concerned in the UK, each country must develop its own ethically acceptable method for obtaining the genuine consent of patients to support biomedical research through the donation of surplus surgical tissue. The UK HTB uses a donor-information form similar to that used for cadaveric donors. This form has been developed to ensure that the RTB is given relevant anonymised details of the patient's medical history, and that the operating surgeon has signed to confirm that consent has been given by the patient. Confidentiality is an important issue when recording the consent of the donor or donor's family. All information stored in manual or computerised systems should be fully anonymised in compliance with European and national standards.

The Donation Process

The procurement of organs and tissues for research must be undertaken by trained professionals. In the case of cadaveric donors, transplantation surgeons or pathologists should retrieve the organs. In the case of living patients, the tissue removed at surgery by the surgeon should first be inspected by a pathologist, who should excise any tissue required for diagnostic purposes. Any remaining tissue can then be collected, without delay, by RTB personnel. Appropriate courier systems to transport the material to the laboratory should be set up by the tissue-bank staff, and should involve a dedicated nationwide service. Transport boxes, sterile plastic bags and fluids should also be supplied by RTBs, so that the resources of the hospital or transplantation team do not have to be used. RTBs operating on a cost-recovery-only basis are the most reliable method for collecting tissue for research and for distributing it to accredited biomedical researchers. This buffer between the hospital and commercial research companies is essential to ensure that controlled ethical practices are followed without the influence of commercial vested interests (6). Tissue banks have a duty to record any donation, to track its distribution, and to monitor the end user with regard to such issues as respectful disposal in a recommended manner.

Tissue banks must ensure that all the documented information about the donation is kept secure within the RTB's premises. The RTB must also be able to demonstrate that it can track the movement of human tissue, and must take all reasonable measures to advise recipients concerning the recommended methods of disposal of any tissue left over after the experimental process has been completed. Tissue banks must also send information regarding the use of human tissue to a member of the team involved in the procurement process. Surgeons as well as transplantation and tissue coordinators who are willing to support the concept of non-transplantable human material being used in biomedical research have a right to be kept informed, in general terms, of the types of research undertaken with donated organs and tissues. Once again, this UK HTB policy has been found to encourage hospital health professionals to support the donation of human material for research programmes.
Steps can be taken to ensure that details of the end-user of the human tissue are anonymised and that the anonymity principle is not violated in any way. It is hoped that other countries in Europe will find that some of the protocols and operational procedures detailed in this report, which have been found to work in the UK, will be suitable for use within their own RTBs.

Tissue banks can also teach those involved in the process of procurement about the importance to medical and pharmacological research of the use of human tissue. End users must also contribute, by ensuring that up-to-date information is made available to the staff of the RTB in order to help with this process.

Responsible reporting in the media can help to inform the general public of the need for human tissues for ethically approved research. It is important to use every opportunity to emphasise to all concerned (especially the recipients of donated human material) that organs and tissues will be used (if appropriate) for transplantation purposes firstly, and for biomedical research secondly. Information about RTBs should be publicised in medical, nursing and scientific journals. The ENRTB could usefully establish a relationship with authors writing for journals such as Toxicology in Vitro and Cell and Tissue Banking. Annual reports and information concerning the work of the ENRTB should be made available to the readers of those and other journals. Existing national mechanisms of donor recording in each country, especially national organ donor registries, could also be used. The wording on existing donor cards could be altered (provided that approval can first be obtained from the relevant government department), to include the question of donation of tissues for research. This request could also be entered on national computerised registers, to help to ensure that a donor’s wishes are fulfilled.

Government-approved non-profit human RTBs can offer a regulated and transparent service to academic and industrial research institutions. A research tissue banking service of this kind should, in future, minimise the risk that biomedical researchers will attempt to seek unregulated sources of human tissue. This type of service can also ensure that ethically approved programmes of biomedical research are no longer compromised by lack of access to a reliable supply of human material. In the UK, the Government has established a network of multicentre research ethics committees (MRECs) and local research ethics committees (LRECs). The UK HTB has gained the approval of an MREC and several LRECs. In addition, all the biomedical institutions receiving donated human tissue from the UK HTB are expected to demonstrate that they have received LREC approval for their work. Each country will, of course, have its own framework for dealing with the ethics of organ and tissue donation for research.

Relationships with Other Tissue Banks and Transplantation Centres

A human RTB must establish contact with the existing network of national organ transplantation and tissue coordinators. National transplantation and tissue coordinators’ associations should be contacted by medical and scientific personnel wishing to establish a tissue-banking service, in order to seek available information concerning public attitudes to the use of donated human tissue for research purposes. Human RTBs must ensure that they operate without risk of detriment to existing organ/tissue donation programmes. Human RTBs operating in different countries can benefit from clearly established ethical and operational guidelines agreed by all participants, and arrived at through consultation with experts in legal, ethical, biological, safety and other scientific fields. Nationally and internationally acceptable guidelines on every aspect of the human research tissue-banking service to academia and industry, should be made available to all the public, scientific and medical/nursing communities through the media and through the creation of a Web-site giving information about the aims and objectives of ENRTBs.

Conclusions and Recommendations

1. A regulated human research tissue bank (RTB) service, created to facilitate ethically approved biomedical research, is in the long-term interests of a national health service programme, and should remove the risk of bioscientific institutions seeking unrecorded and/or unethical supplies of human organs and tissues.
2. Human RTBs established to facilitate programmes of ethically approved biomedical research must operate without risk of detriment to national organ donation for transplantation schemes.

3. An international network of human RTBs would be able to provide a stronger collective voice when approaching national government health departments or international agencies on behalf of the members of the network.

4. An ad hoc European Network of Research Tissue Banks (ENRTBs) should be formed, to develop and implement an agreed set of standards and guidelines for the optimal use of human material donated to facilitate programmes of ethically approved biomedical research.

5. The ENRTB should encourage and facilitate communication concerning the importance of the availability of non-transplantable organs and tissues to programmes of basic medical and pharmaco-toxicological research.

6. Initially, a representative from each founder member RTB of the ENRTB should be appointed to take part in an ad hoc steering group, which should be responsible for providing a framework for discussion leading to agreement on common ethical and operational standards.

7. Subsequently, when an ENRTB management board had been appointed, this board would take over the work of the steering group. Each RTB should nominate a representative to the membership of the ENRTB management board. In addition, each RTB should be encouraged to nominate an organ transplant/tissue coordinator and a lay representative to this board.

8. The ENRTB should welcome additional RTBs from other countries, provided that they were prepared to meet the administrative and operational procedures agreed and set by the ENRTB.

9. The ENRTB should seek to develop “best practice” protocols concerning the following issues relevant to a human research tissue banking service:

10. The ENRTB should seek specialist advice from clinical tissue banking associations that already have published standards and guidelines on safety and other issues relevant to research tissue banking.

11. National governments and appropriate international agencies should be encouraged by the ENRTB to officially recognise and regulate a non-profit research tissue-banking service to academia and industry.

12. After the aims, objectives and procedures of the ENRTB have been established, this information should be made available on an ENRTB Web-site.

13. The ENRTB management board should obtain funding to be used to support an annual conference on the progress of research tissue banking in ENRTB member countries.

References