

*Meeting report*

## **Fourth meeting of the European Network of Research Tissue Banks – Future strategy to increase collaborations in the supply of human tissue for biomedical research**

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### **Abstract**

This report records the Fourth meeting of the European Network of Research Tissue Bank (Brussels, 18th March 2004) which was attended by Mel Read MEP. The existing membership of this informal group represents European Human Research Tissue Bankers, biomedical researchers seeking access to human tissue and allied groups including animal welfare representatives. This Fourth meeting provided a forum to update members on individual activity in this area. A particular focus of this meeting was to consider the status of this group and future affiliations to increase the profile and activity of this Network. This meeting addressed differences in legislative and ethical requirements governing the use of human tissue in biomedical research in the different countries represented. Future activity of the ENRTB, planned at this meeting, will target harmonisation of current differences which are currently barriers to increased access to human tissue for biomedical research. Through the harmonisation of procurement, processing and distribution of human

tissue specimens the ENRTB will provide a mechanism to benefit human health through increased use of human tissue in pharmacotoxicological studies and the associated replacement of animal tests.

*Abbreviations:* DoH – Department of Health; ENRTB – European Network of Research Tissue Banks; HTCR – Human Tissue and Cell Research charity; NTRAC – National Translational Research Against Cancer; PTB – Peterborough Tissue Bank; RTBs – Research Tissue Banks; UKHTB – UK Human Tissue Bank

## Introduction

The European Network of Research Tissue Banks (ENRTB) is an informal group of like-minded individuals. It has met on three previous occasions across Europe and has published workshop reports from these meetings (Anderson et al. 1998, 2001; Orr et al. 2002). Its membership represents European human research tissue banks (RTBs) and end users of human tissue donations including representatives from the Pharmaceutical Industry. The group also includes representation from allied special interest groups including organisations seeking to reduce the use of animals in medical research. At present the group has no formal status and seeks to encourage the sharing of expertise and experiences in research tissue banking with a view to harmonising the procurement, processing and supply of human tissue for biomedical research.

The fourth meeting was held on 18th March 2004 at The Centre, 22 Avenue Marnix, B1000, Brussels and was supported by Mel Read MEP. The meeting provided a forum to review progress to date achieved through previous workshop meeting. The meeting provided an opportunity to discuss strategies to develop the group with a view to increased European collaborative ventures and opportunities to formalise the network and opportunities to extend the current network membership. The meeting included an extended invitation to interested members given the need to develop pan European strategies and harmonised ethical guidance and legislation to deal with collaborative European human tissue collection and supply for research purposes. For this reason Brussels, as the home of the European Parliament, was chosen as an appropriate venue. Mel Read was the only MEP represented at the meeting.

This one-day meeting included presentation and discussion from each member attending. This report seeks to summarise the activity of the day and

associated discussion and conclusions with strategies for future activity of ENRTB.

## Summary of presentations of ENRTB membership

*Tambet Teesalu and Retlav Roosipuu – Estonian Research Tissue Bank*

During the last 2 years the Estonian Research Tissue Bank has begun distribution of human tissue for research. The Tartu University project to establish this research tissue bank began in early 2000. The project was funded through a collaboration between the Finnish Academy and Tartu University. Tambet described how the bank provides an independent intermediary unit of the University Department of Pathology. The operation has been reviewed and approved by the University ethics committee. The supply and distribution of human tissue samples has grown year on year. In 2002, 105 samples were procured and distributed; this increased to 240 samples in 2003 and is set to reach 500 samples in 2004. Procurement occurs on a project basis and is undertaken on a cost recovery, not for profit basis. To date the bank only supplies human tissue samples for research to research and development institutions listed by the Estonian Ministry of Education and Science. Listed institutions include academic and non-academic units. The bank has recently appointed an ethics advisor. Currently researchers are requested to provide details of their proposed research project including a list of tissue required. Once sample availability has been confirmed researchers must additionally obtain the approval of Tartu University Ethics committee. Currently the bank places no demands on researchers to provide formalised feedback on the use and suitability of samples.

As the bank is part of the University Pathology department human tissue samples are subject to standardised processing including fixation and paraffin embedding. The bank has additionally developed a number of specialist techniques. The samples provided by the bank are predominantly normal samples but include tumour specimens from breast and colon. Future strategy will include efforts to increase the volume of samples procured, processed and supplied for research and to extend supply beyond researchers based in Estonia. This will in part be facilitated by the new ethical advisor.

*Chris Womack – Peterborough Tissue Acquisition Unit*

The tissue bank at Peterborough District Hospital (PTB) was established in 1996 to collect and provide surgical residue and post mortem tissue for research purposes (Gray et al. 1999; Womack et al. 2000). The tissue bank has relied upon a predominantly commercial client base to fund activity through the payment of cost recovery fees associated with the collection of human tissue specimens. The hospital also set up a parallel service (Peterborough Cellular Pathology Services – PCPS) to provide cellular pathology expertise including tissue processing, to generate income that was fed back into the host pathology department. Development and expansion of PCPS within the hospital was limited by lack of funding and could never be seen as a priority in a publicly funded health care system. In order to support the vision of the staff for the future, the hospital management board agreed to transfer PCPS to a private company and after a selection process chose Medical Solutions plc as the preferred provider. The main strength of Medical Solutions plc is its network of more than 80 specialist histopathologists. These doctors are in a shortage speciality but with valuable skills for the pharmaceutical and biotechnology industries. The former tissue bank manager Neil Gray (a member of the ENRTB) moved to Medical Solutions plc. This arrangement between Medical Solutions plc and Peterborough includes a licensing arrangement and profit share for the hospital.

Tissue acquisition remains cost recovery under the control of a public service (National Health Service) with the associated beneficial controls

including clinical and research governance. The restructured Tissue Acquisition Unit (from Jan 2001) under a new manager provides an opportunity to extend the role of the nurse and biomedical scientist with the output of improved strategies to gain patient consent for donation for research. The Unit is a supplier of unprocessed tissue rather than a primary researcher but does have an interest in patient and family attitudes to research donation Jack et al. 2003, Womack et al. 2003a, b).

*Neil Gray – Medical Solutions*

Neil is a cofounder of PTB. As part of the partnership between Medical Solutions and PTB, Neil transferred his employment to Medical Solutions in December 2002. As a cofounder of PTB Neil highlighted that his motivation to make this move stemmed from frustration of the wasted opportunity. He described an apparent mismatch of human tissue retrieval in UK National Health Service (NHS) hospitals, generated surplus to diagnostic requirements as a consequence of routine surgical procedures, and the apparent lack of such tissues to facilitate biomedical research. A key issue for resolution which Medical Solutions seeks to address is the lack of standardisation in sample collection and storage across UK hospitals. These differences translate into differences observed by researchers when evaluating human tissue samples. It is likely that some of the differences observed by end users of human tissue samples have more to do with the nature of sample collection as opposed to the 'human factor'. Medical solutions seeks to address methodology to ensure standardised collection practices. Such work is also motivated by evidence that to date many samples procured for human tissue research are unsuitable for the highly sensitive research methods available. The increased move towards personalised medicine where individuals will be selected for the most appropriate treatment regimen on the basis of their genotypic and phenotypic profile as much as from the presenting condition makes the need to standardise human tissue collection ever more apparent.

Medical solutions are keen to participate in collaborative ventures including the UK initiated National Translational Research Against Cancer

(NTRAC). This initiative will include the collection of human specimens into a central repository with improved access to all researchers irrespective of the affiliations or the nature of their employing institution. Such efforts it is hoped will enable a more equitable access to human tissue samples. Current disease priorities which Medical Solutions are choosing to focus their collection efforts on include cancer, diseases of the central nervous system and immune, metabolic and degenerative disorders. Medical Solutions have created a customised database and tissue inventory management system to record and audit tissue collection. This data is available to researchers through the Medical Solutions website and enables identification of available specimens for subsequent despatch. This standardised approach will improve human tissue research by access to an increasingly uniformly procured and processed product.

*Carina Syring – German Institute for Cell and Tissue Research (DIZG)*

Carina attended her first meeting of the ENRTB. The German institute was previously represented by its director Rudiger Von Versen. The DIZG primary focus is the provision of clinical samples however since the last ENRTB meeting this group is increasingly required to supply human tissue for research. Donating hospitals are approved by the German FDA. Samples for research are prepared in a dedicated research facility. Preparation of research samples utilises the same processing methods as for clinical use samples but without a final sterilisation phase as this is rarely required for current research projects. The institute sought guidance with a view to approval from their local ethical committee. At this stage this ethical committee felt that approval of research activity was beyond the remit of the committee. Researchers seeking samples from DIZG, irrespective of the nature of their employing institution must complete a research application. This application is subsequently reviewed by the Centres internal committee before supply can be made.

All human tissue samples, although procured primarily for clinical use can be provided for research where the informed consent of the donor has been obtained. The majority of samples pro-

cured are musculoskeletal in nature and include joint tissue. DIZG is increasingly asked to provide other types of human tissue including primary cells. This is the focus of much in house work and include efforts to isolate such cell lines from normal tissue. Samples are provided on a cost recovery, not for profit basis.

*Comment from Mel Read MEP*

Mel Read was invited to the ENRTB workshop meeting by the UKHTB which is based in Mel's home town of Leicester, United Kingdom. Previous dialogue had highlighted the issues associated with European collaborative human tissue banking for research. Mel had responded through suggested strategies and resolutions to existing differences ethically and legally across the European member states and the members of the European Network.

Mel has been a member of the European parliament for 15 years and will complete her service in May 2004. During this time Mel has had a primary responsibility for issues associated with health prevention and has an interest in association between poverty and disease. In her retirement Mel plans to continue these interests through a Network focussed on Women's Health. Mel highlighted her involvement with the Framework 6 funding initiative and indicated that the network of nominated representatives should be proactive in offering guidance including an offer of expertise to the commission. Such efforts may guide future funding opportunities in efforts to secure pan European strategies and guidance for Europe-wide research tissue banking. Mel was keen to highlight the limited budget available from such initiatives and reminded the group that for this reason only 10% of applications are funded. Mel encouraged us to invite European commission representation at future ENRTB meetings and subsequently highlighted Eduardo Fernandez-Zinckea as a suitable future contact.

*Wolfgang E. Thasler and Thomas S. Weiss – University of Regensburg Hospital, Germany*

Continued efforts since our last ENRTB meeting at Regensburg and Munich University have resulted in the establishment of a Human Tissue

and Cell Research charity (HTCR) Thasler et al. 2002). This is a not for profit project for cell and tissue banking. The HTCR has established regulations to ensure transparency from procurement through to end user research. Informed consent is obtained by a hospital clinician. The clinician is reimbursed by the HTCR for the time taken to consent patients irrespective of whether the patient consent to the use of samples in research. The clinician involved in obtaining informed consent is not involved in the research and all samples are supplied to HTCR in an anonymised format (Thasler et al. 2003). Donated human specimens are checked by a pathologist and then processed to isolate for examples RNA, primary cells as appropriate and distributed according to the charity protocol. The allocation of samples is governed by the Ethical and scientific advisory board of the HTCR (Thasler 2002, 2003).

*Lysiane Richert, Eliane Alexandre – University of Besancon and Fondation Transplantation, Strasbourg, France*

Lysiane updated the network on efforts in Strasbourg and Besancon to provide human hepatocytes for research. The liver tissue is predominantly donated from patients undergoing a liver resection. Patients consent to the use of tissue in this way and donation is subject to the samples being supplied without making profit. Samples are utilised by the research groups based in Besancon and Strasbourg and also facilitate research in Pharmaceutical Industry collaborative partners.

Since the last network meeting, a change in legislation has extended the use of non-transplantable cadaveric liver tissue to pharmacotoxicological research where the donor or their family has consented to the use in this way. Previously where such a donation was found to be unsuitable or where a recipient was unavailable it was only possible to utilise in transplant allied focus. Lysiane described import and export law (673–22 Code de la Sante Publique) which governs the transport of tissue and isolated products to and from the different member states. In order to facilitate such transfer an application must be made to the Ministry of Research in France.

*Timo Ylikomi – University of Tampere*

Timo described the activity of a network of cell and tissue engineers based in Tampere. Seventy researchers are currently using cell-based models instead of animals. These advanced cell models increasingly require access to human tissue. The analysis of these systems is time consuming and efforts focus on improved automation including increased use of micromanipulation. This technology enables manipulation of individual cells according to cell type. Current efforts seek to establish a collaborative centre for regenerative medicine with dedicated clean room facilities.

*Ann-Cathrine Jonnson-Rylander – Astra Zeneca Sweden.*

Astra Zeneca includes multiple sites across the world including those based across Europe including Sweden and the UK. Astra Zeneca are anticipating an impact of the new tissue legislation and seeking to harmonise and standardise human tissue research globally to the highest ethical standard. The demand for human tissue to facilitate research within Astra Zeneca is ever increasing. New Swedish Biobank law relates to tissue specimens which have been taken from human beings, which are collected and preserved for an indefinite or a definite period for a certain specified purpose and whose origin is traceable. Biobanks can only be established in medical institutions but can be made available by the care provider for other research projects conducted in public research institution, on the premises of a pharmaceutical company. Establishment and use of a Biobank requires research ethics committee approval. Anonymised samples are not covered by the Biobank law.

### **The users of human tissue**

*Brian Clarke – Pharmagene, Royston, United Kingdom*

Pharmagene is a small UK based Pharmaceutical company which requires human tissue to facilitate all internal research projects. Since our last ENRTB meeting Pharmagene has continued ef-

forts to maintain and expand tissue supply relationships in the UK and abroad. Internal research projects of interest to Pharmagene at present include disease areas of migraine, cystic fibrosis, irritable bowel syndrome (IBS) and heart failure. Pharmagene continues to validate the human tissue model in favour of animal models.

Brian used the meeting as an opportunity to share some of the outcomes of internal research projects. Brian acknowledged as a worker in the pharmaceutical industry that there was still a need to increase the sharing of information of the value of human tissue in research which was often restricted due to concerns over intellectual property.

Internal work on migraine relief at Pharmagene has utilised the known high levels of PGE2 detected in venous blood plasma and saliva of sufferers. The causative role of this has been confirmed by the exogenous administration being associated with migraine like symptoms. Internal research is focused on antagonism of the vasodilatation of the meningeal artery using human tissue models.

Strategies against cystic fibrosis have targeted the secretin receptor following Target evaluator<sup>®</sup> gene expression which revealed high levels of secretin receptor expression in the tertiary bronchus. Work has been undertaken using human bronchial mucosa and passage of cells. This agent is now in Phase II clinical trials. Strategies against IBS have focussed on 5HT2B receptor as the target for therapy. High levels are present in the GI tract. Although 5HT is well studied other groups research efforts predominantly focus on the 3 and 4 receptor isoforms on the basis of animal work. These isoforms do not seem to be so important clinically and hope to reveal a therapeutic advantage for Pharmagene's targeted agent. Pharmagene has studied the R93 protein an adipokine found on the surface of fat cells. This may have causative role in obesity and heart failure and offer a target for therapeutic agents.

*Jan Van Der Valk – Dutch Research Tissue Banking*

Jan Van Der Valk, Rivka Ravid, Johan Hauman and Genny Groothuis formed a coordinating

group to undertake a feasibility study to explore the establishment of a Dutch Human Research Tissue Bank. This group unfortunately had to conclude that the time is not right to establish such a bank. Johan Hauman undertook this study on behalf of the group and focussed on consideration of surgical residue tissue and non-transplantable post mortem tissues. During his efforts he visited members of the ENRTB. Johan investigated the opinion and current interests of relevant groups including the Dutch Federation of Pathology, surgeons, potential donors and transplant representatives including Eurotransplant and the Dutch Foundation for Transplantation. Transplant coordinators were clear in their recommendation that if established such a bank must have official status. As for now, non-transplantable donor tissue can only be used in transplant-related research. The study revealed support for a bank collecting post mortem tissue but the coordinating group were uncertain of the value of such tissue. Currently the Netherlands Brain bank, run by Rivka Ravid based in Amsterdam successfully procures, processes and supplies human brain tissue for research.

The coordinating group were disappointed with the outcome of the feasibility study and are considering ways to revisit this opportunity in the future. A key area for consideration is to address concerns of the Dutch population of potential exploitation of human tissue. The group requires the full support of the Dutch Federation of Pathologists in future feasibility studies.

Jan reminded the group of the Netherlands Code for proper secondary use of human tissue. This is available to download in English from [www.fmwv.nl](http://www.fmwv.nl). The code although well written and offering good guidance is yet to be fully disseminated. New legislation of this subject is still awaited.

Jan also described the European Human Frozen Tumour tissue bank [www.tubafrost.org](http://www.tubafrost.org) which is a useful resource for all researchers seeking access to tumour tissue.

*Samantha Orr, Jacki Trafford, UK Human Tissue Bank (UKHTB), Leicester, United Kingdom.*

The UKHTB continues as a project of De Montfort University in Leicester and supplies an ever

increasing researcher base. UKHTB have recently updated their ethical approval to extend their current supply beyond the UK. Currently the team considering the logistical issues associated with supply including import and export issues.

Legislation governing the use of human tissue for research is awaited following recent UK organ retention scandals (UK DoH 2001). The Human Tissue Bill requires careful revision in view of potential adverse effects the legislation created for UK researchers ([www.gov.uk/tissue](http://www.gov.uk/tissue)). The Bill proposed an enormous increased burden on the NHS when obtaining informed consent for each and every human tissue sample removed including blood and urine from living and dead patients and for whatever purpose (including research). There has been significant pressure on the UK Government to address the concerns of the biomedical research community. The proposed new legislation seeks to provide a Human Tissue Authority who will be tasked to regulate and licence the retention of all human tissue. The Bill requires individuals and not the employing organisation to gain a licence for the collection of human tissue for all purposes including research. The UKHTB are currently addressing the impact of this and EU legislation including the Tissue and Cells Directive though this specifically excludes research.

## **Discussion of members of the Network**

### *Views of the group on commercialisation*

Members of the network shared concerns over the negative association with commercial groups. Researchers working with human tissue and seeking access to the donations received by the ENRTB are based in academic institutions, medical institutions and commercial organisations including the pharmaceutical and biotechnology industry.

Members of the Network are confronted with conflicts over definitions of not-for profit organisations and highlighted that concerns over profit were not just relevant to monetary gain. It was felt that profit could also be seen to apply to non-commercial organisations where for example an academic would gain through opportunities to increase the profile or number of research publi-

cations. This indirectly can introduce a financial gain through the researcher being more attractive to funding bodies. Members highlighted the research and development risk that the pharmaceutical industry must make to secure improved future therapeutic strategies. Members discussed that although the ultimate goal of the Pharmaceutical Industry is to make a profit this is as a consequence of the research effort and not the human tissue donation.

### *Future affiliation*

Chris Womack had been asked to propose to the ENRTB membership a future alliance with the European Association of Tissue Banks (EATB). Although the EATB is currently focussed predominantly with clinical tissue banking the ENRTB represents a special interest group and can offer guidance to existing members of the EATB on mechanisms for research tissue banking in addition to guidance on research initiatives with human tissue. Other affiliation worthy of consideration may include a link with the European Tumour Bank. The membership voted to seek further information about such affiliations.

### *Future funding opportunities and collaborative ventures*

The network agreed to offer expert members to advise members of the European Parliament. It was acknowledged that efforts should seek to highlight the network as an area worthy of bids for future funding. Future activities must include efforts to seek funding to establish the ENRTB in a formalised manner with a view to offering guidance on future pan European legislation.

Our current Estonian membership and the imminent EU member state incorporation is positive. The ENRTB seeks further EU representation. Positive association with MEPs must include representation to the EU on the Tissue and Cells Directive. Members were encouraged to support the European Society of Toxicology *In Vitro* (ESTIV) initiative to seek current requirements for human tissue. This survey may well be facilitated through ENRTB members. The results of the

survey it is hoped will be made available at the annual INVITOX meeting in Poland September 2004.

### *Legal and ethical review*

It was agreed to approach the ethical adviser to the Estonian Research Tissue Bank about the feasibility of conducting or coordinating a review of current European Member State law and ethics in relation to collecting and storing human tissue for research purposes.

### **Acknowledgements**

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