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[www.ncri.org.uk/ccb](http://www.ncri.org.uk/ccb)

## Note from the Editor

*Caroline Magee, Communications Lead, onCore UK*

Welcome to the second issue of CCB Update – the newsletter from the National Cancer Research Institute's Confederation of Cancer Biobanks (CCB).

We're pleased to bring you this issue earlier than planned as there's been so much happening we didn't want to wait until the Autumn. A number of key events are reported on and the launch of a new biosample directory is highlighted as well as information on CCB's planned initiative to benchmark biobanks.

Four biobanks have become CCB members in the last couple of months and we are pleased to be able to feature three of them in this issue. Biobanks at the ECMC network centres have also been invited to join and we look forward to featuring more new members in our Autumn issue. I hope you find the articles interesting and I welcome your feedback and suggestions for future articles.

For more information on CCB visit [www.ncri.org.uk/ccb](http://www.ncri.org.uk/ccb)

## Biobanking in Support of Clinical Trials: CCB Workshop Report



Over two hundred delegates gathered at the King's Fund's central London conference venue in March 2010 for the latest in the CCB's workshop series. The topic for this one day workshop, organised by the Confederation's secretariat in collaboration with Wales Cancer Bank

and the Experimental Cancer Medicine Centre (ECMC) Network, was Biobanking in Support of Clinical Trials. This is not a small subject and the programme was a packed series of presentations from experts in the field interspersed with wide ranging discussions.

Representatives of CCB member banks were joined by delegates from academia, industry, funders and regulators, as well as members of the public. Beyond the informative presentations and debate, there were excellent opportunities for networking and catching up with old colleagues as well as viewing the trade exhibition of companies providing technical support to the biobank and clinical trials communities.

The day began with a discussion of the importance of biosamples to clinical trialists, from both an academic and industry perspective. From this basis the presentations moved on to discuss the

practicalities of biobanking in support of clinical trials - in particular the crucial importance of quality management systems. After lunch, the focus shifted to the ethics and governance of biobanking in support of trials and the role that patients and the public can play in supporting and advising biobankers and trialists. This provided the foundation for a discussion of access, custodianship and ownership issues, from both an academic and an industrial perspective. Finally, the audience heard two examples of the integration of biobanking with multicentre clinical trials, closing the day with a very practical demonstration of what is possible.

The key message from the day was that the availability of large numbers of well-defined and curated biosamples will be critical to the development of stratified medicine. Meeting this need requires patient involvement from the outset, the collection of samples pre- and post-treatment where possible and collaboration between banks through transparent and fair access policies to provide a 'critical mass' of samples. Above all is the need for quality assurance, without which the samples so generously given by donors will be wasted.

The speaker's presentations and videos of the question and answer sessions are available through the CCB website ([www.ncri.org.uk/ccb](http://www.ncri.org.uk/ccb)). A report of the day is also being prepared and will be published by the CCB this summer.



## New Members

CCB is pleased to welcome four new members to the Confederation. These are:

- University of Birmingham Human Biomaterials Resource Centre
- Manchester Biomedical Research Centre Biobank
- Leeds University Research Tissue Bank
- King's College London Haemato-Oncology Tissue Bank

Here is more information about three of them (Leeds will be featured in a later issue):

### University of Birmingham Human Biomaterials Resource Centre

The University of Birmingham has recently established the Human Biomaterials Resource Centre (HBRC) - the first of its kind in the West Midlands. The HBRC is temporarily housed within the College of Medical and Dental Sciences, but the University has secured funding through the Advantage West Midlands Science City Translational Medicine Programme for a new facility which will be functional by Spring 2011.



The HBRC is dedicated to the collection and storage of appropriately consented, quality assured biomaterials in a variety of disease settings for distribution to biomedical research groups both in academia and industry. Although still in its infancy, the HBRC can offer access to existing sample collections, and also bespoke tissue collection and processing for specific research projects.

The Director of the HBRC, Dr Jane Steele, is working with NHS Trusts to develop the processes for collecting samples with minimal disruption to clinical pathways, and has just received ethical approval for the bank. Jane told CCB Update "With the rise in numbers of tissue banks being established in the UK it is vital that there is interaction and knowledge sharing; we are delighted to be accepted into the CCB and to be involved."

For more information on HBRC contact [j.c.steele@bham.ac.uk](mailto:j.c.steele@bham.ac.uk)

### King's College London Haemato-Oncology Tissue Bank

The King's College London Haemato-Oncology Tissue Bank was established in 2005 with funding from Leukaemia & Lymphoma Research (formerly Leukaemia Research Fund). It is based on the Denmark Hill Campus adjacent to King's College Hospital.

Their aim is to serve as a national bioresource for research into the aetiology, diagnosis and prognosis of blood cancers and to pursue this in compliance with all laws, regulations and industry standards applicable to our sector. They have received over 7,000 samples to date (May 2010), mostly from King's College Hospital, but their ethics approval is valid throughout the UK and they are actively seeking new contributors.

They have facilitated more than fifty research projects, including

studies of sub-cytogenetic allelic imbalance and novel TET2 mutations in myelodysplastic syndromes, as well as work implicating T-regulatory cells in the pathogenesis of bone marrow failure. Most of the tissue has serviced genomics-based research to date, but a new Cryostore has just been built which vastly increases the capacity to conserve viable cells: this was much needed by their users who conduct functional cellular biology.



Dr Nigel Westwood, Manager of the Tissue Bank told CCB Update that he decided to join the CCB after attending the CCB's workshop on Biobanking in Support of Clinical Trials in March, "I really enjoyed this meeting and found it a very useful networking opportunity. We hope that joining the CCB will allow us to play an active role in shaping the future of biobanking in the UK."

Nigel Westwood can be contacted at [Nigel.Westwood@kcl.ac.uk](mailto:Nigel.Westwood@kcl.ac.uk)

### Manchester Biomedical Research Centre Biobank

Central Manchester University Hospitals NHS Foundation Trust (CMFT) in partnership with The University of Manchester, through the NIHR Manchester Biomedical Research Centre (BRC) and other partners, is gaining a global reputation for pioneering research and innovation. The Manchester BRC Biobank has been established to facilitate research within universities, NHS Trusts and private industry. The Biobank is licensed by the Human Tissue Authority and has approval from the National Research Ethics Service to operate as a Research Tissue Bank. The Biobank supplies samples of fresh, frozen or fixed/embedded human tissue, blood, body fluids and processed derivatives for use in ethical biomedical research. Biomaterials are provided with anonymised donor information and pathology data.

Biobank services:

- Frozen storage with 24hr monitoring and alarm system
- DNA, RNA and protein extraction
- Tissue microarray construction
- Sectioning of frozen and fixed tissues

High-quality biomaterial for the Biobank is supplied by a network of clinicians, surgeons and pathologists. All patient donations are given with informed consent for research.

The Biobank currently hosts collections in the areas of:

- Gynaecology (Endometrial cancer, ovarian cancer, endometriosis)
- Gastroenterology
- Endocrinology
- Oncology (Head & neck cancer, renal cancer).

For more information on Manchester BRC Biobank visit <http://www.cmft.nhs.uk/brc/resources.aspx> or contact [Jay.Brown@cmft.nhs.uk](mailto:Jay.Brown@cmft.nhs.uk)

**For details of CCB membership benefits and how to apply contact [ccb@ncri.org.uk](mailto:ccb@ncri.org.uk)**

## State of Biospecimen Science is focus of NCI Conference

The 2010 Biospecimen Research Network (BRN) Symposium, **Advancing Cancer Research Through Biospecimen Science**, took place in Bethesda, Maryland, USA, on March 24-25, 2010 (archived proceedings available at <http://brnsymposium.com/meeting/brnsymposium/2010/>). The BRN Symposium is sponsored at the National Cancer Institute (NCI) Office of Biorepositories and Biospecimen Research (OBBR) and organised by OBBR's Dr Helen Moore and her colleagues. Helen has kindly sent us the following report from this year's symposium.

Now in its third year, this annual Symposium highlights challenges, opportunities and new research findings in the field of Biospecimen Science. Participants in the symposium heard about efforts in the BRN and across the world to better understand how different biospecimen collection, processing, and storage procedures affect the molecular integrity of biospecimens and how these biospecimen procedures in turn affect the cancer research and molecular medicine dependent on these essential gifts to research. The symposium also included an update on the NCI's new cancer Human Biobank (caHUB) initiative (<http://biospecimens.cancer.gov/cahub/default.asp>), in which biospecimen science will play an integral part in developing evidence-based biospecimen protocols.



Several of the speakers noted the central importance of biospecimens to the development of personalized cancer medicine, enabling the discovery of the "biomarkers" that will serve as targets for drug development, as diagnostic indicators, and as predictors and indicators of response to therapy. It was also noted that the availability of high quality biospecimens is a critical limiting factor for the cancer research community. The Cancer Genome Atlas (TCGA) initiative ([\[cancergenome.nih.gov/\]\(http://cancergenome.nih.gov/\)\) was highlighted as a powerful example of how the availability of high-quality biospecimens can empower paradigm-changing research. To accomplish such research, it is essential to develop, through Biospecimen Science, a better understanding of the contribution of biospecimen preanalytical variables to molecular data.](http://</a></p></div><div data-bbox=)

There is an enormous opportunity for biospecimen science to enable better, more reproducible cancer research; to develop better products from that research; to do so faster and more reliably; and to translate better research into better products for patients. An

important obstacle to capitalizing on that opportunity is that the dozens of biorepositories in the United States each follow a different set of practices for collecting, processing, storing, and annotating samples. These practices result in multiple pre-analytical variables that can affect the molecular integrity of a biospecimen and in turn impact molecular readout from a given biospecimen. The BRN has compiled a set of over 300 published papers in Biospecimen Science, available on the Web as the Biospecimen Research Database (<http://brd.nci.nih.gov/>). In addition, the BRN is funding a number of research programs to understand how pre-analytical variables affect the molecular integrity of the biospecimen. The knowledge gained from these and other research studies will underpin the operations of caHUB. The BRN and the European Union-funded SPIDIA (Standardization and Improvement of Generic Preanalytical Tools and Procedures for In Vitro Diagnostics) program have similar goals in advancing the field of Biospecimen Science and are sharing information to take advantage of complementary research approaches and findings that may speed progress in both programs.



Upcoming  
Event

### MRC Regulatory Support Centre in association with onCore UK Sharing Human Tissue: New Opportunities, New Horizons

15 September 2010, National Motorcycle Museum, Birmingham

The MRC Regulatory Support Centre in collaboration with onCore UK, are pleased to announce **Sharing Human Tissue: New opportunities, new horizons**.

A UK-wide conference for investigators, managers, funders, regulators and patient representatives to discuss the sharing of human tissue resources to maximise their potential for translational research.

#### Keynote speakers:

**Professor James Ironside, UK Brain Banks Network**  
**Baroness Diana Warwick, Human Tissue Authority**  
**Professor William Rosenberg, NIHR Office for Clinical Research Infrastructure**  
**Roger Wilson, Sarcoma Trust and tissue donor**

#### Audience:

Investigators working with human material  
HTA Licence Designated Individuals and managers of human tissue collections  
Policy makers, regulators and funders  
Research Ethics Committee members  
Patient groups

See [www.rsconference.mrc.ac.uk](http://www.rsconference.mrc.ac.uk) for full details of the day and registration.

**MRC Regulatory Support Centre**  

**Sharing Human Tissue:  
New opportunities, new horizons**

**Key themes**

- Sharing tissue to realise its full potential: opportunities and barriers
- Best practice in the management of human tissue collections and associated data

**National Motorcycle Museum,  
Birmingham,  
15th September 2010**

[www.rsconference.mrc.ac.uk](http://www.rsconference.mrc.ac.uk)

## NCRI Cancer Biosample Directory goes live



May 2010 saw the launch of a directory which is intended to be a signpost for researchers to find human biosamples for

use in their research. This directory lists sources of biosamples (tissue, blood and other biological samples, including extracted derivatives) held in the UK in cancer biobank collections. It can be searched by a variety of parameters, including specific tumour and biosample type. The directory provides information about how to contact custodians and how access may be possible. Inclusion of information in the directory provides custodians with the chance to make researchers aware of their resources, invite requests for access to samples and provide opportunities for collaborations.

the NCRI Biomarker and Imaging Clinical Studies Group, Cancer Research UK and the NCRI Informatics Initiative. Funding to initiate the directory was provided by the NCRN Coordinating Centre. The directory is contained within the NCRI ONIX designed and maintained by the Informatics Initiative, and can be found within the Resource Catalogue (see <http://www.ncri-onix.org.uk/portal/#S103a>). At the time of writing 11 organisations have submitted information for the directory and several other organisations have committed to doing so. In addition, a similar NCRI Cancer Clinical Trials Biosample Directory has also been designed and will provide a separate listing of cancer clinical trial biosamples collections held in the UK. Submissions of information about clinical trials collections are being sought at present for inclusion in this directory. For further information, please contact [info@oncoreuk.org](mailto:info@oncoreuk.org).

This directory is the result of joint work between onCore UK (on behalf of the NCRI Confederation of Cancer Biobanks),

To view the portal visit <http://www.ncri-onix.org.uk/portal/#S103a>



## Getting to know you: Wales Cancer Bank's Suzanne Williams

Suzanne Williams is the lead nurse for Wales Cancer Bank (WCB), line-managing 9 nurses within Wales. She is passionate about her role within WCB and feels their success is down to effective communication skills within the team and with the patients that they meet who donate their tissue to the bank for future cancer research. She is based in Swansea where they collect 20 cancer types and have gained consent from around 1,700 patients to date. WCB can be found at [www.walescancerbank.com](http://www.walescancerbank.com)

**What's the most enjoyable/satisfying part of your job?**

Speaking with patients and their families and telling them about WCB and the work we do. Patients I meet, despite their illness, are more than happy to help in any way to contribute to the WCB. I have been overwhelmed with the enthusiasm of people to take part in this exciting project.

**What's been the toughest challenge your organisation has had to overcome?**

Breaking down barriers and introducing professional bio-banking to hospitals.

**What are you doing to engage with patients/donors and the public?**

I am a member of the Patient Forum Group for Swansea and the LLEG (Lay Liaison Ethical Group) for the WCB. I also fund raise for Cancer Research Wales.



**What's the 'must-attend' conference you're going to in the next 12 months?**

I attend the annual Wales Cancer Trials Network symposium and hope to attend the NCRI Cancer Conference later in the year. I also try to attend CCB workshops as they are very informative events.

**What single thing would improve the quality of your biobank service?**

More funding, more staff!

**What's the most useful thing you've learnt from your tissue banking colleagues/CCB network?**

That we all aim for the same thing – better patient treatments, targeted therapy, high-quality samples for better research.

**You wouldn't know it but I am really good at...**  
Computer skills!

**Which words or phrases do you most overuse?**  
'I'm not going to lie to you' (from Gavin & Stacey!).

**What keeps you awake at night?**  
Snoring!



**Anne Carter, Portfolio Lead for onCore UK gives her thoughts on the new CCB initiative to develop best practice guidelines and a way to benchmark biobanks.**

I'm sure you will agree that biobanks are an essential resource for the procurement,

preservation and provision of biological samples for cancer research – after all that is the business we are in. There is, also, no opposition to the idea that high quality samples are needed if research is to be meaningful and reproducible. But how do you define 'high quality' with respect to biosamples and how can we ensure that the samples and data in our biobanks are of high quality?

The simplest definition of quality with respect to any product is that it is "fit for purpose". This is a good definition for biosamples used in research, because the results obtained from any analysis will be affected by factors in the sample (how it was collected, stabilised, processed, stored and transported, for example) but will also depend upon the analytical technique used. Samples that are suitable for one technique may not be suitable for a different technique – there is no single way of handling samples that will suit all users.

The challenge of biobanking, as opposed to collecting samples for analysis in research such as a clinical trial, is that it is not possible to know exactly what the samples will be used for. The best we can do is to standardise our procedures and keep meticulous records so that any differences between samples can be attributed to the sample itself rather than the way in which it was collected, processed and stored. This leads to difficulties when different biobanks standardise on different procedures; samples from the different banks may not be equivalent or have equivalent information stored. Why is that important? Well, researchers often need more samples than a single biobank can supply and so their research is slowed down while samples that have been handled and annotated appropriately are collected.

The need for harmonisation and standardisation in biobanking is recognised widely and several organisations have produced guidelines<sup>1-4</sup>. Despite the availability of such guidelines, however, no relevant, internationally accepted standard against which biobanks can be assessed exists.

onCore UK, acting on behalf of the CCB, has begun a project to develop best practice guidelines and standard procedures to allow benchmarking and a voluntary accreditation or certification system for the CCB members. The publications referenced above provide a good starting point for this project and will be invaluable in ensuring that any system is aligned with other organisations' and countries' views on current best practice.

There is also a move towards accreditation schemes for biobanks. As long ago as 2001 the OECD (Organisation for Economic Cooperation and Development) suggested that national governments should "support the development of an accreditation system for (biobanks) based upon scientifically acceptable objective international criteria for quality, expertise and financial stability". The Marble Arch Working Group on International Biobanking<sup>5</sup> looked at all of the available guidelines and ISO standards, and developed a draft ISO standard, specific to human tissue banks. This publication provided the basis for a French national standard used to accredit biobanks, *NF S96-900 July 2008 Quality of biological resource centres (BRCs) - Management system of a BRC and quality of biological resources of human and microbial origin*<sup>6</sup>.



At their recent meeting in Rotterdam, the International Society for Biological and Environmental Repositories (ISBER) recognised the need for an accreditation scheme for biobanks and plans to set up a working group to make recommendations on a suitable system. I have volunteered to sit on this working group and will ensure that CCB views are represented.

It is clear that the CCB's interest in harmonisation, standardisation and accreditation mirrors the views of other organisations connected to biobanking. It is essential that the views of CCB members are represented in this project so that the outcomes are suitable for all of us. Therefore, anyone with an interest in biobanking who wishes to take part in the best practices, benchmarking and accreditation working group should contact Anne Carter on 020 8731 4595 or e-mail [anne.carter@oncoreuk.org](mailto:anne.carter@oncoreuk.org). Regular progress reports will be published in CCB Update.

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## Working on your Ethics



While the use of human tissue in research is growing, the complexity of the regulations around using human tissue in research has been recognised for some time and diversity of guidance available is known to confuse researchers and discourage them from

undertaking this type of research. The Academy of Medical Sciences is currently reviewing medical research regulation and governance, which may influence future changes in the landscape. In the meantime the research community is still trying to navigate the current landscape.

Creating a clear and practical pathway through the regulatory and governance framework is one of the key action areas identified in the NCRI's Task Force report *Fostering the Role of Pathology in Research 2009* - specifically to help researchers. A specific action contained within this objective was for onCore UK to host an event, in collaboration with the National Research Ethics Service (NRES), to clarify the ethical principles relating to when consent is or is not required for use of anonymised biological samples in research. This action has been developed by onCore UK and NRES into a series of five one-day workshops held across the UK in association with the Human Tissue Authority (HTA) and the National Information Governance Board for Health and Social Care (NIGB) as well as the MRC Regulatory Support Centre and Chief Scientist Office for the Scotland workshop.

David Neal, Deputy Director (Policy) of NRES, told CCB Update, "The development of this workshop series has seen a strong level of collaboration and active involvement between the regulators and those providing support to researchers such as MRC RSC. I feel that this has led to a programme that is comprehensive but also highly accessible for the target audience."

The workshops are aimed at Research Ethics Committee (REC) members, researchers and R&D officers/managers and are structured as two distinct parts. The morning session comprises of three presentations covering the regulatory frameworks and ethical considerations for use of human tissue and accompanying data in research and the afternoon session is more interactive and discussion-based. In this latter session delegates work in small groups to review the legal and ethical issues presented by a number of example research scenarios.

Three workshops have been held to date in London, Stirling and Leeds with around 70 delegates attending each workshop. Feedback from the delegates has been very positive with

100% of respondents to an evaluation form saying they would recommend the workshop to others. The workshops are also proving very popular – both of the first two events were over subscribed. The demand was so high in Scotland a second workshop is being considered.

Brian Clark, CEO of onCore UK, commented, "We are really pleased by the interest in these workshops and it really emphasises the need for ongoing and consistent training to be offered to the research community on this subject." He added, "The key to approaching this is co-education - bringing the REC, research and R&D communities together to understand each other's perspectives."

Future workshops are planned in Manchester (22 September) and Bristol (2 November) and are currently open for registration at the NRES website – [www.nres.npsa.nhs.uk/training-events/](http://www.nres.npsa.nhs.uk/training-events/)



### Upcoming Events

#### onCore UK/NRES Training Workshops

22 September 2010, Manchester  
2 November 2010, Bristol

#### Ethical Principles Relating to Consent for Use of Samples and Related Data in Research

These workshops aim to provide information that will clarify the ethical principles relating to when consent is or is not required for use of anonymised biological samples in research.

Visit [www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk) for more details on the programme and how to register

#### NCRI Cancer Conference

7-10 November 2010,  
BT Convention Centre, Liverpool



The NCRI Cancer Conference is the major forum in the UK for showcasing the best British and international cancer research.

The 2010 NCRI Cancer Conference will take place from 7-10 November at the BT Convention Centre, Liverpool.

To secure your place at this year's Conference, register online by Friday 17 September 2010.

Visit [www.ncri.org.uk/ncriconference](http://www.ncri.org.uk/ncriconference) for more details