Human Tissue Act Newsletter

Note from the QA Manager

Welcome to the June edition of the HTA newsletter! I am now back from maternity leave and very busy catching up with everything that has happened in my absence. I huge thank you to everyone that has helped to cover my duties in my absence, in particular Emma Raine and Debbie Lett. Please bear with me whilst I catch up, and feel free to contact me anytime for any support.

E-Learning update

Good news! The Human Tissue Act E-Learning course for the research sector is back on line, and ready for use. The training has recently been updated to reflect the changes in the regulations which came into place on the 3rd of April 2017, with new Codes of Practice and Standards.

Anyone with a Newcastle University email address can access the training for free by contacting the E-Learning team (HTA.elearning@ncl.ac.uk) to request access to the course on Blackboard.

If you do not have a Newcastle University email address, but do work to actively collect samples to be transferred to one of Newcastle University’s NRES REC approved Research Tissue Banks, including taking consent and managing the samples in the clinic for transfer for the University, you are eligible to access the training for free. Please contact the email address above stating the name of the Research Tissue Bank you are working under.

For all other external parties, access to the course can be gained via the webstore. The training takes approximately 2 hours and must be completed every 3 years.

Staff update

Emma Raine

Emma now has a new job title “Bioresources Coordinator” – previously Biobank Coordinator. Emma is now working with two main roles. The first is to coordinate the activities of the generic research tissue bank, “Newcastle Academic Health Partners Bioresource” The second aspect is to coordinate the Newcastle centre of the NIHR Bioresource (https://bioresource.nihr.ac.uk/).

As Emma is now considered to support the operational aspect of human tissue research rather than the governance aspect, she will now report to Dr Amy Peasland (based at the Central Biobank). However, Emma will continue to be based at the Newcastle Joint Research Office in Gosforth.

Gillian Brown

A warm welcome to Gillian who is the new Achiever sample tracking software project manager, replacing Peter Holmes. Gillian will be splitting her time between the NJRO and the main campus. See her update on page 2.

Rachael Gray

Our fantastic Biobank Administrative Assistant, Rachael, has been successful in obtaining a secondment in Grants and Contracts within the NJRO, until the end of January 2018. Well done Rachael! Whilst we try and recruit a replacement, please contact Mhairi or Emma individually.

HTA Licence update

Newcastle University currently holds a research sector Human Tissue Act licence (ref. 12534) for the main campus “hub” and three satellite sites, as shown below:

- Satellite: Campus for Ageing & Vitality
- Satellite: International Centre for Life
- Satellite: Freeman

Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) also hold a research sector HTA licence, however this only covers the RVI.

As the Freeman is an NHS premises, it is now proposed to move the Freeman to sit as a satellite under the NUTH research HTA licence, rather than the University. However, as the Institute of Transplantation (IOT) at the Freeman is covered by the University, the University will continue to licence this unit. The new licensing model will be as follows:

- Satellite: Campus for Ageing & Vitality
- Satellite: International Centre for Life
- Satellite: IOT

The change is currently being discussed however if staff have any concerns or questions about the changes, please contact Mhairi.Anderson@ncl.ac.uk or c.m.morris@ncl.ac.uk

If you have any questions, comments or ideas for future issues, please get in touch: Mhairi Anderson, Newcastle Joint Research Office, Regent Point, Gosforth, Newcastle upon Tyne, NE3 3HD. Tel: 0191 282 5501 Email: Mhairi.anderson@ncl.ac.uk Website: www.newcastleiro.org.uk
It’s all change in the Achiever project!

Many of you will know that Peter Holmes, Project Manager, retired on 5 April. We all wish Peter a very happy and healthy retirement.

I am his replacement, Gillian Brown, and I commenced the role on 10 April. I do have a history with the University having worked here from 1998-2013, firstly within the IT department and then within the School of Medical Sciences Education Development.

NICR (Phase 1) is fully operational and we are very grateful to NICR staff for continuing to test and feedback on new functionality. We’re into Phase 2 of the project and, as you may know, Central Biobank staff are busy migrating their large collections across; Freeman Hospital are currently formatting their data for input into the Achiever spreadsheet; and Academic Haematology have submitted data to be tested, tweaked and used within their training programme which begins in June. Next in the rollout is the Brain bank (NBTR) so Chris, Atif and I will be talking to them next week to discuss their requirements.

Chris Humphreys, our Achiever Analyst/Developer, has developed fantastic new functionality within Achiever, which allows users to transfer whole batches of samples between different collections and studies. This option will greatly assist researchers to move samples around within the system, for example, moving samples from REC approved studies into biobanks when the study ends.

Last month I chaired the new Achiever Working Group, giving current users the opportunity to discuss requirements, issues and any questions about the system.

During the meeting I realised that not all groups who are due to receive Achiever as part of phase 2 were represented in the meeting. Involving these groups early in the discussions may allow them to prepare for the migration and keep them updated so they know what to expect.

As diary availability may be limited, I have created a private group within the University’s social media platform, Yammer. Staff can log on with their Newcastle University credentials. This offers users and potential users the opportunity to keep in touch about new developments, new functionality and upcoming training sessions. The Yammer platform can be set to email you each time there’s a new topic for discussion which saves you having to visit the website regularly. Should anyone wish to join the new Achiever Working Group, or if you have any other questions about the roll out please email me (Gillian.Brown1@ncl.ac.uk).

Update from Bioresources Coordinator

Since the last newsletter the Newcastle Academic Health Partners Bioresource (NAHPB) has had a change of Chief Investigator (CI) to Dr Chris Morris, and we have taken on 4 Research Tissue Banks as part of the consolidation project; The Mitochondrial Control Tissue Bank based at the Centre for Life, the Primary Ovarian Cultures Tissue Bank based at the NICR, Dr David Steel’s Retinal Biobank, and the Haematology Biobank, amalgamated after the retirement of their CI, Professor Andy Hall. In addition to these I have also taken on management of Professor Sophie Hambleton’s Great North Biobank which is the paediatric arm of the NAHPB. If you would like to access samples from any of these collections or have a collection that you would like the Bioresource to adopt please get in touch. Continued overleaf!...
New HTA Codes of Practice & Standards

In April the Human Tissue Authority (HTA) published updated Codes of practice.

What are the Codes of Practice?
The HTA’s Codes of Practice provide practical guidance on the human tissue legislation and set out the HTA’s licensing standards. The Codes are important resources which help researchers and establishments comply with our regulatory framework. They can be found at this link.

Why are there new Codes of Practice?
The previous versions of the Codes were published in 2009. Since then, there have been a number of changes in the sectors regulated by the HTA. Our aim in reviewing the Codes was to make sure they better reflect current practice and guidance. We also wanted to improve the structure of the Codes and Standards and make them more accessible.

Has much changed?
The new Codes have been restructured so they provide a clearer flow of information. There are now seven Codes, rather than nine; there are no longer separate Codes on disposal or on import and export. Instead, guidance on these topics is in the individual codes, where it is relevant. We’ve also introduced new guiding principles into Code A: Principles and Consent. This is the overarching Code and should be read alongside the sector specific Codes. In terms of content, little has been removed. More than half of the research sector Code is new, with more examples to reflect current practices. The new information covers topics such as:

- cost recovery and charging;
- consent requirements for DNA analysis;
- licensable storage;
- Research Tissue Banks (RTBs) and diagnostic archives;
- xenotransplantation.

What implications are there for Biobanks?
The new research sector Code is as relevant for Biobanks as it is for any person or organisation involved in human tissue research. The Standards have been reviewed so they are clearer and more specific. This does set a higher benchmark. But, it is now easier to understand how to meet the Standards and what we expect from you.

What should tissue custodians do about these changes?
If you are a researcher working with human tissue, you should familiarise yourself with the new Codes and Standards. You can also access webinars on the Codes on our website to help understand the new Codes and Standards. If you have any questions about the Codes and Standards, you always get in touch by emailing enquiries@hta.gov.uk.

Is it likely these will change again?
Yes, but not for a few years. But, just because the Codes and Standards won’t change any time soon, that doesn’t mean our guidance will remain the same. We’ve published guidance on how to meet the Standards on our website. We intend to review this guidance on an on-going basis to reflect good practice and share learnings between organisations.