Welcome from Brian Shine, Designated Individual for HTA Licence 12217

Welcome to the Hilary newsletter. As we prepare for the HTA inspection in April, I would like to thank you all for the hard work that everyone has put into improving our management of human tissues in research.

We had a great turnout for the HTA forum in January. Thank you to all who attended and helped to make it a valuable experience, especially those who chaired and took part in the discussion groups. The governance team were amazing.

Best wishes,
Brian

2019 HTA Forum
The annual HTA Forum of HTA Licence 12217 was run for the first time in its new format on the 10th of January 2019 in the Richard Doll Building on Old Road Campus. It was well attended with nearly 100 participants. Attendees included researchers holding human tissue samples under the Licence, governance and laboratory staff involved in looking after these samples, biobank staff, personnel working under REC exemption, representation from the University’s other HTA Licences, a few staff members from the Oxford University Hospitals NHS Foundation
Trust and colleagues from the University’s Research Services.

The day started with a presentation on the status of HTA Licence 12217 to give context to the discussions and update the audience about the 2017 HTA inspection findings and resulting corrective and preventative action plan (CAPA plan), as well as progress made against the identified shortfalls. This was followed by a panel discussion chaired by Prof Helen McShane, on how to achieve good governance whilst facilitating research within the regulatory framework. Panel speakers and audience members discussed the challenges and opportunities presented by the changing face of governance for PIs and researchers, with increasing focus on quality systems. The difficulties of achieving good governance when staff are also expected to deliver research outcomes were highlighted.

A second panel discussion chaired by Dr Richard Liwicki was focused on sample storage and sample sharing with collaborators, exploring the reasons legacy collections are stored for potential future research and whether this is always justified. The challenges of making these samples and associated data available to other researchers were also explored, contrasting resources such as research tissue banks with using external storage facilities such as the UK BioCentre.

Feedback received after the event was very positive, with close to 80% of respondents saying the event surpassed their expectations. The panel format was appreciated and the topics were relevant to most respondents.

Suggested future topics for next year’s events included fostering collaboration across the University, extending support to researchers conducting research under REC approval to facilitate a seamless transition into HTA compliance at the end of a study, tools to encourage a culture change towards better governance and quality processes, and ways in which existing resources such as tissue banks can be supported to fit the needs of Oxford’s researchers. More involvement of Research Services staff and departmental governance staff was also suggested, in particular staff involved in finances, and those concerned with ethical approval and sponsorship of studies; similarly, we will aim to have more representation from the NHS Trust at next year’s event.

A few pieces of feedback on the event:
“The initial update was informative and enthusiastic. The panel discussions worked well, thanks to the diverse panel members, highly engaged audience and effective chairs.”
“The structure was very informative and did highlight the issues groups are facing. The format was well thought out and having pre prepared questions was sensible to stimulate discussion.”
“I think for researchers working under the license, the format was good. However, the organisers failed to accommodate attendees from UAS”.
“Very useful to have funder perspective”
“Excellent gender balance on both panels.”
“All [the topics were interesting] - that only 4% of stored samples are being used/shared was an eye opener.”
“I work for a funder and so was particularly interested in areas of discussion that might require financial support that could be scientifically justified e.g. collaborating via tissue sharing or making most use of existing stored tissue.”
“Please do this again!” “Thank you and well done. The Forum was a very good use of time.”
“Excellent. Very efficiently and professionally run. Generated excellent discussions and proposals for solutions. Great to see engagement from senior PIs”.

A summarised transcript of the discussions will be circulated on the HTGT’s website in the coming weeks
--Marie Hamard
**Inspection Preparation**

We sent key areas for pre-inspection focus and preparation in an email on 08 January. As a refresher:

**Audit**
- If you have not already sent your 2019 internal/local audit schedules (requested along with the annual returns) to HTGT, please do so.

**Document control / iPassport roll out**
- The plan is to get documents from every collection onto iPassport before April.
- Ahead of roll out, ensure you have a register of controlled documents (i.e. a list of all your documents) and that if you have printed controlled copies of documents, that these also include ‘date printed’ information as well as the other document control information.

**Traceability**
- Undertake internal/local two-way traceability audits according to your internal audit schedule.
- Ensure your traceability database or spreadsheet is up-to-date.

**Mapping exercise**
- Please see dedicated “Mapping Licensed Collections” article below

**General ‘housekeeping’**
- Close any open actions relating to HTA matters (e.g. adverse events, registration audits, annual audits etc.) as soon as possible, but especially by the agreed deadlines.
- Ensure relevant staff have completed their HTA training (and that their certificates are available) and have read/acknowledged the core SOPs on iPassport.
- If you obtain samples from healthy volunteers – make sure you have the relevant documentation and processes in place.
- Review and update HTA-related risk assessments.

--Rachel Lloyd

**iPassport Quality Management System**

Following the successful introduction of the iPassport quality management system (QMS) for the Licence level back in September 2018, work continues on a pace to implement iPassport as the QMS for all collections registered under the Licence. As you know, the HTGT have taken a risk-based approach to this rollout meaning that those with the greatest need (e.g. the large Research Tissue Banks) have been approached to implement the system first, with smaller collections due to start in the next couple of months. The rollout includes not only using the system for controlled documents, but also for internal audits, adverse event management and recording of meetings. Our thanks to the Oxford Brain Bank for being the pilot for the rollout back in October. Since then the Oxford Musculoskeletal Biobank and Oxford Radcliffe Biobank have started the process and are actually going live with the system.
soon. NDWRH, NDMRB and Pharmacology are at the fledgling stages and we hope they will go live in February and March.

The audit module is now in use by the HTGT to record and track the annual audits of collections. This is a great leap forward in terms of trying to reduce the administrative burden of managing the audit process. It also means that there are audit checklists against the HTA standards available on the system for anyone to use for their own internal audits.

Look out for updated core Licence SOPs relating to iPassport processes coming soon!

--Rachel Lloyd

Annual Returns…and audit schedules
Thanks go out to all CROs who have compiled and sent in their collection’s annual returns. Many of you noticed that we also requested your internal (local) audit schedule for the upcoming year. If you have not finalised the schedule and sent it to the HTGT yet there is still time to do so before a withering email reminder.

Mapping Licensed Collections

“A label a day could keep the auditor at bay”…well, not quite, but we can always make things better!

The team have recently begun visiting CROs as part of the mapping exercise. So far, this has been a great opportunity to check the information that we have on record for each collection. The main priority being to check that the correct number of authorised copies of the Licence are in use and to confirm their location. This ensures the annual audits run smoothly and will assist our own auditors and the inspectors, when they visit in April, to the correct storage locations on our premises. In the same way that your Register of Controlled Documents should help to remind you which document is specifically used for recognised REC studies and which for material under the Licence, we really want to help you (and us) by using the appropriate signage in your sample storage areas.

To support this, the following are a few suggestions to make things simpler.

Copies of the Licence:
- Please ensure copies are displayed in a clearly visible location within the area storing material registered under the licence.
Please return any unused copies to the HTGT as soon as possible and indicate the location and collection it was associated with. This will ensure we retain up-to-date and accurate records.

Copies should not be transferred to other buildings or collections nor photocopied!

Only the HTGT can authorise the release of copies of the Licence.

Labelling samples storage areas:

- Ensure that samples registered under the Licence are clearly labelled in their storage location. The premises searches that were performed last year should have been a good indicator of the storage locations in use within a department. Please note that team would like to receive this information if it has not already been sent. We must emphasise that we want to know the locations that human material is stored. For recognised REC approved studies, include REC number/project ref and for samples under the Licence, please include the collection number. We also require any disposal logs that may have been generated as a result of the searches.

- See our ‘hot tip’ section below for more information on labelling sample storage areas.

By implementing some of the points above, we hope to improve our audits and enhance our knowledge of your collections. These points will also prepare you in case any questions are asked regarding samples under REC approval. Please take a look at: [https://www.hta.gov.uk/policies/hta-and-hra-sharing-information](https://www.hta.gov.uk/policies/hta-and-hra-sharing-information) for further information on this topic.

--Ben Haxton

**Licence 12217 ‘Thank you’ coffee and cake event**

Thank you to everyone who attended our ‘thank you’ coffee and cake event on 8th November 2018 to celebrate the end of the CAPA. We raised £56.97 for Winston’s Wish charity, which is a childhood bereavement charity that provides support to grieving children and their families. A very worthwhile cause.

[https://www.winstonswish.org/](https://www.winstonswish.org/)

--Rachel Lloyd

**Web Pages Update**

[https://researchsupport.admin.ox.ac.uk/governance/human-tissue](https://researchsupport.admin.ox.ac.uk/governance/human-tissue)

What guidance would you like to see in the FAQs and other HTGT web pages? In case you’ve missed it, we now have more comprehensive information on training requirements for staff working with human tissue on our page here: [https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training](https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training)

Please have a look at our pages and let us know what information you’d find helpful, especially as you prepare for the April inspection.
Calendar

04 March 2-4pm **Governance Management Committee** meeting
05 March **MRC Handling health-related findings in research Workshop** at Univ of Southampton: [Registration link](https://www.eventbrite.co.uk/e/mrc-handling-health-related-findings-in-research-workshop-at-univ-of-southampton-registration-69363510368)
07 March 9-11am: free **drop-in clinic** with HTGT at Boundary Brook House
08 March 10am- noon: **Operational Management Committee** meeting
19 March 11-12:30pm **Obtaining ethical and HRA Approvals**, Boundary Brook House **Fully booked**
19 March 6-7:30pm **Donating Tissue: What Do People Want to Know?** Cambridge-MRC Cambridge Stem Cell Institute [https://www.eventbrite.co.uk/e/donating-tissue-what-do-people-want-to-know-tickets-55966931599](https://www.eventbrite.co.uk/e/donating-tissue-what-do-people-want-to-know-tickets-55966931599)
04 April 9-11am: free **drop-in clinic** with HTGT in NDCLS Seminar Room, Level 4, John Radcliffe Hospital
23 May 11-12:30pm **Obtaining ethical and HRA Approvals**, Boundary Brook House, to book a place contact Mark Crossley at mark.crossley@admin.ox.ac.uk

HTA News


Keep up-to-date with the HTA by subscribing to their e-newsletter below: [https://www.hta.gov.uk/newsletter/signup](https://www.hta.gov.uk/newsletter/signup)

Hot tip: Labelling Sample Storage Areas

- If you can define a storage area (which includes fridges, freezers, cupboards or shelves) as “Material registered under the Licence only” or “Recognised REC only” with clear signage- please do!
- Where space is at a premium, please create simple storage maps and use a **consistent colour coordinated key across the collection/department** to indicate whether cupboards, fridges, freezers and other storage locations are the home of material under REC (including the REC number) or registered under the Licence. In all cases, including the REC approval number or project name is helpful and will serve as a visual aid during the inspection and helps staff working in the area know about the samples.

*Please ensure that your sample traceability SOPs reflect this. For those of you with a departmental human tissue use policy, please reinforce the importance of clear labelling.*
• Fridges and freezers that are not connected to temperature monitoring systems should be labelled “Not suitable for storage of human tissue”. Similarly, use signage to state that certain rooms are not suitable for storage of human tissue.

--Ben Haxton

The Human Tissue Governance Team: here to help

Brian, Marie, Rachel, Ben, and Gretchen

The best way to reach us is via email: hta_help@admin.ox.ac.uk

Please use this email address for Adverse Event/Incident reporting, too