Welcome from Brian Shine, Designated Individual for HTA Licence 12217. May you find this first newsletter informative. If not, your feedback will help greatly.

Progress on the Corrective and Preventive Action plan (CAPA) for Licence 12217
We are entering the ninth month of the CAPA plan agreed with the Human Tissue Authority (HTA) to resolve shortfalls identified against Human Tissue Act standards during the April-May 2017 inspection. So far, with the help of all personnel working under the Licence, I as the Designated Individual (DI), have been able to deliver the expected evidence for compliance at each of the set deadlines and the HTA has closed 15 out of our initial 18 shortfalls! So my thanks to everyone for their hard work in achieving this.

To recap on the work that has been achieved to date: in November 2017, a set of core documents was created and published and training was provided to staff working under the Licence. Since then, the Human Tissue Governance Team (HTGT) have been working on a series of template SOPs for staff working under the Licence to adapt to local needs, with the first ones already available on the Research Services website (https://researchsupport.admin.ox.ac.uk/governance/human-tissue/resources under “template documents”). The adverse event reporting process has greatly improved with many of you working tirelessly to close adverse events in good time and provide assurance that issues have been resolved, thank you! We hope that processes surrounding blood collection from healthy volunteers have been clarified and we continue to work with the University’s ethics committees to provide clear guidance for researchers on this matter. Another achievement was the training of over 2,000 staff members across the Medical Sciences Division on the Human Tissue Act and the HTA’s codes of practice. The HTGT is already busy preparing updates to this training to make it more relevant to the different groups of people working with human tissue at the University. With your assistance, we reviewed some of the induction materials used in different departments to ensure new staff and visitors are in the process of completing it (the HTA's codes of practice). The HTGT have reviewed our risk management procedures and produced a core risk assessment, which is available from the Research Services website. Finally, the HTGT are happy to have started conducting more regular audits on the collections – they have been finding these invaluable to understand how you are working, what challenges you face and how best they can support your efforts.

An update on remaining actions to complete as part of the CAPA
We are nearing the end of the year-long plan to improve compliance in Licence 12217. In the last four months before the end of the CAPA we still have to complete one of the most ambitious tasks of all: the systematic search of licensed premises to identify any sample collections partly or completely uncatalogued. The aim of this search is to ensure that any sample held on licensed premises is either covered by an exemption to licensing (for example valid and current REC approval), or appropriately registered under an HTA licence. We thank our two “pilot” departments who have either completed their search (the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science) or are in the process of completing it (the Nuffield Department of Surgical Sciences). Thanks to them, we have learnt valuable lessons which we have been able to communicate to our Persons Designated (PDs). With the search now extending to all departments, we will count on you all to communicate your knowledge to your colleagues and help them through the steps required for registration or disposal, if required. It’s important to remember that part of this task is also to ensure that a comprehensive and accurate inventory of ALL tissue held in each registered collection is completed before 30 September 2018. Speak to the HTGT at hta_help@admin.ox.ac.uk if you are worried about this task: the earlier we know, the earlier we can help!

Training on HTA Standards and Codes of Practice
On 12 March 2018 we reported to the HTA on training uptake across Medical Sciences and we greatly appreciated all of the efforts made to coordinate training for staff working with human material. It’s worth mentioning that
some departments had at least 90% of their pertinent staff trained by the deadline: the Dunn School, NDCLS, NDM SGC, NDORMS, and Psychiatry. NDCLS had all declared staff trained by the deadline and NDORMS had the greatest number of employees trained, over 200 people. Going forward, departments are now responsible for recording HTA training for new staff (including visiting staff) and for the refresher training due every two years. This can be done by requesting certificates from staff. As of mid-April 2018, over 2,000 university staff had passed the WebLearn training course. As a reminder, if you have not yet completed the training and work with human material, you are required to complete the training at https://weblearn.ox.ac.uk/portal/site:medsci:hta

The HTGT's workshop series
Following the success of the Best Practice Workshop run in December 2017, which touched on a range of topics including sample traceability, consent tracking, document control and risk assessments, the HTGT is running a series of workshops to help collections achieve better compliance with some of the HTA standards. On the 20th of April, a successful workshop held at Boundary Brook House focused on document control. After a presentation on the basics of document control, representatives from several collections under the licence were able to participate in two activities: first spotting inadequacies in a mock SOP; and then reflecting on which documents they may need to control in their professional practice. The next workshop, scheduled for Friday 15th June 2018 at Boundary Brook House (Churchill Hospital site), will focus on risk assessments; it will consist of a short presentation followed by group activities to practice using template risk assessments, risk matrices and risk scoring for continuous compliance improvement. Please register your interest by emailing hta_help@admin.ox.ac.uk to book a place on the workshop! The HTGT are also happy to hear your suggestions of topics for upcoming workshops. –Marie Hamard

Update on peer-to-peer audits
One of the CAPA deliverables was to introduce a ‘peer-to-peer’ process of audits whereby PDs audit neighbouring departments. However, the implementation of other parts of the CAPA during 2018 has placed a large workload on PDs. It is therefore felt that peer-to-peer auditing would be better implemented from 2019 onwards, to give PDs time to solve issues related to the CAPA and gain a deeper understanding of local issues. The increased manpower in the HTGT allows it to perform more audits in order to cement the progress achieved during the CAPA plan. Audits of registered collections against selected HTA standards and led by the HTGT have started and will continue for the rest of 2018. In order to ensure PDs are trained in the audit process, the audit schedule includes PDs shadowing audits of other departments. The HTGT will be in touch with individual PDs to obtain their availability to shadow future audits. –Rachel Lloyd

Outreach
On Friday 18th May 2018, Boundary Brook House opened its doors to mark the International Clinical Trials Day 2018. Hosted by the Joint Research Office, the event was for all those involved in running clinical research in Oxford to come and talk with its teams to better understand their roles in supporting research studies. The HTGT were kindly offered the opportunity to attend and present a poster to outline the focus of Licence 12217 and to answer any questions. There were also a number of representatives from the University and Oxford University Hospitals NHS Foundation Trust.

With a very well-advertised cake sale for charity and a wealth of friendly staff to answer all manner of questions, there was steady flow of people ranging from other members of the Joint Research Office, trust staff and nurses involved with clinical trials, students and clinicians; all stopped by to read our poster and were interested to hear about our work and achievements with the CAPA. It also presented an opportunity for our colleagues who work under different licences to say ‘hello’. It was a great day that led to some interesting questions and a great opportunity to meet the people involved in the University’s research programmes. The HTGT certainly hope to be back again next time! –Ben Haxton
Annual returns for registered collections
Thanks to those of you who have filled in your annual returns for registered collections under the Licence. We’d like to remind those who have not yet returned their form that the DI and HTGT really need the information contained in the form! The annual returns form helps us know who to contact with any questions regarding the collection, as well as give us up to date information about what is stored, where, and under what conditions. It’s a really useful tool for us to see whether we need to raise specific questions with any collection staff and to offer help where it’s needed. You may have noticed first of all that the forms were very late this year and we apologise for this; this was due to a much needed update of the contents of this form to reflect the information that the DI is required to provide to the HTA on a yearly basis. That’s why some new questions have cropped up, such as the one on storage of non-relevant material! Please don’t hesitate to ask us any questions about the form at hta_help@admin.ox.ac.uk and remember to send in your form as soon as possible, if you haven’t already. The next form will be coming in January 2019 for information about the year 2018. –Marie Hamard

Template SOPs and Forms on Website
Earlier this year our website changed its look and we hope it is now easier to find all core SOPs; templates for creating local SOPs, forms, and risk assessments; as well as the current authorised version of six core forms and the overarching risk assessment for the licence. Only current versions of documents are available on the site, so it is best to access forms here: https://researchsupport.admin.ox.ac.uk/governance/human-tissue/resources
Please expect further improvements in the near future, as the HTGT works hard to provide more resources.

Calendar
12 June CTRG’s Obtaining Ethical and HRA Approval session
15 June Risk Assessment Workshop: Register at hta_help@admin.ox.ac.uk
28 June SharePoint User Group lunch: Registration details link
30 September final CAPA deadline
27 November UK Biobanking Showcase in London

HTA News
Nicola Blackwood became Chair of the HTA in March: https://www.hta.gov.uk/news/nicola-blackwood-appointed-chair-human-tissue-authority

A new HTA Establishment button on our site gives information on our licence, including inspection reports

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

GDPR Comes into Force 25 May
Guidance on the upcoming General Data Protection Regulation (GDPR) can be found at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/
Hot tip: storing and using human tissue samples from collaborators in other institutions

Getting samples from a collaborator for storage and use in Oxford? Ensure you take the following steps so you can rest assured you’re compliant with the law:

1- Ensure that the research you’re planning to conduct in Oxford is covered by appropriate ethical approval (this may be the collaborator’s ethics approval in the UK or abroad, or it may be your own ethical approval including CUREC approval). More information on where and how to apply for ethical approval is available here: [https://researchsupport.admin.ox.ac.uk/governance/ethics](https://researchsupport.admin.ox.ac.uk/governance/ethics).

2- For samples stored under ethical approval from a research ethics committee (REC) which is not recognised by the HTA (e.g. University REC including MS IDREC and OxTREC, approval granted in another country): you must ensure the samples are registered under an HTA licence. Please note that registration must be completed BEFORE the samples are transferred to Oxford. Guidance on how to register samples under Licence 12217 is available in the Licence’s core SOP on Quarantine, Registration and Audit: [https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/hta006_quarantine_registration_and_audit.pdf](https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/hta006_quarantine_registration_and_audit.pdf).

3- Ensure the terms of the transfer are set out in an appropriate research contract (most often, a Material Transfer Agreement) which must be finalised and signed by Research Services on behalf of the University BEFORE the samples are transferred. More information on Research Contracts is available here: [https://researchsupport.admin.ox.ac.uk/contracts](https://researchsupport.admin.ox.ac.uk/contracts) (information accessible with University Single Sign On).

4- You must seek assurance from the provider of the samples that informed consent is in place for the research you are planning to conduct; if you are not getting consent forms with the samples, you must ensure that your research contract clearly documents that the provider of the samples warrants that consent is in place for all samples.

5- For imported samples, ensure that the shipment is appropriately declared to Her Majesty’s Revenue and Customs (HMRC).

Links

MRC Guidance on Staff Blood Donation: [https://www.mrc.ac.uk/documents/pdf/guidance-for-staff-awaited-to-volunteer-samples/](https://www.mrc.ac.uk/documents/pdf/guidance-for-staff-awaited-to-volunteer-samples/)

CUREC Guidance on Use of Samples from Healthy Volunteers: [https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/bpg_15_ethics_review_of_research_with_human_tissue.pdf](https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/bpg_15_ethics_review_of_research_with_human_tissue.pdf)

MRC Human Tissue Forum supports MRC Designated Individuals (named on Human Tissue Authority licences) their Persons Designated as well as managers of other MRC-funded tissue collections held in the UK: [https://byglearning.com/mrcsc-lms/course/view.php?id=8](https://byglearning.com/mrcsc-lms/course/view.php?id=8)

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](mailto:hta_help@admin.ox.ac.uk)

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