Message from Brian Shine, Designated Individual for HTA Licence 12217

Welcome to the new academic year and to the Michaelmas newsletter. The previous newsletter was released before the inspection by the HTA in June. That seems a long time ago: as you know, the inspection team was very impressed with what all of you have achieved, and they found only a small number of problems, and we are on track to complete all of the Corrective and Preventative Actions by the end of next month. I would like to say a big "Thank you" to everyone for all your hard work, and especially to the Governance Team. All of us working under the Licence benefit from the greater compliance and peace of mind knowing that we are good stewards of the valuable material entrusted to us by donors. Let’s continue finding important uses for these collections.

Best wishes,
Brian

Thank You for Sharing
This term we thank Philippa Kemp from Cardiovascular Medicine for hosting HTGT staff and demonstrating how iPassport can be used to deliver and track training and Tiphaine Bouriez-Jones of the Kennedy Institute has shared some documentation with NDMRB staff. Andrew Graham and Mark Evans in NDCLS made sure that we had adequate space and a working projector during the HTA inspection. Extra thanks to Mark Evans for presenting a Departmental Administrator’s perspective on culture change in HTA matters at the annual RISN conference. Sophie Baines organised an MTA workshop for Research Tissue Bank staff replete with biscuits!

https://www.pexels.com/photo/person-playing-mini-fig-1660662/
Changes to the University’s HTA training platform and related training web pages

The Human Tissue Governance Team is in the process of updating their training web pages to reflect a change in the HTA training platform used by MSD for all staff working with human tissue. The previously required WebLearn course has been retired and can no longer be accessed. Instead, staff need to complete the freely available MRC e-learning entitled ‘Research and Human Tissue Legislation’ and pass the assessment (for England, Wales, and NI only) with a score of 70% or higher. This change has been agreed by the Division’s Human Tissue Governance Committee and has been discussed in Licence 12217’s Risk Management Committee and Operational Management Committee.

Further details (including a new flowchart, updated FAQs, contacts page and glossary etc) and a link to the course will be available on the updated web pages when they go live at the end of October (exact date to be confirmed and is subject to the technical time taken to amend the relevant pages). In the meantime, if you or a colleague need to complete/renew the training then the links to the e-learning and related assessment are as follows:

1. MRC’s e-learning module: ‘Research and human tissue legislation’ training: https://byglearning.co.uk/mrcrsclms/course/view.php?id=42
2. MRC’s England, Wales and NI assessment (where you get your certificate at the end): https://byglearning.co.uk/mrcrsclms/course/view.php?id=43

Of note:
- Staff will need to create a user account and the training page is hosted by the MRC
- The pass rate is 70%
- Staff need to dedicate time to complete the training in one go as there isn’t the option to save and complete at a later date
- Staff need to download their certificate and keep hold of it (you cannot download it again once completed)
- Training still needs to be completed every two years
- Responsibility for tracking completion of training remains with the departments

Watch out for further updates on the University’s Human Tissue Governance training website: https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training

Use of iPassport for tracking completion of training for staff working under Licence 12217

Tasks coming to an inbox near you soon!

As well as a change of training platform, Licence 12217 will be introducing an extra layer of assurance of completion of training for staff working under the Licence. The team will be using iPassport to create tasks for 12217 users to attach their valid HTA training certificate to the system in the form of a ‘competency test’. This doesn’t necessarily mean that everyone has to suddenly take the new MRC training straight away (although I think lots of people will be close to the two year renewal mark soon), we’re just asking that staff attach a valid HTA certificate – so a WebLearn or electronically scanned hard copy of an appropriately in-date (i.e. within the last two years) certificate is acceptable. This is a great opportunity to check the date on your HTA training certificate and ensure that it is in date!

It is hoped that this new process will not only make auditing of training easier, but will help staff ensure they always have in-date training as the system will send a reminder email ahead of the renewal date to remind the staff member to re-take the training. Further information on this point will be included in an update to the core Licence SOPs HTA013 and HTA009. Specific communication will be sent separately to Collection Responsible Officers in due course as there will be a requirement to audit this new process and create the initial renewal tasks. This change of process will be in addition to any local/departamental arrangements for storing HTA training certificates.
The core documents for the Licence are being updated – ensure your references are correct too!
The core documents have been reviewed and updated to align with the updates to the HTA training. This has been an additional piece of work for the team because we realised we referenced/linked directly to the WebLearn training in all of the documents (doh!). To futureproof this process, we’ve amended any HTA training reference link to be to our training web page (https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training) instead of a specific training platform. The website will always have the latest information on it. We would recommend that everyone reviews their relevant documentation and ensures that any reference to HTA training links to the website too. At least it’s given us an opportunity to review all the information in the documents to ensure they are tip-top.

--Rachel Lloyd

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<th>MRC Regulatory Support Centre Human Tissue Forum</th>
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<td><strong>Kathryn Robson</strong>, DI for HTA Licence 12433 at the WIMM, hosted the MRC Regulatory Support Centre on 11 July for their Human Tissue Forum. The event was attended by representatives of HTA research licences from across the UK, as well as staff from the University’s Research Services. Guest speakers covered discussing animal research with donors and the sustainability for biobanks. MRC staff spoke about delivering on donors’ expectations and working with European collaborators, as well as leading interactive workshops. It was a wonderful opportunity to discuss governance issues with staff from many other universities. You can read more about the forum on the UKCRC’s blog by following this link.</td>
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<td>We welcome <strong>Katie Ewer</strong> as Collection Responsible Officer of new collection 00106: Jenner Malaria and Outbreak Pathogens, based at ORCRB. We also welcome the new CRO of the existing CIG Archive collection (00042), <strong>Viorica Liebe Lastun</strong>. Governance Manager Marie is on leave until January, keeping very busy with new family member <strong>Annabel</strong> (who is very cute).</td>
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<th>Operational Management Committee meeting</th>
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<td>CROs from across the Licence met on 04 September and discussion included updates on the inventory system tender, Nexus 365 Teams, the new CAPA plan, and adoption of new samples into existing collections. All CROs have access to the meeting minutes (in draft) available on iPassport (Licence Governance &gt; Meetings &gt; in the Name field search for “Oper” and choose 04 Sept. The minutes are under the Attach tab). The next meeting takes place Wednesday, 04 December.</td>
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The McClouds from Chicago &4039;burbs, USA [CC BY-SA 2.0 (https://creativecommons.org/licenses/by-sa/2.0)]
Drop-in Clinics to Resume
Monthly drop-in clinics for all University staff (whether working under an HTA licence or not) will resume on 14 November. The team is eager to find out whether these are considered helpful, and this will determine whether they continue. Feel free to send new starters and students to the clinic with their questions. The 14 November clinic will be held at the JR in the NDCLS Meeting Room, 9-11am.

Teams update:
A Teams site has been created specifically for our CROs to connect and collaborate with one another across the Licence. However, the Microsoft Teams platform is freely available for all to use within the University! Please contact the Nexus Team for more information.

As our Collection Responsible Officers will be aware, the CROs’ Teams site is still under development, however, the final changes are due to be completed the week commencing 21 October 2019 when the CROs’ access will be enabled. Please remember that the first email will be from the HTGT email account and will include ‘How to use Teams’ guidance, as an attachment. A second email from the platform will follow and include a link to access the Teams site. If you have any questions, please start with the ‘How to use Teams’ guidance.

--Ben Haxton

Did You Know?
The Safety Office will be rolling out online reporting for incidents: https://projects.it.ox.ac.uk/incident-reporting-and-investigation-system-iris

Reminder about risk assessment awareness
A minor non-compliance was identified during the June 2019 HTA inspection of the Licence. The inspection finding was:
Although there are core risk assessments for all processes and practices requiring compliance with the HT Act and HTA’s Codes of Practice, there is no reference to them in the individual biobanks/collections documentation. As a result not all staff are aware of them.

We have put the following measures in place to rectify this issue:
- We have added the core risk assessment for the Licence (HTA_RA001) into the Licence Level skilled groups on iPassport so that all staff working under the Licence read and acknowledge the document.
- We discussed this non-compliance with Collection Responsible Officers during September’s Operational Management Committee. This meeting is for key governance staff working in individual biobanks/collections

As a reminder: please ensure there is reference to the core risk assessment HTA_RA001 (iPassport link: https://htg.ipassportqms.com/show_document?doc_id=e1cacf45cd187bb910a2eee7a9e295d9&latest=true) in any relevant research tissue bank/registered collection documentation.

Calendar
18 October 14.00-16.00 Governance Management Committee meeting (by invitation only), Boundary Brook House
31 October 09:30 to 14:00 Introduction to GRP, Boundary Brook House, to book a place contact Mark Crossley at mark.crossley@admin.ox.ac.uk
01 November deadline to register for UK Biobanking Showcase
06 November Human Tissue Authority annual conference in London
Register for waiting list at https://www.hta.gov.uk/HTAconf19 also being live-streamed 10am – 4pm at https://www.youtube.com/channel/UCMx0CFhYhXDMebrlZZjzVFA/videos
12 November 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

14 November 9-11am **HTA Drop-in Clinic**, NDCLS Meeting Room (Level 4 of the JR Academic Block) Open to all University staff, no booking required. Bring your HTA-related questions

19 November **UK Biobanking Showcase**, Nottingham [Link]

27 November Safety Office Risk Assessment training [waiting list link]

28 November 09:30 to 16:00 **Introduction to GCP**, Boundary Brook House, to book a place contact Mark Crossley at mark.crossley@admin.ox.ac.uk

04 December 13.30-15.30 **Operational Management Committee** meeting, (by invitation only), Boundary Brook House

12 December 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

17 December 09:30 to 14:00 **Introduction to GRP**, Boundary Brook House, to book a place contact Mark Crossley at mark.crossley@admin.ox.ac.uk

**HTA News**

The HTA has made extensive updates its FAQs, which can be found at [this link](https://www.hta.gov.uk/). Their free, all-day annual conference takes place in London on 06 November. You can watch it streamed live at [https://www.youtube.com/channel/UCMx0cFhYhXDMfbriZj2VFA/videos](https://www.youtube.com/channel/UCMx0cFhYhXDMfbriZj2VFA/videos) or get on the waiting list for tickets (see link in Calendar above).

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: Temperature monitoring and looking for trends**

The recent inspection by the HTA of our licence highlighted that our efforts to monitor the temperatures of our storage equipment could be improved. Specifically, “to ensure all temperature controlled units storing relevant material are monitored, maintained and deviations in storage conditions acted on when required” ([note: if you must store relevant material in a temperature controlled unit, but you do not monitor the equipment, you must ensure that you have a valid explanation for this activity](#)).

This raises the question: how can we improve how we monitor temperatures, if the monitoring software is doing its job properly and why should we? Our passive reliance upon a temperature monitoring system to alert us to an issue has served many of us well and certainly gives us peace of mind and time to respond when an alarm message is received at 11pm on a Friday night. However, when the need arises for staff to respond to an alarm out of hours, this is associated with an increased risk to the samples and personnel’s safety, even when the risks have been identified and mitigated against.

1) Using the software to actively monitor temperature trends on a week by week basis allows us the opportunity to pre-empt issues. Managing this process will allow us time to implement controls as a team and manage the risk to our collections in a coordinated way during core hours, reducing the risk to our staff and our samples.

2) How can we demonstrate to the HTA that we have responded effectively to their advice? Keep it simple and document the basics:

- Use either a paper log or electronic, whichever fits your processes best.
- Record the equipment name, serial number or the reference used on your temperature monitoring system - either way, be consistent.
- Room location of the piece of equipment - sometimes this changes, so it is useful to include this.
- Temperature in range? Yes/no?
- Observations/Trends/Comments: this is where your input matters! Are you seeing intermittent readings? Is there a general increase or decline in temperature over the week? Make a note and raise with your lab manager or facilities team - ask if anyone else sharing the room is affected? What measures have been
taken to resolve it, is it a ‘near-miss’ or an actual non-compliance? If so, remember to log either on iPassport.

3) Who should be responsible for this? As long as the weekly checks are documented, one person does not need to take sole responsibility for this activity, therefore, a team can take shared responsibility under the supervision of the lab manager or similar responsible person. Consider collating this information into an end of year internal audit on iPassport for the PFE3 standard.

Other considerations

Use of a spare temperature probe as a backup sentinel will either confirm or refute the readings you are seeing. Where this is not available, think about raising a case to purchase one and ensure your battery supplies are replenished for when batteries fade!

--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