Welcome from Brian Shine, Designated Individual for HTA Licence 12217. Welcome to the latest newsletter. We have done really well over the past year, completing the CAPA. Nearly everyone who needs training has had it. We are starting to extend iPassport to departments, and this will allow us to have coordinated SOPs in most areas, and to plan and carry out audits. Over the next few months, we will produce an option appraisal for software for sample tracking, to improve the safety and reliability with which we store and use tissue.

Best wishes,
Brian

Update on the Corrective and Preventive Action plan (CAPA) for Licence 12217
The mammoth task of addressing the shortfalls identified by the HTA during the 2017 inspection necessitated such a sustained and collaborative effort by so many of you that I am sure the news that the corrective and preventative action plan (CAPA) has been completed will fill you with as much joy as it did us in the governance team.

The HTA has written to Brian Shine to state that they are satisfied that Licence 12217 now fulfils its obligations under the legislation. This would not have been possible without all of you working tirelessly to improve compliance, so from the bottom of our hearts, thank you.

Notably, one of the most ambitious tasks of the CAPA was completing systematic searches of licensed premises. We hope that beyond the hassle of such an undertaking, the exercise helped each group, institute or department identify areas of concern, resolve problems and put in place systems to strengthen governance at the local level. Those of you who have not shared the results of your searches with the HTGT, please do so at your earliest convenience, so that we can check that everything is as it should be. It’s particularly valuable for us to be able to track samples under specific REC approvals so that when the time comes for the end of a study, we’re able to assist the researchers in managing any leftover samples. All that data that you collected is a gold mine for our team, so please do share it!

We cannot rest on our laurels, though, as there are still many improvements we can make for the Licence: implementing quality management systems, improving traceability, sharing best practice, capturing end of study arrangements to avoid licensing breaches, providing better and more relevant training, etc. But if we could complete the CAPA, we can do anything, right?
–Marie Hamard
Persons Designated (PD) meeting
On 21st September 2018 the DI and HTGT organised a PD meeting where 18 PDs (or their deputies) attended to hear updates on a wide variety of topics related to the Licence, including:
- The HTA closing the CAPA on 30 May 2018, but HTGT are still under direction to continue weekly updates to the HTA
- That 59 weekly updates have been submitted to the HTA
- More consistency seen in adverse event reporting, auditing and disposal of samples
- Premises searches have been undertaken
- The issue of needing a traceability system for the Licence
- That the training is currently being updated
- That the iPassport quality management system was ‘going live’ for document control on the following Monday (24th September 2018)
- That HTGT are working with other colleagues in CTRG, OUHFT R&D, and Contracts etc. to streamline processes and share knowledge amongst the teams

It was also an opportunity for the DI to thank everyone for their hard work and commitment to quality improvement, and to discuss the learning from the previous inspection and what the Licence structure and governance processes could look like in the future.

Of note: the name of the PD meeting will be changing to the ‘Governance Management Committee for HTA Licence 12217’ in future.
--Rachel Lloyd

Licence 12217 ‘Thank you’ coffee and cake event for charity, 8 November
Boundary Brook House, Churchill Drive

What better occasion to celebrate than the closing of the CAPA plan?
With this in mind, we’d love to gather all of you working under the Licence, and all of you who helped make the CAPA a success, for a social get-together around baked goods. Please look out for an invite to this event, which will feature a charity bake sale, the opportunity to catch up with colleagues in a relaxed setting, the chance for us to thank you warmly, and no PowerPoint presentations whatsoever.

iPassport Quality Management System
At the end of September HTGT released login details and access to iPassport quality management system (QMS) to over 200 staff working under HTA Licence 12217. Using an electronic QMS reduces the administrative burden of producing evidence that staff working under the Licence have read and acknowledged core SOPs and risk assessments. It also replaces HTGT web pages as the source of current versions of forms and templates. Other benefits soon to be realised include automated document control for groups with licensed collections that do not have their own electronic QMS or who wish to replace SharePoint for document control. The Oxford Brain Bank is piloting its use currently. HTGT are already using iPassport to track adverse reports behind the scenes and the module will become available soon to all concerned with incident reporting. Collection Responsible Officers will be contacted with training dates. Roll out of a module for audits is coming, too.
Operational Management Committee, 7 December

In evaluating the governance meeting structure for the Licence, and to support the CROs further in their quality improvement work, the HTGT are convening a termly Operational Management Committee (OMC). The first meeting of this committee will be held on 07 December from 10am to 12pm. These meetings will allow CROs the opportunity to come together to receive updates on Licence-level activity, discuss adverse events and audit findings, and to share best practice across collections. It will also be a great way to meet other CROs and supports the requirement of the HTA standards and guidance, in particular GQ1 that: “matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff”.

Licence-level Annual Audit Schedule

As the licence-level annual audit schedule for 2018 is coming to an end, the HTGT would like to take this opportunity to thank everyone for their engagement and input at each stage in the process. We hope you found them as useful as we did. If you have any feedback on your experience then please do email us at: hta_help@admin.ox.ac.uk and we’ll look to incorporate that into next year’s audits.

Talking of next year’s audits, the 2019 audit schedule was presented and approved at October’s Risk Management Committee. It follows a similar pattern to this year’s audit schedule in that all collections registered under the licence will have an audit. However, some slight changes have been made following learning from this year’s audits:

- Collections that have connections to each other have been grouped together to be audited at the same time. The intention behind this is to allow the HTGT to understand the overall governance arrangements for those collections and to homogenise any resulting actions; and
- Rather than having PDs shadowing the audits, we have instead included CROs from similar collections into our audit team. The intention behind this is to allow a peer review element to the audit to encourage shared learning across collections. This aspect of the audit schedule will be discussed with CROs at the OMC on 07 December.

--Rachel Lloyd

Calendar

01 November 9-11am: free drop-in clinic with HTGT at Boundary Brook House
01 November 12:30-13:30 Copyright and Research Data: free, registration link
08 November 10amnoon: Licence 12217 ‘Thank you’ event
15 November MRC Human Tissue Workshop in Oxford: Registration link
27 November UK Biobanking Showcase in London
07 December 10amnoon: Operational Management Committee meeting
10 January 2019 annual HTA Forum

Please note that there will not be a drop-in clinic on the first Thursday of December

HTA News


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

Hot tip: what if my samples are not for research?

One of the more confusing areas of the Human Tissue Act is the concept of “scheduled purposes”. These are defined as purposes which require consent, but they also influence the licensing requirements of the Act. This is because HTA licences are granted to establishments to store human tissue of relevant material for scheduled purposes – from this stems the fact that if an activity is not a scheduled purpose, it lies outside the scope of the Human Tissue Act.

Research is a scheduled purpose, for which consent and HTA licensing are required, whether the samples are collected from living or deceased donors (unless exemptions apply). Other activities are considered scheduled purposes when conducted on samples from the deceased, but not on samples from the living: for example, teaching, performance assessment and quality assurance.

The interpretation of what constitutes a scheduled purpose is not always straightforward, because the categories are not well defined: what constitutes “performance assessment” or “quality assurance”, for example? How do we define “research”?

In short, when storing / using samples of relevant material, whether what you are doing requires HTA licensing depends on:

- Whether the sample was removed from a living participant / patient, or from a deceased person; AND
- Whether what you are doing with a sample (or what you are keeping a sample with the intention of doing later) directly contributes to a scheduled purpose.

For example, using a sample from a living donor as a way to calibrate an instrument before analysing samples from a research cohort is not a scheduled purpose: no research data is derived from running that calibration sample through the machine, the sample is not contributing to the scientific question and isn’t included in the results of the study. In this case, the activity more closely fits with quality assurance, which is not a scheduled purposes for samples from the living.

Examples of activities and whether they should be considered a scheduled purpose (and therefore require HTA licensing unless an exemption applies) can be found in the table below:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Scheduled purpose or not?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using a sample as a reagent (e.g. feeder cells)</td>
<td>NO</td>
</tr>
<tr>
<td>Using a sample from the living as an immunohistochemistry control slide, where the slide will not be analysed as part of the results and only serves to check the method worked</td>
<td>NO</td>
</tr>
<tr>
<td>Using a samples from the deceased as a control slide</td>
<td>YES</td>
</tr>
<tr>
<td>Testing a commercially available kit or antibody with a sample from the living to check the method works, where no data will be derived from this test</td>
<td>NO</td>
</tr>
<tr>
<td>Testing a commercially available kit or antibody with a sample from the living to check the method works, where the results will be used as baseline data</td>
<td>YES</td>
</tr>
<tr>
<td>Testing a commercially available kit or antibody with a sample from the deceased</td>
<td>YES</td>
</tr>
<tr>
<td>Developing a new analytical method / antibody with samples from any donor</td>
<td>YES</td>
</tr>
<tr>
<td>Using samples from the living to teach medical students</td>
<td>NO</td>
</tr>
</tbody>
</table>
When in doubt, always assume that the HT Act does apply to what you are doing, rather than the other way around.

The important take-home message here is to consider not just what is being done with the tissue right now, but what is the intention for holding the sample: samples kept after a completed study or trial, for example, may not be immediately used, but if they are being stored on the basis of their usefulness (or potential usefulness) for future research, then they are stored for a scheduled purpose.

To facilitate governance it is helpful to label samples for use for different purposes; for example, labelling a box of frozen blood samples as “samples for use as feeder cells” or “samples for FACS calibration” makes the purpose they are stored for clear. Similarly, label control blocks collected from the living for use as immunohistochemistry controls, or any other samples which are stored for an activity which is not a scheduled purpose. If doing work with samples from living and deceased donors, ensure yourself and colleagues can tell at a glance which is which so that everyone knows which samples need to be under the governance of an HTA licence.

Please remember that teaching collections comprised of samples from deceased donors must be stored under an HTA licence; Licence 12217 has a number of registered teaching collections which are valuable resources. The HTA’s website has helpful information and Frequently Asked Questions about research, including some about scheduled purposes. https://www.hta.gov.uk/faqs/research-faqs. The HTGT also has a FAQ section available on our website https://researchsupport.admin.ox.ac.uk/governance/human-tissue/faqs-glossary/faqs. Please do remember that our drop-in clinics are available to all and take place every first Thursday morning of the month, alternating between the Churchill Site (Boundary Brook House) and the John Radcliffe Hospital (typically the NDCLS seminar room on level 4 of the main JR). Please see the HTGT website for details of the next clinic.

--Marie Hamard

Miscellaneous

A gentle reminder not to send participant-identifiable information to HTGT: https://researchsupport.admin.ox.ac.uk/governance/human-tissue/faqs-glossary

The new Governance arrangements for Research Ethics Committees (GAfREC) policy took effect on 17 September 2018


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