Compliance update questions: Research.

1. **Which of the following terms describes your establishment (Please select all that apply?**
    - Commercial
    - Academic
    - NHS
    - Charity
    - Other

    If you answered 'other', please explain here.

Guidance: We recognise that establishments may be involved in other types of collaborations/ partnerships that do not fit within a category. Please feel free to select all that apply and use the free text box to provide us with information.

2. **How many relevant material samples do you store under your licence?**

Guidance: Please provide an approximation of the total number of relevant material samples stored under the authority of your HTA licence. This number can be tens, hundreds or thousands of samples. This figure does not include any samples stored for research projects with current ethical approval from a recognised (e.g. NHS) Research Ethics Committee (or pending such approval).

3. **How many relevant material samples do you currently store with current ethical approval from a recognised (e.g.NHS) Research Ethics Committee?**

Guidance: Please provide an approximation of the total number of relevant material samples stored for research projects with current ethical approval from a recognised (e.g. NHS rather than a University) Research Ethics Committee. This number can be in tens, hundreds or thousands of samples. This figure does not include any samples being stored under the authority of your HTA licence.

4. **Does your establishment have common policies to manage relevant material, whether stored under your HTA licence or for research projects with current ethical approval from a recognised (e.g. NHS) Research Ethics Committee?**
    - Yes
    - No

5. **How are the expiry dates of REC approvals tracked?**

6. **Relevant material is stored at (please select all that apply)?**
    - Room temperature
    - 4°C
    - -20°C
    - -80°C
    - -140°C
    - Liquid Nitrogen

7. **Is your establishment a Research Tissue Bank (RTB), or does is contain one or more RTBs?**

    - Yes
    - No

    If yes, please provide the RTB title(s) and REC approval numbers

Guidance: NHS RECs can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. Such research tissue banks need to be licensed because at least some of the tissue being stored is not for specific projects holding REC approval. Please provide the RTB title(s) and approval number(s) for all the RTBs at your establishment.

8. **If you release tissue from a tissue bank to researchers, what arrangements do you have in place to ensure that decisions about release are made fairly and consistently?**

Guidance: If there is an access committee, please explain how it operates and how it is constituted (names of individuals are not required). If you do not have a committee, please describe the other arrangements you have in place.

9. **Is relevant material transferred to or from your establishment?**

- Yes, we transfer all relevant material under documented agreement/s
- Yes, however only some agreements are documented
- Yes, however there are no agreements in place
- Not applicable, no relevant material is transferred to or from our establishment

Guidance: If relevant material is transferred between establishments or is stored on behalf of other establishments, consideration must be given to minimising the likelihood of theft, damage or loss during transport. Some form of formal arrangement, for example, as part of a Material Transfer Agreement (MTA) should provide assurance that consent has been obtained in accordance with the Human Tissue Act 2004, and the HTA Codes of Practice; it should also define how the human tissue is preserved during transport, any potential contamination risks associated with it, and who is responsible for disposal, if applicable.

10. **Donors whose samples may be used in research linked to the establishment are (please select all that apply)?**

- NHS patients
- Private patients
- Healthy volunteers (who are not staff)
- Establishment staff
- Other

If 'other', please explain

11. **Is your establishment subject to either of the following types of inspection?**

- Good Laboratory Practice (GLP)
- Good Clinical Practice (GCP)
- UKAS accreditation

Additional information (optional)

Consent questions

12. **Which of the following research activities are you involved in? (Please select all that apply)?**

- Genetic analysis
- Use of animals
- Commercial sector
- Storage for specific research
- Storage for future use (unspecified research)
- Export

13. **The information used to support consent seeking (consent form/s and information sheet/s) includes the range of expected research to be undertaken (as selected above)?**

- Yes
- No
- Not applicable

14. **There are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice?**

- Yes, there are agreements in place that stipulate consent is obtained in accordance with the HT Act
- Yes, but at least some agreements are not documented
- No, there are no agreements in place but there is an informal confirmation that consent is in place
- No agreements are in place
- Not applicable, third parties are not involved in consent taking – please explain why?

If you answered 'no agreements are in place' or 'not applicable', please explain why:

Guidance: Please answer this question if consent is obtained on behalf of your establishment by other organisations.

15. **When did members of staff who seek consent last receive consent training?**

- Within the last two years
- More than two years ago
- They have never been formally trained
- Not applicable, consent is not obtained by our establishment

Governance and Quality Systems questions

16. **Are overarching documented policies and procedures in place for all licensable activities?**

- Yes
- No

Please provide details?

Guidance: Where licensable activities are taking place under different management arrangements, for example research groups led by different Principle Investigators, please indicate whether these are governed by policies and procedures developed for each group individually or there are overarching governance arrangements in place.

17. **Which of the following do your SOPs cover (select all that apply)?**

- Consent
- Consent withdrawal
- Receipt
- Labelling
- Storage
- Cleaning and decontamination
- Disposal

18. **Which of the following incidents would be covered by your system to manage adverse events. Please check all that apply?**

- Specimen loss
- Missing or incorrect documentation
- Security breach
- Abnormalities in storage temperature records
- Inappropriate disposal
- None of the above

19. **How many adverse events (relating to HTA-licensed activities) have been managed in the past two years? Please include details?**

20. **If removal of relevant material from the deceased for research takes place under the licence, please provide details on this activity ('N/A' if not applicable)?**

21. **Are risk assessments in place for all licensable activities?**

- Yes
- No

Please provide details

Guidance: risk assessments relating to licensable activities include storing specimens without appropriate consent, storing specimens after consent withdrawal, storage failure, loss of relevant material, loss of traceability, security breach, incorrect disposal (see Code E G&S).

22. **Does your establishment provide HTA specific training to relevant staff that work under the licence?**

- Yes
- No

Please provide details of staff training

Traceability questions

23. **Does your establishment use a system to trace all relevant material that is acquired, stored, used, transferred or disposed of on the premises?**

- Yes, a system is used which is secure to mitigate the risk of data loss
- Yes, an electronic and/or paper based system is used but there is no provision to mitigate risk of data loss
- No, there is no formal system to capture traceability

Guidance: Records may be in various formats, including paper based, electronic, or stored on other recordable media.

24. **What type of audits have been undertaken over the past 2 years?**

- Traceability audit of records and specimens
- Horizontal audits of processes
- Document audits
- Audits of consent forms
- Audits against the HTA standards
- Other (please describe)

Premises, Facilities and Equipment questions

25. **Do you have formalised contingency arrangements in place in case of failure in the storage area?**

- Yes, the contingency arrangements are documented and formally agreed
- Yes, the contingency arrangements are in place but informally agreed
- No, there are no contingency arrangements in place
- Not applicable – please provide more information

If you answered 'No, there are no contingency arrangements in place' or 'Not applicable', please provide more information here:

26. **Are your critical storage conditions monitored and alarmed?**

- Critical storage conditions are monitored and alarmed
- Critical storage conditions are monitored but not alarmed
- Critical storage conditions are not monitored but are alarmed
- Critical storage conditions are not monitored or alarmed
- We do not require critical storage conditions to be monitored or alarmed – please provide more information

If you answered 'We do not require critical storage conditions to be monitored or recorded', please explain here: