HTA Stakeholder and Fees Group meeting agenda

Date 29 May 2019

Time 2.00pm – 4.00pm

Venue 110 Rochester Row
London
SW1P 1JP

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1.	Welcome and introductions	Oral
2.	Minutes, actions and matters arising	Oral
3.	HTA licensing and fees project	Paper (1/19)
4.	Digital transformation project	Oral
5.	Developing learning resources for licensed establishments	Paper (2/19)
6.	EU exit update	Oral
7.	Human Application sector risk project	Paper (3/19)
8.	HRA/HTA public dialogue joint project	Paper (4/19)
9.	Deemed consent for organ donation in England	Paper (5/19)
10.	Horizon scanning	Oral – all
11.	Proposed items for next meeting	Oral
12.	Any other business and date for next meeting	Oral

Minutes of the tenth HTA Stakeholder and Fees Group meeting

Date	22 October 2018
Venue	151 Buckingham Palace Road London SW1W 9SZ
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Present	
In attendance	**Apologies**
Stakeholders	
Fidelma Murphy, NHS Blood & Transplant (FM)	Ann Russell, Independent Cancer Patients' Voice
Kay Wadey, Public representative (KW)	
Ceri Davies, Anatomy Associations Advisory Committee (CS)	Emma Radway-Bright, Anthony Nolan
Wendy Birch, Institute of Anatomical Sciences (WB)	Ben Charles, Biovault
Sarah Dickson, MRC Regulatory Support Centre (SD)	
Sarah Rappaport, Wellcome Trust (SR)	Dr Kamal Ahmed, HCA Healthcare
Kirstin Goldring (AstraZeneca) (via phone) (KG)	
Rachel Maxwell, Belfast Health & Social Care Trust (via phone) (RM)	Veronica English, BMA
HTA	Hirasine Sengomona, Anthony Nolan
Hazel Lofty (HL), Richard Sydee (RS), Amy Thomas (AT), Chitvan Amin (CA), Matthew Silk (MS), Maria-Paulina Socarras (MPS) – minutes	
Chair and Board Members	
Bill Horne, HTA Authority Board Member (BH) – SFG Chair	
Prof. Dame Sally Macintyre, HTA Authority Board Member (SM)	

Item 1 – Welcome and introductions

1. The Chair (BH) welcomed Stakeholder and Fees Group (SFG) members to the meeting.

2. BH also welcomed two new members to the group, Sarah Dickson of the MRC Regulatory Support Centre and Kirstin Goldring of (AstraZeneca).

3. BH thanked Ceri Davies for attending the meeting on behalf of Claire Smith who was unable to attend.

4. The chair introduced Prof. Dame Sally Macintyre, HTA Authority Board Member, who was attending her first meeting of the group.

Item 2 – Minutes and matters arising

5. Minutes of the meeting of the 9 May 2018 were reviewed and agreed following slight amendment to paragraph 28.

6. The progress made against each action is summarised in the table below.

Stakeholder Group Actions	Progress
HL to speak to Richard Sydee regarding the potential impact on licence fees if adding licensable activity from another sector to an existing licence.	**Action complete.** HL stated that this is an issue that has been raised in the past. Public Display has its own legislative requirements under the HT Act, therefore an Anatomy establishment would need to ensure it met those specific requirements in order to obtain a licence.
MPS to seek feedback from ERB regarding her experience of dialling into the meeting.	**Action complete.** MPS sought feedback and suggestions from members dialling into the last SFG meeting. BH encouraged those dialling into this meeting to share their feedback on the quality of the new conference call equipment being used after the meeting. Members were encouraged to avoid shuffling papers as the noise was amplified for those dialling in.

Stakeholder Group Actions	Progress
To include an agenda item on the GDPR at the next meeting	**Action complete.** HL stated that GDPR has not been included onto the agenda as the HTA do not want to compound any misunderstanding of our role in this area. It is an establishment's responsibility to ensure they comply with the GDPR and DPA. SD informed the group that the MRC have done a lot of work to support the Research sector to comply with recent changes to data protection legislation. **ACTION: SD to forward any useful information for the Research sector that can be shared in the HTA newsletter with MPS.**
Send proposed dates for October 2018 meeting	**Action complete**

7. A discussion took place on the GDPR. SD flagged that there is a potential issue with how certain data is defined, particularly with anonymised and pseudonymised data. HL stated that it would be useful to have specific examples of this so the HTA can update any guidance. **ACTION: Members to forward any examples of difficulties in this area for consideration by HTA.**

Item 3 – Fees 2019/20

8. RS led a discussion on the proposed fees budget for the 2019/20 business year.

9. The HTA has seen a reduction in fee income. There have been superficial cost savings for licence holders but not for the HTA. The proposal is to raise 2019/20 fees in line with CPI inflation.

10. There is a need to charge licences to reflect the current environment that we're working in. The HTA has no other way to raise necessary funds to cover regulatory effort except through licence fees.

11. The HTA will be consulting with stakeholders in early 2019 on a revised fees model. The last review of the fees model took place in 2016.

12. FM raised concerns that the HTA should be transparent in showing how it is saving money in time of austerity. It would be useful for stakeholders to have this information.

13. SD stated that there is a big difference between main and satellite licence fees costs in the Research sector. There is a query as to whether the HTA are finding that there is an increase in those applying for satellite licences and if there is a risk inherent in this scenario.

14. RS explained that there is a concern about where we spend regulatory effort. Some sectors are reducing and others are going above inflation. The fees consultation will help the HTA understand what causes the increase in regulatory demands in some areas in a transparent way.

15. The HTA is cognisant of the fact that a lot of establishments are facing financial pressures and are seeking the right governance framework in order to charge establishments the right fee.

16. Members requested that they be involved in the 2019 discussions at an early stage. **ACTION: RS to build in discussion with SFG members as part of the early 2019 consultation.**

Item 4 – Opt out update

16. CA led the group through a discussion and update on the Government's intention to move England to an opt-out system of consent for deceased organ donation and the HTA's project to develop and update the Codes of Practice to reflect changes to legislation.

17. The Deemed Consent Bill that is currently making its way through parliament only applies to organs, tissues and cells for transplantation.

18. The Bill intends to amend the interpretation of 'appropriate consent' set out in the HT Act to mean that where a person has not made a decision regarding organ donation during their life, or appointed a representative for this purpose, then consent may lawfully be deemed.

19. Once consent is deemed to have been given, there will not be a legal basis for the family to overrule or change the decision. However, the Government's response to the public consultation introduces the possibility of a personal discussion between the family, the specialist nurse and clinicians at the bedside, before donation goes ahead. This is to reflect faith and cultural considerations and the views of the family.

20. FM stated that current discussions with families and loved ones at the time of bereavement are long and sensitive. Medical professionals are skilled in handling discussions on faith and ethics. It is important that families are given

adequate time and space when making these decisions. The input of faith and beliefs in these discussions would introduce a change in how they are handled.

21. BH informed the group that Wales undertook a significant communications campaign to encourage donors to have conversations with loves ones on their donation decision. This involved ensuring that the information provided to the public was clear and accessible. The HTA has no say in changes to the legislation but would need to develop processes that help families and medical professionals understand the new system.

22. The HTA will be consulting with stakeholders and the public on what the new Code should look like and what will be involved in discussions with the family.

Item 5 – Post Mortem sector development project

23. AT provided the group with an update on the HTA's Post Mortem sector development project and upcoming report publication.

24. The HTA are looking to develop targeted advice and guidance for the sector. This includes specific information that establishments need to be aware of in future editions of the professional e-newsletter.

25. AT explained that the HTA will continue to maintain visibility in the PM sector and will undertake a comprehensive review of the guidance that currently sits with PM licensing standards.

26. The issues that the HTA have found in the sector are not at the same scale as when the organisation was established. We are finding problems at a more local level, specifically with individual Trusts. Quite a few establishments have struggled to embed the changes from the revised Codes and Standards.

Item 6 – EU exit update

27. AT led a discussion on EU exit and the Government's publication of technical notices regarding organs, tissues and cells.

28. The HTA are working closely with DHSC through a series of monthly meetings. The HTA are committed to maintaining strong links with EU colleagues.

29. The current situation is unclear, however the HTA need to ensure that establishments understand the licensing requirements for how organs, tissues and cells can be transported between EU Member States in the event of a 'no-deal' scenario.

30. The key messages coming from DHSC are that establishments must continue to work to the same quality standards. The technical notices are available on the

Government's website and there is likely to be further information published in November.

31. FM stated that NHSBT are in the midst of contingency planning. They may encounter issues with transportation and therefore they would need to know how they can work with the HTA when it comes to moving organs or cells.

32. AT explain that the HTA is unable to give any certainty to establishments at this stage but will continue to share information as and when appropriate.

Item 7 – Horizon scanning

33. BH introduced a new rolling horizon scanning agenda item to SFG meetings. The purpose of this item is for the group to share emerging policy issues for discussion amongst members. There are three policy and development areas that the HTA have been looking at.

    i. ***Cosmetic regulations***
    The HTA have been asked by DHSC to look at cosmetic regulations. There are certain tissue and cell based products that are exempt from our regulation, for example a "same surgical procedure" or an advanced therapy medicinal product (ATMP) that is subject to medicines legislation. However, it is unclear whether this is something the HTA needs to investigate as part of borderline regulation. It is likely that the public will be approached for their views on this area.

    ii. ***Organ perfusion devices***
    The HTA is aware of devices that are being used to deliver treatment to organs prior to implantation. The use of these devices has increasingly become more routine, rather than used as part of research. They are classified as medical devices so would be regulated by the MHRA, however we are looking at whether we need to make our guidance more robust. It may also result in some changes to our ODT framework document.

    iii. ***Consent for imported material***
    There has been some media coverage on recent exhibitions such as *Real Bodies* and *Body Worlds* that have been displaying imported anatomical specimens to the public. The consent requirements of the HT Act for the public display of human material do not apply to material sourced outside of England, Wales and Northern Ireland albeit our Codes of Practice do require that any laws in the country of origin have been respected.

34. RM updated the group on plans for bodies to be transferred from the Belfast Health and Social Care Trust to Alder Hey for paediatric post mortems, due to staffing issues. The HTA have been notified and the have advised the

establishment to consider their processes to maintain traceability and good governance.

35. MS raised concerns that this could potentially lead to adverse media coverage, given that Alder Hey still has emotive connotations, and due to the sensitive nature of the material being transported.

36. WB enquired whether the HTA were aware of any plans to develop a forensic taphonomy facility in the UK. HL stated that there are currently no concrete plans to develop such a facility, although some universities were looking into the possibility of whether one could be established.

37. Taphonomy is not an area that is covered by HTA legislation. It would not be covered under a Research licence as consent can't be given by those in a hierarchy. If it were to be made legal in the UK, it would be more akin to body donation for public display or anatomical examination, as a donor would need to give consent in their lifetime for their body to be used for the purpose.

38. If and when there is a concrete proposal to establish a taphonomy facility, then the HTA would work with DHSC to ensure that the dignity of the deceased is factored in and maintained.

39. SD updated the group regarding a CJD surveillance unit that are testing people who die of dementia or prion disease. Both conditions can display similar characteristics. There have been some concerns that the HT Act and its consent requirements would act as a barrier to enabling the surveillance. MRC will continue discussions on this issue and will notify the HTA if any further issues arise.

40. FM informed the group that NHSBT are looking at ATMPs, specifically areas of complexity with how tissues, cells and devices are bridged.

Item 8 – Any other business

44. MS informed the group that the HTA have published information for the public on the cryogenic freezing of a body.

45. BH reminded members of the upcoming HTA conference in November. The Communications Team have held spaces for SFG members, however these would shortly be allocated to others, if not taken up, as the waiting list for spaces is very long.

Item 13 – Proposed items for next meeting

45. The following items will be added to the agenda for the next meeting in May 2019:

- DI training
- Updated Fees model work
- Digital Transformation

46. Additional items welcome.

Summary of actions for the next meeting:

Stakeholder Group Actions	Action Responsibility	Due
1. **SD to forward any useful information for the Research sector that can be shared in the HTA newsletter with MPS.**	**SD**	**May 2019**
2. **ACTION: Members to forward any examples of difficulties in this area for consideration by HTA.**	**All members**	**May 2019**
3. **ACTION: RS to build in discussion with SFG members as part of the early 2019 consultation.**	**RS**	**May 2019**

Stakeholder and Fees Group paper

Date	29 May 2019	**Paper reference**	01/19
Agenda item	3	**Author**	Nicola Fookes

HTA licensing and fees project

Introduction

1. The licensing and fees project has been commissioned to explore areas where the licensing and fee structure may no longer be representative of the regulatory work undertaken by the HTA.

2. The project group will consider aspects of both the current licensing and fees structures, with the aim of exploring potential changes that will realign both with the regulatory work undertaken by the HTA across sectors and in relation to licensable activities.

3. This project is separate from the annual process of fee setting. Although changes from this project may well impact on how fees are recovered the process that establishes the operating budget requirement of the HTA, and therefore the total amount that needs to be recovered through the fee structure, will take place independently of this work.

Project considerations

<u>Review current licensing set up</u>

4. The main features of the current licensing structure have been in place since 2005 and were appropriate for the regulatory activity at the time. However as the HTA and the sectors it regulates have evolved, we are aware of areas where this structure is no longer representative of the regulatory effort required to effectively oversee certain sectors and licensed establishments. As the

sectors have become more diverse and the activities undertaken more complex it feels appropriate to review our approach and consider the following topics:

- The HTA's approach to Satellite sites and whether this should in future take account of:
  - Size
  - Geographical location
  - Complexity of activities undertaken

- The current approach to licensing specific activities:
  - Research tissue banks held under other licences
  - End use storage and distribution

- Designated Individual oversight of multiple sites (and use of Persons Designate)

Fees Structure

5. The fees structure was last reviewed and consulted on in 2016, the main impact of which was a change to the banding for satellite sites. A further review of the fees structure will likely be required as a result of any conclusions from the project topics listed above. We are also likely to explore other potential changes to the fees structure including:

- Fees for returning to compliance
- Temporary licence fees
- Activity based fees versus site fees
- Introduce TPA's to fees structure
- Import – weighting of activity fee
- Storage under the Act for Human Application licences
- Ensuring sufficient flexibility to respond adequately to changes in our operating environment, e.g. clinical trials of ATMPs and EU Exit

Other Considerations

5. As with any review to licensing and fees this project will look to consider the wider regulatory picture. Effective regulation should facilitate and promote high levels of compliance. The aim of this work will ultimately be to address and improve standards and how we can incentivise compliance.

6. The HTA will continue to improve its horizon scanning and aim to be in the best position to prepare for, adapt to and shape changes in the sectors it regulates.

Next Steps

7. The internal project working group will undertake a series of reviews to explore each of the areas identified in this paper, with findings and any potential proposals reported back to the Authority at the end of the Summer. We will aim for early engagement with stakeholders on consideration of any substantive licensing or fee changes as part of this process to ensure we can represent this perspective to our Authority.

8. Following our review with the Authority we may look to undertake a wider consultation on proposed changes which we would look to conclude ahead of the next Stakeholder and Fees Group meeting and before any decisions or recommendations would be made regarding substantive change.

Stakeholder and Fees Group oral discussion

Date 29 May 2019

Agenda item 4

Protective Marking: **OFFICIAL**

Digital transformation project

Overview

Hazel Lofty (Director of Regulatory Development) will lead on this item.

The discussion will cover:

Our strategic vision is to be operating in a more sustainable way by 2021, building in greater resilience and agility in the face of increasing complexity and uncertainty in our external environment.

In order to meet these challenges ahead we remain focused on:

- **People:** recognising our staff as our key asset, widening the pool of candidates for recruitment and investing in training and development
- **Business Technology:** ensuring our systems are not reliant on location and making strategic choices about key business systems
- **Information and data:** meeting our obligations relating to data security and using information and data as a key strategic resource

In order to achieve our vision, the HTA is embarking upon a multi-year change programme, which aims to see the organisation working in smarter ways to make most effective use of our people, business technology and information and data. Preparations for a move to a new office location in 2021 provide additional opportunity to improve how we operate, building in better support for remote working by design.

The benefits of this programme to the HTA and its stakeholders are based around improvements to systems and processes that facilitate a more targeted, risk-based approach to regulation. This will also lead to a streamlining of our interactions with the public and professionals ensuring the information needs of each audience are met in the timeliest and most appropriate manner, and that the regulatory burden can reduce where possible. We will continue to reinvest savings and efficiencies to address emerging business needs.

The benefits include improved horizon scanning, better targeting of regulatory effort to risk and more innovative use of data and technology to improve regulatory outcomes.

Stakeholder and Fees Group paper

Date Friday 10 May

Paper reference: 02/19

Agenda item 5

Author(s) Philip Bergin and Maria-Paulina Socarras

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Developing learning resources for licensed establishments

Purpose of paper

1. The purpose of this paper is to provide Stakeholder and Fees group members with an update on the learning resources available for Designated Individuals (DIs) and other licensed establishment contacts.

2. To provide an outline of what is currently available and propose a series of webinars as additional learning resources.

Action required

3. SFG Members are asked to note the content of this paper, and are invited to comment on the issues for consideration.

Background

4. In 2017, we consulted Stakeholder and Fees Group members on a programme of work intended to build on the relationships we have with people working at our licensed establishments. Part of this work was to examine the feasibility of providing more training and learning resources for those working at licensed establishments.

5. We are aware that DIs and establishment staff often request HTA training and we receive these requests through a number of mediums.

    a. Regulation Managers (RMs) are often asked about HTA training on inspection or when attending meetings and events.

    b. DI training has been raised at various advisory group meetings.

    c. Requests for training have been received by the licensing team, often following a change of DI or a new licence contact.

    d. Feedback received through various stakeholder surveys.

    e. We also regularly receive requests regarding training through the standard enquiries system.

6. Currently, the HTA has a number of key projects underway which demand considerable resource from across the organisation, for example deemed consent for organ and tissue donation in England (item 9 on the agenda) and EU exit (item 6 on the agenda). Our limited resources must be deployed strategically and priority given to these important initiatives, in addition to our regular inspection and licensing commitments.

7. Our current strategy is therefore to continue to make our information as clear and accessible as possible, whilst making the most of available face-to-face opportunities to engage with our professional stakeholders.

Online Resources

8. Over the last 18 months, we have developed a dedicated area on the HTA website which signposts key information for DIs and those working at licensed establishments.
https://www.hta.gov.uk/useful-information-dis-and-named-contacts-0

9. The information has recently been supplemented with a series of short online tests, taken anonymously, to support and inform individual learning. The tests cover a range of topics including consent and licensing, as well as sector specific tests for research, anatomy, post-mortem, public display, human application and organ donation and transplantation.

10. Since their launch at the end of March 2019 the tests have been taken over 1000 times. We will continue to promote these via our usual channels over the coming months.

Face-to-face learning and engagement opportunities

11. We know that establishments want more opportunities to engage with the HTA face-to-face. This is evidenced by the large number of sign-ups we receive for our conference each year.

12. In 2018 we changed the format of our conference to focus more on a professional audience and extended the event to a full day. In addition to a range of external speakers covering current topics aligned to our regulation, we also provided feedback on key themes from the year and time for sector specific round-table discussion.

13. Feedback from the event was exceptionally positive, and we hope to be able to build on this for future events.

14. We acknowledge that we limited in the number of attendees we can accommodate at our annual conference.

15. In addition to our HTA conference, we also regularly attend and present at sector specific events, including:

    a. Post-Mortem consent workshops twice a year at the Association of Anatomical Pathology Technology's (AAPT) conference and events

    b. Sessions on research using human tissue at Health Research Authority's (HRA) training events.

    c. Institute of Anatomical Sciences' (IAS) annual spring conference

    d. British Transplantation Society's annual congress

16. We are keen to identify other organisations, particularly from sectors not represented above, with whom we can partner to offer more face-to-face opportunities.

Improving information on our licensing requirements

17. We recently undertook a review of the content of our website to ensure that the information is accurate and up to date. Following on from this work, we are currently evaluating the existing resources on our website which explain the licensing requirements of the legislation which we superintend.

18. We are looking at producing clear and accessible information on the activities that require an HTA licence. This will be in the form of an interactive decision tree that will encompass all HTA licensing requirements into one easy to use tool.

19. We will also look at developing a guidance document for those working in key roles at licensed establishments explaining the roles and responsibilities under the HT Act, Q&S Regulations and ODT Regulations for the DI, Licence Holder, Person/s Designated and Named Contact (ODT).

Webinars

20. In response to the demand for additional interactive resources, we are scoping the potential for a series of webinars to supplement our online resources.

21. Webinars would enable the HTA to trial the relative uptake of this form of online training and examine whether it meets the aims of stakeholders and the HTA. As previously stated, evidence already gathered from our recent online tests suggests that establishments will engage with online learning resources.

22. The HTA are familiar with conducting webinars, the most recent of which were on the new Independent Assessor (IA) reaccreditation process. Approximately 50% of all IAs attended and 100% of post-webinar survey respondents rated the sessions either ‘excellent’ or ‘good’. Equally, we received positive feedback from the Codes and Standards webinars that were held in 2017.

Suggested webinar topics

23. In terms of webinar format, the HTA could produce *either* a number of standalone 30-45 minute presentations followed by a Q&A/interactive segment, or a series of 2-3 hour subject based online events containing 3-4 linked presentations.

24. HTA webinars should cover core topics, roles and requirements of DIs and others working under the licence with respect to the Human Tissue Act.

25. Suggested subjects could focus on the following:

    a. Licensable activities and scheduled purposes
    b. Licensing and consent exemptions
    c. Role of the DI and governance framework
    d. The licensing process
    e. Compliance with licence conditions
    f. HTA inspections
    g. Introduction to the Human Tissue Act and Q&S (Tissues & Cells) Regulations
    h. Consent and guiding principles
    i. Governance and quality systems
    j. Premises facilities and equipment
    k. Disposal / traceability

26. Single session webinars could cover a range of targeted subjects, for example:

    a. Licensing and varying an existing HTA licence.

    b. Roles and responsibilities, of the DI/ LH/ CLHc and PDs, under the Human Tissue Act 2004 and EU Directives.

    c. Import and coding Directives, the use of the Single European Code (SEC), requirements under the EU Tissues and Cells Directives.

27. Members of the Stakeholder and Fees Group are invited to discuss and provide comment on the proposals, to be factored into planning of future learning resources.

Stakeholder and Fees Group oral discussion

Date 29 May 2019

Agenda item 6

Protective Marking: **OFFICIAL**

EU exit update

Overview

Hazel Lofty (Director of Regulatory Development) will lead on this item.

The discussion will cover:

- In the first part of this year, we issued advice for establishments on importing arrangements, operational preparedness and business contingency planning in our professional e-newsletters and separately in targeted communications to the HA and ODT sectors.

- Discussion at the meeting will focus on our communication activities with stakeholders and how we intend to proceed with these in coming months.

HTA Stakeholder and Fees Group Paper

Date	29 May 2019	**Paper reference:**	03/19
Agenda item	7	**Author**	Rob Watson
Protective Marking	OFFICIAL		

Update on the implementation of the recommendations of the HTA's Human Application (HA) risk project

Purpose of paper

1. To update the Stakeholder and Fees Group (SFG) on the work that is underway to implement the recommendations of the HTA's HA risk project.

Action required

2. SFG members are asked to note the content of this paper and are invited to comment on the work.

Background

3. In 2017/18, the HTA undertook a piece of work, the HA risk project, which aimed to establish a more comprehensive understanding of the risks inherent in the HA sector. The work was carried out, in part, to enable us to target our resources effectively and ensure that our regulatory approach remains risk based and proportionate and that non-compliance is identified and dealt with appropriately.

4. The HA risk project objectives were discussed at our public Authority meeting/conference in June 2017. See pages 57-64 of the papers.

5. The outcome of the project was a series of recommendations relating to three keys areas of risk; inspections, oversight of third party agreements (TPAs), and Preparation Process Dossiers (PPDs).

6. The HTA is now working on implementing the recommendations of the HA risk project as set out below.

Ongoing work

TPAs

7. Work is underway to ensure that the HTA holds accurate information about all third parties carrying out licensable activities on behalf of licensed establishments under the terms of TPAs, and that procedures are in place to ensure that this information is kept up-to-date.

8. Data collected through annual activity submissions has been collated and is being reconciled with the information held by the HTA against each establishment's licensing record. Establishments will be contacted in the coming months to resolve any discrepancies.

9. The HTA's inspection scheduling procedures have been amended to embed a review of current TPAs as part of the planning phase. This will help determine the scope of inspections, including whether an inspection of relevant third party premises is needed.

10. An audit of TPA-related information on the HTA's website has been conducted and out-of-date information has been removed or updated. In the coming weeks, a new TPA landing page will be added to the HTA's website to help establishments locate TPA-related guidance and forms.

11. This work is being carried out in conjunction with a wider piece of work on HTA licence fees.

Inspections

Changes are being made to the HTA's inspection processes to ensure that the focus of inspections is better aligned to risk, whether sector-wide or establishment-specific.

12. HTA procedures are being updated to ensure that indicators of risk, such as SAEARs or significant organisational change (e.g. personnel, activities), inform both the interval between, and resource allocated to, inspections.

13. As part of this work, consideration is being given to the greater use of short notice or unannounced inspections, the role of compliance self-assessments in

the inspection process, and the incorporation of observational audits (e.g. of tissue/cell processing) as a standard part of all site visit inspections.

14. This work is being carried out as part of a wider piece of work concerning the development of a more robust, risk-based model for inspections across all HTA-licensed sectors.

PPDs

15. A series of operational changes are being implemented to ensure robust, consistent, and timely review of PPDs; particular consideration is being given to the HTA's processes relating to the conditional authorisation of preparation processes, the handling of incomplete submissions, and the rejection of PPDs.

16. The HTA is also developing tissue-specific quality and safety benchmarks to facilitate the authorisation of preparation processes. This work is being carried out in conjunction with the EU-funded GAPP project (facilitatinG the Authorisation of Preparation Processes).

17. Work is also underway to strengthen the HTA's approach to the review of authorised preparation processes as part of its routine regulatory activities; this work will extend to the oversight of well-established procedures and the information the HTA holds about these.

Next Steps

18. The implementation phase of the HA risk project will run throughout the 2018/19 business year.

19. Regular updates will be provided to the sector via the HTA newsletter, sector-specific correspondence and our website.

Stakeholder and Fees Group paper

Date	29 May 2019	**Paper reference**	04/19
Agenda item	8	**Author**	Christopher Birkett

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Update on the joint HRA/HTA work in response to the public dialogue on *Consent to use human tissue and linked health data in health research*

Purpose of paper

1. To update the group on HRA's/HTA's plans for joint work arising from the aforementioned public dialogue.

Action required

2. SFG Members are welcome to comment on this paper.

Background

3. In May 2017, Ipsos MORI was commissioned by the Health Research Authority (HRA) and the Human Tissue Authority (HTA) to undertake a public dialogue to explore views of consent to use patient data linked to human tissue in health research. This project was co-resourced by the HRA and the HTA, and largely funded by the UK Government's *Sciencewise* programme. The dialogue findings were published in July 2018 and will inform new HRA and HTA guidance for consent procedures that will maintain public trust, support informed consent, and facilitate better health research.

4. The growth and popularity of well-characterised and regulated sample collections has made the UK an attractive place to do research with human tissue. However, despite the crucial role of biobanks, the value of their stored tissue diminishes when it cannot

be linked to patient health data. This gap between current and potential performance was the motivation behind the HRA and the HTA working together on this project. We wanted to better understand the public's awareness of the importance of donated tissue being linked to patient health data, and to learn what reassurances the public may need in order to provide their consent.

5. Both regulators were keen for Ipsos MORI to set us the challenge of raising the bar on consent quality for modern donors in modern times. A public dialogue approach was considered the best way to explore this topic.

6. In total, 75 participants were involved in the dialogue. They were recruited 'on-street', using quotas for gender, age, socio-economic group and ethnicity; this ensured participation of individuals from a range of backgrounds reflective of the areas they came from, and the broad diversity of the UK population. Reconvened workshops were held in London, Sheffield and Birmingham in September and October 2017. Between (and after) the workshops, participants took part in an on-line community.

Opportunities and challenges arising from the findings

7. Amongst many others, the project gave us an opportunity to recheck the public pulse on accepted consent practices, with the aim of improving joint guidance.

8. While a range of useful points were raised in the public dialogue, the main challenges for the regulators were set out by Ipsos MORI in six 'key tests'. The project identified a need for absolute clarity on the uses of tissue and data, the need to future proof consent processes, and the requirement to provide a straightforward and accessible consent process. The Six Key Tests therefore confirm the expectations of today's donors when they are asked to provide their consent.

The Six Key Tests

1. **Who can access tissue and data?**
   This would entail providing examples of the different types of organisations and individuals that can access the research findings, how likely this would be and whether there are any associated risks with such access e.g. detected conditions affecting a donor's lifestyle.

2. **Data- de-identification**
   Information should make it clear what de-identifying means, making it clear that only de-identified data will be shared with researchers, and explain both the interest in aggregated and individual level health data.

3. **How will donated tissue and data be used?**
   Information should make it clear the different types of research the tissue and data can be used in; as it is not always possible to be exact then the public called for some direction in terms of listing the possibilities of things which might be found out.

4. **Who can access the findings at an individual level?**
   Information should make it clear all parties which could access the research findings at an individual donor level and the likelihood of this changing in the future.

5. **How will the donor be protected?**
   As genetic data was seen as more personal and sensitive, there was the perception of a greater risk of identification, and more opportunities for the data to be looked at, the role of safeguards took on more prominence. The public want independent scrutiny of the entire process, with published information about the decisions taken by bodies that do this.

6. **Sharing the research findings**
   Participants understood that it would be difficult to feedback research study results to the participants that supplied their tissue and data but thought that it would be feasible for the study results to be made available by Biobanks / Researchers which participants could access.

While the Six Key Tests are useful in determining the content of the consent process and scope of the relationship with the donor, the findings from this project led us to identify the following key principles for an modern, effective consent framework:

- **Informed consent**
  Potential donors should be provided with clear, accessible information. Regulators will always play a key role in supporting this through their guidance on what the consent process should include.

- **Research transparency**
  It should be clear about who research partners are likely to be and how research results will be made public.

- **Withdrawal of consent**
  Donors should be able to withdraw their consent at any time. Withdrawal should be discussed at the outset, when consent is being sought. The ability for donors to be able to withdraw their consent, whether generic or specific, is an essential partnering principle of research transparency as donors may subsequently object to a research institution’s change in research direction, collaboration or projects, etc.

- **Trust**
  Donors need to be able to trust that their tissue and data will be used in the public interest in accordance with their consent. Tissue banks are the custodians of both a valuable public resource and the trust of their donors. They need to ensure that robust, transparent governance processes are in place to ensure that tissue and data are released appropriately, particularly where these have been donated with broad consent for unspecified future research.

Access committees

9. Access committees involving both experts and members of the public can play an important role in ensuring that health-related research is in the public interest. When an access committee reviews an application from researchers to access tissue, it may ask for further information from applicants about the aims of their proposed research or for guidance from relevant experts regarding science, law or ethics. An access committee will need to be satisfied that a research application meets the requirements outlined by the consent given by individuals and also meets any conditions set out by the Research Ethics Committee as a condition of approval of the Research Tissue Bank.

10. Participants in the public dialogue saw access committees as a key reassurance, having a critical role in balancing the interests of researchers with the common-sense interests of the donors, within an agreed ethical framework.

11. HRA are leading on the guidance and policy work around access decision-making structures and how these will be agreed as part of their Research Tissue Bank approval process.

Dynamic consent

12. Dynamic consent is intended to give donors greater control and ownership of their consent. The concept typical involves an online platform, where donors can give their consent to specific research on an ongoing basis. In theory, it also provides opportunities for researchers to give feedback to donors.

13. Whilst dynamic consent was an initially appealing concept, participants felt that realistically they would not want to engage with a complex consent process on an ongoing basis and generally would prefer to give broad consent at the outset.

14. There is a wealth of existing information and advice on dynamic consent. As a result of the project findings, HRA/HTA are not intending to do any further joint work specifically on dynamic consent. However, we recognise the benefits of technology in enhancing

the interfaces between donors and researchers, thereby supporting the important principles and assurances identified in this document, not least with regard to transparency.

Commitment to the recommendations and actions identified from the findings

15. Both organisations are using the findings from the public dialogue on *Consent to use human tissue and linked health data in health research* and working together to develop new guidance and improve existing materials for researchers. Some of these outputs will involve further collaboration; for example with the UKCRC Tissue Directory and Coordination Centre and the Cellular Molecular Pathology (CM-Path) initiative.

Stakeholder and Fees Group paper

Date:	29 May 2019	**Paper reference:**	05/19
Agenda item:	9	**Author(s):**	Ruth Joyce, Hazel Lofty, Jess Porter
Protective Marking	OFFICIAL / CONFIDENTIAL		

Deemed consent for organ donation in England

Purpose of paper

1. To provide the Stakeholder and Fees group (SFG) with an update on progress with amendments to the HTA's Codes of Practice in preparation for the introduction of deemed consent in England, which is due to come into force in spring 2020.

Decision-making to date

2. The Authority considered the proposed structure and initial draft of Code F - Donation of solid organs and tissue for transplantation at its meetings on 7 February and 9 May 2019.

Action required

3. SFG Members are asked to note the content of this paper.

Background

Legislative update

4. The Organ Donation (Deemed Consent) Bill 2017-2019 received Royal Assent on 15 March 2019. The Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) is due to come into force in spring 2020.

5. The Deemed Consent Act will only apply to ‘permitted material’; the Department of Health and Social Care (DHSC) have drafted regulations which specify the material which will not be covered by deemed consent. A consultation is being held at the moment and closes on 22 July. The regulations largely cover ‘novel transplants’ and will be subject to Parliamentary approval.

6. The Deemed Consent Act places a duty on the HTA to provide practical guidance for professionals working in the field of organ donation and transplantation on deemed consent.

7. In addition, minor amendments will be required to Code of Practice A - Guiding Principles and the Fundamental Principle of Consent, the common Annex which is part of all the Codes, and the Code of Practice on the Human Transplantation (Wales) Act 2013 to reflect the changes introduced by the Deemed Consent Act.

Key Amendments to Code of Practice F

8. The current Code F provides guidance on both living and deceased donation. The revised Code will be split into two sections, published as separate documents, to cover living donation and deceased donation.

9. The first section, living organ donation, provides guidance on legislative requirements to clinicians working in living organ donation and HTA Independent Assessors (IAs). This section will not be affected by the introduction of deemed consent.

10. The second section, deceased organ and tissue donation, provides guidance to Specialist Nurses for Organ Donation (SNODs), Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. The Code will continue to provide practical guidance on ‘appropriate consent’ as defined by the HT Act in both England and Northern Ireland. Specifically, as required by the amended legislation, the Code will give guidance on the circumstances in which consent can be deemed.

The role of family, and faith and cultural considerations

11. The role of family, and faith and cultural considerations, have been highlighted as key issues in the Parliamentary debates and Ministerial correspondence.

12. The HTA hosted a roundtable event in February with representatives of faith, secular, and cultural groups. The purpose of the event was to seek views on how conversations with a donor’s relatives can be conducted in the most sensitive manner, taking both religious and cultural views and traditions into account.

13. The event had 24 external attendees including colleagues from NHSBT, the Welsh NHS, and DHSC.

14. Additions have been made to Code F to reflect the role of the family in different donation situations. The Code has also been updated to reflect amendments made to the Organ Donor Register, including the recently introduced ‘faith and beliefs declaration’

Project Governance

15. Updates on project progress and key milestones are provided to the HTA Management Group and Senior Management Team on a monthly basis as a Development KPI on the HTA business plan. Progress is also discussed at monthly Deemed Consent project board meetings. The project board are also responsible for sign off of key deliverables.

16. The project board membership includes the Head of Education and Professional Development (NHSBT) and the Head of Department, East Grinstead Eye Bank (non-NHSBT tissue bank), to ensure user views are reflected.

17. Work is currently focused on drafting the amendments required to Code F. Specialist advice on technicalities and clinical accuracy continues to be sought from professionals including Welsh Transplant colleagues, SNODs, NHSBT Organ Donor Register team, intensivists, and DHSC policy and legal colleagues.

18. The project team are liaising closely with DHSC colleagues to ensure that the Code is approved by Parliament before the legislation comes into force. Timings post-consultation will largely be driven by the nature and volume of responses to the consultation.

Stakeholder Engagement

19. In addition to the multi-faith roundtable, the HTA have also been participating in NHSBT’s Organ Donation Campaign Advisory Group and Organ Donation Legislation Change meetings, to provide advice and guidance to NHSBT on their public awareness campaign for deemed consent which was launched on 25 April.

Next steps

20. A 12-week public consultation on Code F - aimed primarily at professionals - will be held over the summer, pending submission to the Minister, we anticipate opening the consultation in the first week of June.

Stakeholder and Fees Group oral discussion

Date 29 May 2019

Agenda item 10

Protective Marking: **OFFICIAL**

Horizon scanning

Overview

This is a group item that will cover new HTA policy areas and an opportunity for members to tell us about their developments that we should be aware of.

The discussion will cover:

The aim of this item is to share and identify factors that might impact the HTA's future policy and development work, such as:

- The introduction of perfusion devices in ODT
- Taphonomy

As well as less tangible items that might affect our regulatory function, such as emerging news and public discussion, and developing science and technology relating to the use of human bodies or body parts, including parliamentary discussions and industry matters.

We invite members of SFG to share emerging policy and development areas with the group.