Terms of Reference for Advisory Groups

Histopathology Working Group
Transplantation Advisory Group
Stakeholder and Fees Group

Reference number	HTA-TOR-003	**Version**	17.0
Owner		**Date approved**	May 2018
Author(s)	Amy Gelsthorpe-Hill	**Next review date**	May 2020
Approved by	Authority Members	**Distribution**	Internal and external

Background

1. The Human Tissue Authority (HTA) has established the Histopathology Working Group, the Transplantation Advisory Group and the Stakeholder and Fees Group (the Groups) to maintain a positive and long-lasting impact on the services we regulate and ensure the safe and ethical use of human tissue.

2. The Groups will work in an advisory, not decision-making, capacity.

3. The Groups will not replace any of our existing mechanisms for formal consultation with other organisations, but will contribute to our thinking on work across the areas we regulate and the work we are assigned by the Department of Health and Social Care.

4. The Groups share common terms of reference in relation to their governance and recruitment, which are outlined in this document.

5. The Groups have differing terms of reference in relation to their constitutions, duties, functions and membership, which are outlined towards the end of this document.

Recruitment

6. Authority Members will be appointed to Groups by the Authority Chair.

7. Groups will be chaired by an Authority Member, who is not the Authority Chair and who preferably has relevant experience and expertise. Recruitment of the Chairs and Authority Members to each Group will be undertaken through ‘expressions of interest’ with a personal statement in application. These expressions will be reviewed by the Senior Management Team (SMT) with advice from the HTA Head(s) of function who support(s) the Group and provided to the Authority Chair for consideration.

8. The membership of individuals will be for a maximum term of three years, in line with the terms of Authority Members. It should be noted that Authority Members may be reappointed in accordance with the HTA's business needs.

9. Professional bodies will identify individuals to represent them on the Histopathology Working Group and the Transplantation Advisory Group. Further details of this can be found in the Histopathology Working Group and Transplantation Advisory Group sections later in this document.

10. Groups may make appointments from additional organisations to the ones listed in accordance with business need.

11. Group members who are appointed by professional bodies will hold continuous membership, with a review of the membership of that job role taking place every three years.

Member responsibilities

12. Group members will be expected to provide apologies to the Secretary in advance of the meeting if they are not able to attend.

13. Group members must ensure that the existence and nature of any personal or material interest is disclosed before the discussion of a matter relevant to that interest, so to ensure the HTA is aware of an interest when considering any advice the member provides on the matter.

14. Members will be required to provide comments on the accuracy of minutes by email within the timeframe set by the Chair. This will ensure the key areas of discussion and action points are captured accurately.

Frequency of meetings

15. The Groups will each meet twice a year; they may also meet on an ad-hoc basis, if required.

16. Where necessary, members may be contacted outside of meetings to provide advice as and when it is needed. They may also be contacted to provide a paper, comment on a paper or review progress against agreed actions.

17. The format, frequency and outputs of the meetings will be reviewed annually by Group members to ensure that the Groups are being effective in meeting their objectives.

Attendance at meetings

18. The quorum for each Group will be five, including the following members from each Group:

a) Histopathology Working Group: either a member of the Senior Management Team or Head of Regulation with responsibility for the Post Mortem (PM) sector, one Authority Member and two external representatives, one of whom must be a representative from the Royal College of Pathologists (RCPath);
b) Transplantation Advisory Group: a member of the Senior Management team or Head of Regulation with responsibility for the organ donation and transplantation sector, two Authority Members and two external representatives;
c) Stakeholder and Fees Group: the Group Chair, a relevant HTA staff member and three external representatives.

19. Other HTA staff may attend Group meetings, with the agreement of the relevant Group Chair, to observe, present information or hear views. Their attendance may be limited to specific agenda items at the discretion of the Group Chair.

20. An observer from the Department of Health and Social Care shall be invited to attend Stakeholder and Fees Group meetings.

21. If it is deemed appropriate for other observers to attend meetings, they should be informed by the Group Chair that the views expressed by Groups members are not necessarily the views of the HTA and that the Groups work in an advisory, not decision-making, capacity.

Right to expert advice

22. The Groups may, at the discretion of their Chairs, secure the attendance of any external advisors with relevant experience and expertise in order to discharge their responsibilities.

Reviewing effectiveness

23. The Groups will each draw on the National Audit Office's self-assessment checklist for Audit Committees, as appropriate, in order to undertake periodic (at least biannually) reviews of their own effectiveness and agree actions for improvement. Each Group will report the results of the review to the Authority.

Reporting to the Authority

24. A verbal summary of the issues discussed at each meeting will be reported at the following Authority meeting by an Authority Member who is a member of the respective Group. The Member who will be responsible for providing the update will be agreed at each Group meeting and an 'Advisory Group update' will be a standing item on all standard Authority meeting agendas.

Communication

25. The Group Secretaries will be responsible for ensuring that a short summary of the issues discussed at each meeting is written for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and sent to the Head of Communications for publication.

26. The Secretariat will be responsible for ensuring any issue relating to the work of a specific Head of function is reported to that Head within five working days of the meeting.

Secretariat responsibilities

27. Group Chairs will assume responsibility for ensuring all agreed actions are completed.

28. The following HTA staff members will be appointed as Secretaries:

    a) Histopathology Working Group: a Regulation Manager or Officer with experience in the Post Mortem sector;
    b) Transplantation Advisory Group: the Transplant Officer;
    c) Stakeholder Group: the Stakeholder Engagement Manager.

29. Each Group Secretary will assume responsibility for the following tasks:

    a) inviting members to meetings;
    b) booking meeting venues;
    c) collating papers to be considered at meetings;
    d) liaising with the Chair and relevant Heads to create agendas, ensuring that they are distributed with the minutes from the last meeting and any meeting papers at least one week before each meeting;
    e) taking minutes and recording action points from each meeting;
    f) ensuring minutes are circulated as soon as possible, at least within ten days of the meeting;
    g) approval of meeting minutes by the Group Chair prior to them being published on the HTA website, which will happen no later than two months after the meeting.

Review

30. This document will be reviewed by the Governance and Quality Manager and Authority Members every two years, with comment from the HTA's Senior Management Team and the respective Groups.

Version	Date	Comments	Reviewed by	Approved by
15.0	17 March 2015	New Terms of Reference drafted to update and amalgamate terms for all Groups.	Amy Gelsthorpe-Hill	Authority Members
16.0	February 2017	Updated to reflect changes following review of Advisory Groups	Hazel Lofty	Authority Members
17.0	May 2018	Updated to reflect changes following review by Advisory Groups	Hazel Lofty	Authority Members

Histopathology Working Group

Constitution

31. The HTA has established the Histopathology Working Group (HWG) to maintain a positive and long-lasting impact on the delivery of post mortem services, working with the sector to help drive up standards. Consultation with the HWG helps ensure that advice provided by the HTA remains current and in line with professional guidance.

32. In addition, the HWG considers on an on-going basis issues facing post mortem sector establishments, in order to inform the continued development of HTA regulatory policy affecting the sector and its overlap with the research sector.

Duties and functions

33. The HWG has four core functions:

    a) to maintain strategic oversight of the sector;
    b) to provide a forum for debate on sector-specific issues and inform implementation of resulting work streams;
    c) to consider standards documents and other guidance on the investigation of death created by the Royal College of Pathologists (RCPath) Death Investigation Group;
    d) to report back to the Authority on key issues as necessary.

Objectives

34. The objectives of the HWG are to:

    a) identify areas where advice and guidance is needed by the sector (including organisations that do not fall within our regulatory remit, for examples coroners and the police) and how this may be provided most effectively, such as through the development of policy or through other communication channels;
    b) discuss issues resulting from implementation of the legislation or difficulties experienced by the sector and provide guidance on possible solutions or avenues of approach;
    c) consider other legislation, current and future, and identify areas of overlap and disparity with the Human Tissue Act 2004;
    d) take a strategic approach to unexpected incidents or events and approve the content of regulatory alerts relating to the sector;
    e) perform horizon scanning for potential future changes and developments in the sector which might affect the HTA's regulation;
    f) work with external stakeholders on specific topic areas to achieve identified outcomes.

Membership

35. The HWG will be chaired by an Authority Member, appointed by the HTA Chair, and with support from the Head of Regulation with strategic lead for the post mortem sector.

36. Other members of the HWG will be appointed by the following stakeholder organisations, either by the appointment of individuals or specific job roles:

a) Royal College of Pathologists (RCPath);
b) British Medical Association's (BMA's) Central Consultants and Specialists Committee (CCSC) Pathology Subcommittee;
c) Association of Anatomical Pathology Technology (AAPT);
d) Home Office;
e) Forensic Science Regulator;
f) Coroners' Society;
g) Institute of Biomedical Science (IBMS);
h) Ministry of Justice (on occasion);

37. The HTA will appoint the following members to the HWG:

a) A minimum of two Authority Members: one lay and one professional;
b) the Director of Regulatory Delivery or Director of Regulatory Development;
c) the Head of Regulation with strategic lead for the Post Mortem sector;
d) a representation from the Communications directorate.

Transplantation Advisory Group

Constitution

38. The HTA established the Transplantation Advisory Group (TAG) as a forum for the discussion of issues arising in living and deceased organ donation, in particular:

    a) discussion of new policy issues and emerging novel areas in transplantation;
    b) identification of revisions required to current HTA or NHS Blood and Transplant (NHSBT) policies;
    c) discussion on the complex ethical issues in transplantation in order to ensure the requirements of the Human Tissue Act 2004 and associated regulations are met;
    d) reviewing guidance on issues surrounding Independent Assessors (IAs), including recruitment and performance issues identified during the reaccreditation process.

Duties and functions

39. The TAG has three core functions:

    a) to maintain strategic oversight of living organ donation and to check and challenge the HTA's decision-making processes;
    b) to provide a forum for debate on issues relevant to living and deceased organ donation and transplantation to inform policy decisions and identify work streams / projects;
    c) to report back to the Authority on key issues as necessary.

Objectives

40. The objectives of the TAG are to:

    a) identify areas where advice and guidance is needed by the sector and how this may be provided most effectively, for example through the development of policy or guidance or through other communication channels;
    b) discuss arising policy or legislative issues and difficulties experienced by the sector with the aim of providing suitable guidance or solutions;
    c) work with transplant units on specific subject areas to achieve identified outcomes, such as new programmes in living organ donation (novel organs);
    d) provide informal soundings and advice on emerging policy issues or novel transplants.

Membership

41. The TAG will be chaired by a member of the Authority, appointed by the HTA Chair and supported by the Head of Regulation with strategic lead for the organ donation and transplantation sector.

42. Other members of the TAG will be appointed by the following stakeholder organisations, either by the appointment of individuals or specific job roles:

a) representatives from NHSBT;
b) a Living Donor Coordinator;
c) clinical representation from the transplant community, to include both a Liver Specialist and a Kidney Specialist.

43. The HTA will appoint the following members to the Group:

a) the Director of Regulatory Delivery or Director of Regulatory Development;
b) the Head of Regulation with strategic lead for the Organ Donation and Transplantation sector;
c) the Transplant Manager;
d) A minimum of two Authority Members: one lay, one professional;
e) a representative from the Communications directorate.

Stakeholder and Fees Group

Constitution

44. The HTA has established the Stakeholder and Fees Group (SFG) to provide a forum for regular consultation on our approach to regulatory activities, including fee-setting and an opportunity for stakeholders to make their views known to the Authority.

45. The SFG has been established to ensure the HTA continues to improve transparency and accountability and maintain effective working relationships with establishments we license.

46. SFG members will contribute to the development of our thinking on new initiatives across all sectors, helping to ensure that we understand the demands stakeholders are facing and that stakeholders have confidence in our decisions.

Duties and functions

47. The SFG will have three core functions:

a) to provide an ongoing channel of communication with stakeholders;
b) to provide a forum for regular discussion of regulatory issues;
c) to consider fees proposals annually.

48. The Head of Communications will ensure that advice which is specifically related to organ donation or the post mortem sector will be referred to TAG and HWG respectively, as it is deemed appropriate.

Objectives

49. The SFG will consider regulatory issues across all licensed sectors to inform the continued development of HTA regulation and fee setting

50. Achieving best value for money through a robust fee-setting process is essential to ensure the costs of regulation are both proportionate and fair and that the regulated sector can operate efficiently and competitively. The Authority approves fees in November of the year before they are charged and new fee levels are announced in December. Fees are charged for the year from April to March, with invoices issued in April or September depending on the sector. The SFG shall review fee proposals in October each year, to inform the Authority's consideration.

Membership

51. The SFG will be chaired by a member of the Authority, appointed by the HTA Chair and supported by the Head of Communications.

52. The SFG will comprise of up to 13 representatives from the sectors licensed by the HTA, members of the public and other stakeholders.

53. The HTA will appoint the following staff members to the Stakeholder Group:

    a) the Chief Executive;
    b) the Director of Regulatory Delivery or Director of Regulatory Development
    c) the Director of Resources;
    d) the Head of Communications.