Framework Agreement

between the Department of Health and NHSBT

Annexes

Annex A: Wider guidance

The following general guidance documents and instructions apply to NHSBT. The Department may require NHSBT to provide additional management information on an ad hoc basis. Where this is the case, the Department will provide NHSBT with clear reasons for the request and will allow as much time as possible to comply with the request.

General

- Appropriate adaptations of sections of *Corporate Governance in Central Government Departments: Code of Good Practice* and its related guidance
  https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments

- *Managing Public Money*
  https://www.gov.uk/government/publications/managing-public-money

- *Code of Conduct for Board Members of Public Bodies*
  http://www.civilservice.gov.uk/wp-content/uploads/2011/09/code-of-conduct_tcm6-38901.pdf

- *Code of Practice for Ministerial Appointments to Public Bodies*
  http://publicappointmentscommissioner.independent.gov.uk/wp-content/uploads/2012/02/Code-of-Practice-2012.pdf

- The Parliamentary and Health Service Ombudsman's *Principles of Good Administration*
  http://www.ombudsman.org.uk/improving-public-service/ombudsmansprinciples/principles-of-good-administration

- Consolidation Officer Memorandum, and relevant DCO letters;

- *The NHS Records Management code of practice*
  https://www.gov.uk/government/publications/records-management-nhs-code- of-practice

- Other relevant guidance and instructions issued by HM Treasury in respect of Whole of Government Accounts

- Other relevant instructions and guidance issued by central government departments

- Any statutory duties that are applicable to NHSBT

- Specific instructions and guidance issued by the Department, including requests for information

- Any Departmental plans to ensure continuity of services

- Recommendations made by the Public Accounts Committee, or by other Parliamentary authority, that have been accepted by the Government and are relevant to NHSBT

Audit and Risk

- *Public Sector Internal Audit Standards*
  https://www.gov.uk/government/publications/public-sector-internal-audit-standards-good-practice-guidance

- *Management of Risk: Principles and Concepts*
  http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/psr_managing_risk_of_fraud.htm

Finance

- *Government Financial Reporting Manual* (FReM)
  https://www.gov.uk/government/publications/government-financial-reporting-manual

- Fees and Charges Guide, Chapter 6 of *Managing Public Money*

- Departmental Banking: A Manual for Government Departments, Annex 5.7 of *Managing Public Money*

- Relevant *Dear Accounting Officer* letters

- *Regularity, Propriety and Value for Money*
  http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/Reg_Prop_and_VfM-November04.pdf

- *Improving spending control*
  https://www.gov.uk/government/publications/improving-spending-control

HR

- Model *Code for Staff of Executive Non-departmental Public Bodies* (Cabinet Office)
  http://www.civilservice.gov.uk/wp-content/uploads/2011/09/5_public_body_staffv2_tcm6-2484.pdf

- *DH Pay Framework for Very Senior Managers in Arm's-Length Bodies*
  https://www.gov.uk/government/publications/pay-framework-for-very-senior-managers

FOI

- Relevant Freedom of Information Act guidance and instructions (Ministry of Justice)

Estates and Sustainability

- *Greening Government Commitments* http://sd.defra.gov.uk/documents/Greening-Government-commitments.pdf

- Government Property Unit *National Property Controls* and *standards for office accommodation* (available from the Department)

- *The Department of Health's Property Asset Management procedures* (available from the Department)

Information Governance and Security

- The *NHS Information Governance Toolkit* *https://nww.igt.hscic.gov.uk/*

- HMG IA Standard No. 6: *Protecting Personal Data and Managing Information Risk* (available from the Department)

- HM Government's *Security Policy Framework* *https://www.gov.uk/government/publications/security-policy-framework*

- *Information Security Management: NHS Code of Practice* *https://www.gov.uk/government/publications/information-security-management-nhs-code-of-practice*

- *Confidentiality: NHS Code of Practice* *https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice*

Transparency

- *The Prime Minister's commitments on transparency* *http://webarchive.nationalarchives.gov.uk/20130109092234/http://number10.gov.uk/news/letter-to-government-departments-on-opening-up-data/*

Annex B: Finance and Accounting

1. The Framework Agreement sets out the governance and accountability arrangements between the Department of Health and NHSBT for functions carried out for the health system in England. This annex provides additional detail on the finance and accounting arrangements which complements the Framework Agreement itself.

The Nature and Funding of NHSBT

2. NHSBT is classified as a Public Corporation. The majority of NHSBT's income (85%) derives from sales of blood and specialist products and services to NHS hospitals in England and north Wales. Volumes and prices are agreed in advance of the budget year via the National Commissioning Group for Blood, chaired by a representative of the Senior Departmental Sponsor. Prices are set to recover costs and should be set in line with HM Treasury guidance in respect of fees and charges. The associated expenditure is considered "front-line" and is therefore classified as Programme Expenditure. The remainder of NHSBT's income is provided by way of direct funding from the Department in respect of organ and stem cell transplantation. Contributions (on a population basis) are additionally provided by the other UK Health Departments in support of NHSBT's UK wide responsibilities for organ donation and transplantation. As a Public Corporation, the associated expenditure is considered to be a subsidy and classified as Programme Expenditure.

Annual Expenditure Limits

3. The Secretary of State will confirm NHSBT's programme and capital funding in writing each year. As Accounting Officer, the Chief Executive must ensure that, in any financial year, and unless approved in advance, NHSBT's expenditure does not exceed its income and complies with any individual sub set of technical limits that may apply. The Accounting Officer must also ensure that, in any given year, NHSBT maintains a positive cash balance.

Business Planning

4. The Secretary of State requires NHSBT to produce a business plan each year. The plan will be required to be costed: supporting guidance issued by the Department will provide the format and level of financial detail required. Indicative funding will be reissued with the planning guidance, incorporating any guidance on overall efficiencies relevant to the Department and its arm's length bodies.

5. The business plan will need to identify detailed revenue, capital and cash forecasts for DH funded activity, and also equivalent expenditure associated with NHSBT's other income sources. It will need to clearly

identify the distinction between costs and income falling inside and outside the administration budget regime.

Accounts

6. The Department will routinely have full access to NHSBT's information and files. In relation to financial reporting, the Department is required by HM Treasury to report in-year financial performance and forecasts for all its arm's length bodies, by Estimate Line, and in a specified format, to a strict timetable. NHSBT is required to comply with Departmental plans and schedules which enable the Department to meet HM Treasury deadlines, and the Department's overall financial planning to meet HM Treasury spending controls through the Shared Financial Planning Agreement.

7. NHSBT must prepare annual accounts for each financial year ending 31 March, and interim accounts for shorter periods if required. In relation to these accounts, NHSBT must:
   - ensure that accounts are prepared according to the form, content, methods and principles prescribed by the Treasury in the Government Reporting Manual (FreM);
   - submit these accounts (both unaudited and audited) to the Department by a date to be specified by the Secretary of State; and
   - submit these accounts to the Comptroller and Auditor General (C&AG) for audit as soon as reasonably practicable after the year end (or, in the case of any interim account, as soon as reasonably practicable after the end of the interim period to which that interim account relates).

8. Under Para 6(3) of Schedule 15 of the NHS Act 2006, NHSBT is required to present an Annual Report and Accounts to both Houses of Parliament and to have these audited by the Comptroller & Auditor General after the end of each financial year. Information on performance against key financial targets is within the scope of the audit and should be included in commentary. The report and accounts are to be signed by NHSBT's Accounting Officer and laid before Parliament (and the Scottish Parliament) by NHSBT and made available on NHSBT's website, in accordance with the guidance in the Government Financial Reporting Manual (FReM). A draft of the report should be submitted to the Department in line with the published timetable.

9. The Accounting Officer must also ensure that NHSBT participates fully in all agreement of balances exercises initiated by the Department, and in the form specified by the Department, and that it agrees income and expenditure and payables and receivables balances both with other organisations within the Department's resource accounting boundary. In doing so, NHSBT should seek to agree all outstanding balances but in any case should keep within any level of materiality set by the Department.

Audit

10. Section 8 of the Framework Agreement sets out the high level requirements for audit.

11. To meet the requirements for internal audit, NHSBT must:
    - Maintain a Governance and Assurance Committee in accordance with the corporate governance code for central government departments[1];
    - prepare an audit plan, taking into account the Department's priorities where specified, and forward the audit plan and related reports to the Department when requested
    - submit the NHSBT Head of Internal Audit's opinion on risk management, control and governance as part of the preparation of the Annual Report and Accounts to the Department in line with its published timetable; and
    - keep records of, and prepare and forward to the Department an annual report on fraud and theft suffered by NHSBT as requested, and notify the Department of any unusual or major incidents as soon as possible.

12. The Department is committed to the development of a group assurance model for DH and its arm's length bodies. The NHSBT Board is accountable for establishing its internal audit arrangements but has agreed, in principle, that its internal audit provision will be delivered as part of a shared service once the contract period for its initial provider has expired. NHSBT will engage with the Department in the development of the group assurance model.

13. The Department's group internal audit service has a right of access to all documents prepared by NHSBT's internal auditor, including where the service is contracted out (until such time when the contract expires, after which Group Internal Audit will provide the audit service – including having access to all previous audit documentation).

14. The Comptroller and Auditor General audits NHSBT's Annual Report and Accounts. In the event that NHSBT has set up and controls subsidiary companies, NHSBT will, in the light of the provisions in the Companies Act 2006, ensure that the Comptroller and Auditor General is appointed auditor of those company subsidiaries that it controls and/or whose accounts are consolidated within its own accounts. NHSBT shall discuss with the Department the procedures for appointing the Comptroller and Auditor General as auditor of the companies.

15. The Comptroller & Auditor General:

[1] The corporate governance guidelines (available at http://www.hm-treasury.gov.uk/psr_governance_corporate.htm) are written for central government departments, although, as it says in the guidelines, "the principles in the Code generally hold across
other parts of central government, including departments' arm's length bodies".

- will consult the Department and NHSBT on whom – the National Audit Office or a commercial auditor – shall undertake the audit(s) on his behalf, though the final decision rests with the C&AG;
- has a statutory right of access to relevant documents including, by virtue of section 25(8) of the Government Resources and Accounts Act 2000, those held by another party in receipt of payments or grants from NHSBT;
- will share with the Department information identified during the audit process and the audit report (together with any other outputs) at the end of the audit, in particular on issues impacting on the Department's responsibilities in relation to financial systems within NHSBT;
- will, where asked, provide the Department and other relevant bodies with regulatory compliance reports and other similar reports which the Department may request at the commencement of the audit and which are compatible with the independent auditor's role.

16. The Comptroller & Auditor General may carry out examinations into the economy, efficiency and effectiveness with which NHSBT has used its resources in discharging its functions. For the purpose of these examinations the C&AG has statutory access to documents as provided for under section 8 of the National Audit Act 1983. In addition, NHSBT is to provide, in conditions to grants and contracts, for the C&AG to exercise such access to documents held by grant recipients and contractors and sub-contractors as may be required for these examinations; and is to use its best endeavours to secure access for the C&AG to any other documents required by the C&AG which are held by other bodies.

Delegated Authorities

17. The Framework Agreement requires NHSBT to abide by any relevant cross-Government efficiency controls. These controls will be communicated to NHSBT.

20. Once funding has been approved by the Department, and subject to the Secretary of State's instructions and any other processes set out in this document, NHSBT has authority to incur expenditure approved in the budget without further reference to the Department, on the following conditions:
    - NHSBT will comply with its delegated authorities, which cannot be altered without the prior agreement of the Department, noting that authority to approve novel, contentious or repercussive proposals cannot be delegated from HM Treasury; and
    - inclusion of any planned and approved expenditure in business plan will not remove the need to seek formal departmental approval where any proposed expenditure is outside the delegated limits or is for new schemes not previously agreed.

21. NHSBT must obtain the Department's prior written approval before entering into any undertaking to incur expenditure outside its delegations

or not provided for in its business plan as approved by the Department. In addition, the Department's prior written approval is required when:

- incurring expenditure for any purpose that is or might be considered novel or contentious, or which has or could have significant future cost implications;
- making any significant change in the scale of operation or funding of any initiative or particular scheme previously approved by the Department;
- making any change of policy or practice which has wider financial implications that might prove repercussive or which might significantly affect the future level of resources required; or
- carrying out policies that go against the principles, rules, guidance and advice in Managing Public Money.

22. For major projects, NHSBT will participate in the Department's common assurance and approval process.

Annex C: Public-facing communications

General

1. This annex sets out the principles that govern how NHSBT and the Department of Health will work together to deliver effective and coherent communications in the spirit of common purpose.

2. To ensure that communication activities deliver real benefit for patients, the public, communities, stakeholders and the system itself, these principles will underpin all communications activities, creating an integrated communications approach for the health and care system as a whole.

3. To support this, the NHSBT Director of Communications will take part in the cross-system Arm's Length Bodies Directors of Communications forum that will take ownership of the cross-system communications approach. NHSBT and the Department of Health will also ensure that relevant senior officials from their communications teams meet regularly, build effective working relationships and design detailed working practices.

4. The general principles underpinning the approach to communications to be followed by NHSBT and the Department will be:

    - Mutual respect, co-operation and 'no surprises'
    - Value for money and avoiding duplication
    - A shared responsibility to promote and protect the public's health, aligning these activities where appropriate
    - The most effective communication using the most appropriate voice

Communications strategy and planning

5. NHSBT and the Department will develop annual communications strategies setting out their communications objectives and priorities. Where objectives are the same, the organisations will work together to ensure the associated activities are coherently aligned and add value to each other.

6. The ALB Directors of Communications forum will play a key role in ensuring communications strategies and planning across the health and care system are aligned and coherent.

7. As agreed by the Public Expenditure Committee (Efficiency and Reform) – PEX(ER) – major paid-for communications activity will also be incorporated into the annual health communication and marketing plans developed by the 'Health Hub'. The Hub structure has been developed across government to ensure value for money, reduce duplication and share expertise. The annual Health Hub communications and marketing plan is a requirement of the Cabinet Office's annual cross-government

Proactive Communications Plan.

8. In addition, PEX(ER) agreed to a cross-government freeze on paid-for communications activity and a process managed by the Cabinet Office's Efficiency and Reform Group (ERG) to manage this. The process, and details of the operation of the control, will be communicated to NHSBT by the Department.

Media Handling

9. NHSBT will establish and maintain independent relationships with all those interested in, or affected by its work, including the media. It will have responsibility for dealing with media enquiries received relating to its work and the way in which it exercises its functions.

10. The Department and NHSBT will keep each other informed of plans for media announcements. When it comes to the attention of DH or NHSBT that the media or any other organisation is intending to make public information related to NHSBT or its work, NHSBT or DH will, where possible, bring this matter to the attention of the other.

11. The Department and NHSBT will, where possible, bring to the attention of communications leads in each organisation issues creating media interest and expected media coverage which relates to the work of DH or NHSBT.

Announcements

12. To support the principle of partnership working described in the framework agreement and the commitment to 'no surprises', NHSBT and DH will share a schedule of relevant planned announcements weekly or fortnightly as appropriate. These should be treated "in-confidence" by the receiving parties and care taken with onward circulation.

13. NHSBT and the Department will endeavour to give each other as much notice as possible to enable early discussions on all aspects of the announcement with relevant policy and communications leads from each organisation.

14. NHSBT and the Department will also share, in confidence and principally for information, a near-final draft of any relevant report to be published, including conclusions, any executive summary and recommendations.

Publications

15. 'Publications' in this section refers to documents such as annual reports, anything relating to the structure or operation of the organisation, and statutory reports such as accounts. It does not include green or white papers or any other significant statements of Government policy. In these cases DH will commit to the principle of 'no surprises' wherever possible

and endeavour to share drafts with NHSBT officials for comment where appropriate.

16. There are separate arrangements for publication of official statistics and these are described in the Statistics section below.
17. To support the principle of partnership working described in the framework agreement and the commitment to ‘no surprises’, NHSBT and DH will share a schedule of relevant forthcoming publications weekly or fortnightly as appropriate.

18. NHSBT and DH will, except in exceptional circumstances, share publications with each other ten working days before publication for information and to allow clarification of any issues that may arise. NHSBT and DH officials will liaise as necessary to provide briefing on the publication. NHSBT and DH will, whenever possible, send a final copy of the publication to each other’s officials at least three days before publication. In exceptional circumstances, this period may be shorter and both parties will endeavour to allow as long as possible in such cases.

19. Where NHSBT and the Department of Health cannot resolve an issue relating to the detail in a publication due for release, the organisation publishing the document will respond to the querying organisation in writing before publication explaining why the comments cannot be taken on board in the final copy of the document.

20. When it comes to the attention of DH or NHSBT that another Government Department or public body is intending to publish a report concerning the other party and its work, DH or NHSBT will, wherever possible, bring this matter to the other’s attention.

Digital and channel strategy

21. DH and NHSBT will develop annual digital strategies setting out their digital communications objectives and priorities. These strategies will follow the principles set out in the annual cross-Government digital strategy.

22. The Department and NHSBT will use digital channels as their default channels for communications and services following the "digital first" channel strategy for health and care and the direction of travel set in the May 2012 Information Strategy for health and care, ‘The Power of Information’.

Campaign activity

23. Any major, public-facing campaign activity should be incorporated into the annual health communication and marketing plans developed by the Health Hub and agreed through the ERG process.

24. NHSBT will discuss this activity with DH in advance and ensure that DH has appropriate opportunities to inform the thinking and ensure a strategic fit with other campaigns across the health and care system. This will avoid unnecessary duplication and inefficient use of resource.

Statistics

25. Pre-announcement of statistical publications:

- The planned month of any statistical publications should normally be announced at least 12 months in advance. The precise date should be announced or confirmed at least 4 weeks in advance. To support the principle of co-operation, NHSBT should inform the DH Statistics Team of any changes to planned publication dates for Official Statistics.

26. Sharing data in their final form for briefing:

- Official statistics in their final form, including any press release for publication of official statistics, will be shared with those officials and Ministers for whom pre-release access has been agreed no earlier than 24 hours before the formal time of publication. Access for briefing purposes is limited to requirements to brief Ministers or others who may be required to comment at the time of publication. A list of people should be agreed 10 working days in advance, by the lead official for statistics at NHSBT , who will consult with the DH Head of Profession if they judge necessary (current DH models for pre-release access may be consulted as a guide). NHSBT will not provide media with embargoed access to the press release in advance of publication.

27. Sharing pre-publication data for other purposes

- Official statistics may also, with the agreement of the lead official for official statistics at NHSBT, be shared before publication for other purposes as set out below:

    i. With DH analytical staff where those staff are directly involved in producing the statistics, or related DH statistical products.
    ii. With named DH analysts and subject specialists, where there would be added value derived from expert Quality Assurance (QA) (either on the figures themselves, or on any statement of DH policy positions in the draft publication).
    iii. Where DH officials apply to NHSBT for access for a specified management purpose (if, for example, it is evident that patient health or public finances would be protected by granting such access).
    iv. Where up-to-date data are needed for inclusion in a DH publication planned for release at the same time or shortly after the statistics are to be published.

- In all cases where pre-release access is agreed, the purpose, timings and names of individuals should be agreed in advance by the lead official for statistics. All pre-release access will be documented, and lists of people granted access will be made available on request. Where pre-release access has been granted, the pre-publication uses of the data will not exceed the stated purpose.

Annex D: Relationships with other bodies

In order to deliver its functions efficiently and effectively, and to support alignment across the whole UK health system, NHSBT's key working relationships will be with:

UK Health Departments

- NHSBT is also a Special Health Authority in Wales, and is directed by the NHS Blood and Transplant (Wales) Directions 2005, as amended which govern the arrangements relating to Wales for blood, tissue and organ donation and transplantation services. NHSBT also has responsibilities across the United Kingdom with regard to organ donation and transplantation. NHSBT's accountabilities to the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland are governed via NHSBT's Board arrangements and through Income Generation Agreements, where requested.

Other blood services

- The four UK blood services collaborate, to ensure that there is uniformity of policy and practice as far as it is appropriate and reasonable to do so, providing one another with mutual contingency support, and participating in benchmarking and learning initiatives. Joint working is underpinned by:
    1. **The UK Forum**, comprising the Chief Executives (or equivalent) and Medical Directors of the four UK blood services.
    2. **Joint United Kingdom Blood Transfusion Services and National Institute of Biological Standards and Control Professional Advisory Committee (JPAC)**
       JPAC is an advisory committee to the UK blood services, normally via the Medical Directors of the individual services, who are full JPAC members. Overall accountability is to the UK Forum. JPAC prepares detailed service guidelines for the four UK blood transfusion services through *Guidelines for the Blood Transfusion Services in the UK* ('Red Book'). Each blood service will normally follow its guidance, the objective being to ensure that there is as far as possible commonality of approach across the four UK blood services, notably on donor selection, testing and manufacture. NHSBT retains the freedom to make its own decisions regarding the safety of its products, so there may be occasions when the Board wishes to diverge from JPAC guidance, usually to provide a higher level of safety than the JPAC requirements. JPAC's guidance includes translation of high level SaBTO recommendations into operational guidance. JPAC also advises on routine matters e.g. temporary changes to donor selection in response to new outbreaks of infections.

NHS foundation trusts, NHS trusts and other health providers

- NHSBT's core function is to provide critical products and services directly to NHS hospitals, and to support them in using blood, stem cells and tissues appropriately and effectively. NHSBT will work with them to ensure it provides safe products and services that also provide

demonstrable value for money. As part of this NHSBT will work collaboratively with NHS hospitals and seek to integrate its services where this can be demonstrated to improve safety and minimise wastage from donor through to patient.

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

- The role of SaBTO is to advise the four UK Health Departments on high level issues of safety of blood, tissues and organs. Its relationship with NHSBT is described in Annex E.

Independent and third sector health providers

- NHSBT works in partnership with independent and third Sector providers where appropriate to improve the availability, safety and quality of the products and services it provides to NHS patients.

NHS England

- NHSBT is a provider of specialist products and associated services. The changing health care system may result in changes to commissioning arrangements, led by NHS England, and NHSBT will work with them to implement any changes that are proposed. NHSBT works closely with the National Blood Transfusion Committee in providing advice and resources to hospitals in support of best transfusion practice.

National Blood Transfusion Committee

- The safe and appropriate use of donated blood, and alternatives to donated blood, are important public health and clinical governance issues. Reporting to the Medical Director, NHS England, the NBTC provides national advice on initiatives to optimise the prescribing and safe delivery of blood components. The NBTC and Regional Transfusion Committees comprise a structure that provides education, audit and advice to hospitals and their transfusion committees on best transfusion practice. NHSBT provides data and resources to enable this work to be carried out, and for hospitals to act on NBTC's advice.

Public Health England (PHE)

- NHSBT and PHE have jointly established an Epidemiology Unit, with joint oversight, that allows the organisations to collaborate on laboratory and epidemiological aspects of recognised and emerging infections relevant to transfusion and transplantation. The Unit provides data for use both within the UK blood services and to support the work of other stakeholders. The Unit's activities are covered by an SLA.

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Care Quality Commission (CQC)

- NHSBT is regulated in England by the CQC under the Health and Social Care Act 2008.

Medicines and Healthcare Products Regulatory Agency (MHRA)

- The MHRA is the Competent Authority that regulates NHSBT's compliance with the Blood Safety and Quality Regulations (BSQR), which take into account the requirements of relevant European Directives. NHSBT works with the MHRA to identify and mitigate against the potential impact of any emerging threats to the safety of blood.

Human Tissue Authority (HTA)

- Regulation of activities within organ donation and transplantation, tissue, stem cell and related tissue matching services is covered by the Human Tissue Act 2004 for England, Wales and Northern Ireland. The Human Tissue (Scotland) Act 2006 governs organ and tissue donation and transplantation in Scotland. NHSBT compliance with the Acts and the provisions of EU Tissues and Cells Directives are regulated by the HTA as the Competent Authority on a UK-wide wide basis. NHSBT works with the HTA to identify and manage threats to the safety of organ, stem cell and tissue transplantation.

Health Research Authority (HRA)

- NHSBT conducts research and development, with academic and NHS partners, that is aimed at improving outcomes for the patients and donors it serves. NHSBT will ensure appropriate national governance of its research activities in compliance with HRA guidance.

National Institute for Health and Care Excellence (NICE)

- NHSBT will contribute to, and follow guidance and quality standards issued by, NICE.

National Health Service Litigation Authority (NHSLA)

- The NHSLA manages negligence claims made against NHSBT under its existing NHS schemes.

Annex E: Safety Policy

1. Policy decisions which impact of the safety of blood tissues and organs involve a number of stakeholders, operating within a complex legal and regulatory environment.

2. Blood has been deemed to be a product under Product Liability legislation, with NHSBT therefore being a “producer” in law and falling within the scope of the European Products Liability Directive (enacted via the Consumer Protection Act 1987 in the UK). The NHSBT Board therefore has the ultimate responsibility for the safety of NHSBT blood products and has a duty to take all necessary, reasonable and precautionary steps to investigate, implement or maintain safety measures based on the best available scientific advice. NHSBT has an additional responsibility to investigate and consider new safety initiatives where there is a potentially significant improvement in safety to be gained, and to provide the Board with the information it needs to take informed decisions on implementation. This includes active investigation of relevant new technologies, establishing the international position and seeking the views of regulators or other relevant stakeholders and decision makers. Whilst the Board is not obliged to implement safety measures irrespective of cost, the issue of cost is subsidiary to matters of patient and donor safety, efficacy and supply.

3. To inform decision making and ensure consistency, NHSBT has developed a safety framework. This is used to develop policy where there is no guidance or instruction from other bodies.

4. SaBTO makes high level recommendations on the safety of blood, tissues and organs to the four UK Health Departments. These can result in instructions to NHSBT. UK blood services connect formally to SaBTO by the Chair of JPAC having observer status. Employees of NHSBT may be SaBTO members by virtue of their individual expertise, but do not formally represent NHSBT in that role.