



Department  
of Health

**NHS**

*Blood and Transplant*

**Framework Agreement  
between the Department of Health and  
NHS Blood and Transplant**

**2014**

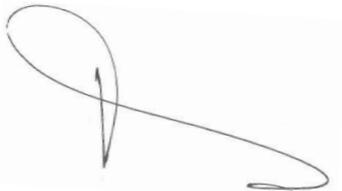
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Signed:



Felicity Harvey  
Director General Public Health

Date: 9 July 2014

(On behalf of the Department)

Signed:



Lynda Hamlyn  
Chief Executive

Date: 9 July 2014

(On behalf of NHSBT)

## Purpose of this document

- 1.1. The purpose of this document is to define the critical elements of the relationship between the Department and NHS Blood and Transplant (NHSBT) for functions carried out for the health system in **England**. The document is focused on:
  - How the Department and NHSBT will work in **partnership** to serve patients, the public and the taxpayer; and
  - How both NHSBT and the Department discharge their **accountability** responsibilities effectively.
- 1.2. This document also briefly sets out the relationship between the other UK Health Departments and NHSBT for functions carried out in the rest of the UK.

## 2. NHSBT's purpose

- 2.1. NHSBT is a Special Health Authority for England and Wales that supplies critical biological products and related clinical services to the NHS within a highly regulated environment. The *NHS Blood and Transplant (Establishment and Constitution) Order 2005*<sup>1</sup> is a joint England and Wales Order which provides NHSBT with a remit to:
  - collect, screen, analyse, process and supply blood, blood products, plasma, stem cells and other tissues to the health services
  - prepare blood components and reagents
  - facilitate, provide and secure the provision of services to assist tissue and organ transplantation
  - carry out any other such functions as directed.
- 2.2. NHSBT is also directed by the NHS Blood and Transplant (England) Directions 2005, and the NHS Blood and Transplant (Wales) Directions 2005, as amended (the Directions<sup>2</sup>), which govern the arrangements relating to England and Wales for blood, tissue and organ donation and transplantation services.
- 2.3. NHSBT's functions in relation to blood apply to England and North Wales<sup>3</sup> only. However, NHSBT also has responsibilities across the United Kingdom with regard to organ donation and transplantation.
- 2.4. In discharging these functions NHSBT will act economically, efficiently and effectively.

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<sup>1</sup> Statutory Instrument 2005 No. 2529

<sup>2</sup> Both sets of Directions are available at [http://www.nhsbt.nhs.uk/about/statutory\\_obligations/index.html](http://www.nhsbt.nhs.uk/about/statutory_obligations/index.html)

<sup>3</sup> The Welsh Blood Service covers South, West and part of mid Wales.

- 2.5. The Directions additionally direct NHSBT to:
- conduct or commission research into the uses of, or development of, blood, stem cells and tissues
  - promote, by advertising, marketing or otherwise the donation of blood, stem cells and tissues, with a view in particular to maintaining an adequate supply of blood, stem cells and tissue
  - promote through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood)
  - conduct or commission research in connection with the field of organ donation and transplantation as NHSBT considers appropriate
  - promote, by advertising, marketing or otherwise, the donation of organs and tissues with a view to maintaining an adequate number of organs and corneas for transplantation.
- 2.6. NHSBT depends entirely on the donation of blood, tissues, solid organs and haemopoietic stem cells and therefore facilitates and promotes altruistic donation within England and across the UK. NHSBT operates 24 hours a day, 365 days a year to deliver vital biological products and clinical services to the NHS, often at times of urgent and critical patient need. NHSBT's underlying supply chains operate under pharmaceutical industry standards and are highly regulated.
- 2.7. NHSBT's Strategic Plan, Annual Report and Accounts and Integrated Governance Framework set out more information about its functions and accountabilities.

### **3. Governance**

- 3.1. NHSBT is led by a Board<sup>4</sup> comprised of:
- a non-executive chair, appointed<sup>5</sup> by the Secretary of State for Health. and who is accountable for the governance of NHSBT;
  - not more than eight non-executive members, also appointed by the Secretary of State. One of these members shall include a person with particular experience suited to the interests of Wales;
  - a chief executive appointed by the non-executive chair and non-executive members; and
  - not more than eight executive board members, including the persons who hold the office of Chief Executive, Finance Director and Medical Director. The non-executive chair, non-executive members and the Chief Executive appoint the executive board members.

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<sup>4</sup> The constitution of the Board is dictated by Statutory Instrument 2005 No. 2529.

<sup>5</sup> The NHS Blood and Transplant Regulations 2005, Statutory Instrument 2005 No.2531, as amended, sets out the appointment and tenure of the board. The non-executive chair and non-executive members cannot hold office for longer than a total of eight years.

- 3.2. The Permanent Secretary has appointed a Senior Departmental Sponsor (SDS) who acts as NHSBT's designated, consistent point of contact within the Department. The SDS acts as the link at executive level between NHSBT and the senior officials of the Department, and also with ministers. Whilst the SDS role is facilitative and recognises the need for direct engagement between NHSBT and other parts of the Department and ministers, it also supports the Permanent Secretary in holding NHSBT to account and providing assurance on its performance. The SDS is currently the Director General for Public Health. The SDS is supported by a Departmental sponsor team, which is the principal day-to-day liaison between the Department and NHSBT. Welsh Ministers are represented in these arrangements by officials from the Welsh Government who attend the NHSBT Board as observers and who participate in the accountability review meetings. Scottish and Northern Ireland officials have similar arrangements. In addition, Welsh Government officials hold separate six monthly meetings with senior NHSBT executive team members to discuss issues specific to Wales.
- 3.3. As NHSBT is an England and Wales body, there is no legislation directing NHSBT to provide organ donation and transplantation services to Scotland and Northern Ireland. In lieu of this, NHSBT's accountabilities to the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland are governed via its Board arrangements and through Income Generation Agreements.
- 3.4. NHSBT is responsible for the delivery of policy objectives set for it by all of the four UK governments and will work with them to facilitate effective delivery solutions in case of policy differences. In the interests of patients across the UK the Department and NHSBT will apply the principles of partnership described by this document when working with the Welsh, Scottish and Northern Irish governments.

### ***Process for setting objectives***

- 3.5. NHSBT comprises three main Divisions, **Blood, Organ Donation and Transplantation** and **Diagnostic and Therapeutic Services**, covering tissues, stem cells, diagnostics and apheresis based therapies. Long term strategies are developed for each of the Divisions (and their constituent strategic operating units), including strategic objectives, targets and action plans, and are reviewed/updated periodically by the NHSBT Board as appropriate. The strategies are prepared by the Executive Team for review and approval by the NHSBT Board. Each year, as part of the Department's annual planning process, the strategies, targets and plans are then summarised and reported to the Department for scrutiny and review. This includes the annual plan/budget for the following year. Once cleared, by the NHSBT Board, and then the four UK Health Departments, NHSBT publishes a five year summary of its strategic plans.
- 3.6. An outcome of the strategic planning process is to establish the projected volume and pricing expectations for sales of blood components and specialist

services to hospitals in England and north Wales, and the subsidy required for funding for organ donation and transplantation across the UK. More detail is set out at 9.7 and **Annex B**.

### ***Discharge of statutory functions***

- 3.7. NHSBT ensures that it has appropriate arrangements in place for the discharge of each of the statutory functions for which it is responsible and is clear about the legislative requirements associated with each of them, specifically any restrictions on the delegation of those functions. It ensures that it has the necessary capacity and capability to undertake those functions, and will ensure that it has the statutory power to take on a statutory function on behalf of another person or body before it does so. NHSBT will also ensure that there is periodic audit<sup>6</sup> of the discharge of its statutory functions in line with the Harris Review<sup>7</sup>.

### ***Cross-government clearance***

- 3.8. In addition to internal governance, cross-government clearance is required for major new policy decisions of the type set out in Cabinet Office guidance.<sup>8</sup> Although such cases are likely to be small in number, the Secretary of State will be responsible for obtaining clearance and NHSBT will adhere to any conditions applied through the clearance process. There will also be cases where the Secretary of State must consult Cabinet colleagues before giving the Government's view, even if collective agreement is not required. In such cases, NHSBT will supply the Secretary of State with any information he or she needs in a timely fashion.

## **4. Accountability**

### ***Secretary of State***

- 4.1. The Secretary of State is accountable to Parliament for the health system in England (its "steward"), including NHSBT. The Department of Health supports him or her in this role. This involves:

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<sup>6</sup> NHSBT should include a review of this in its three-year audit cycle, but ensure that it takes steps to sufficiently assure itself on an annual basis and include details of this within its governance statements.

<sup>7</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/217025/Independent-review-of-the-arrangements-made-by-SHAs-for-the-approval-of-registered-medical-practitioners-and-approved-clinicians-under-the-Mental-Health-Act-1983-.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217025/Independent-review-of-the-arrangements-made-by-SHAs-for-the-approval-of-registered-medical-practitioners-and-approved-clinicians-under-the-Mental-Health-Act-1983-.pdf)

<sup>8</sup> Guide to Cabinet and Cabinet Committees,

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/224997/Guide\\_to\\_Cabinet\\_Committees\\_2012.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224997/Guide_to_Cabinet_Committees_2012.pdf) (pages 6-9)

- setting national priorities and monitoring the whole system's performance to ensure it delivers what patients, people who use services and the wider public need and value most;
- setting budgets across the health system, including for NHSBT;
- setting high level objectives for NHSBT;
- supporting the integrity of the system by ensuring that funding, legislation and accountability arrangements protect the best interests of patients, the public and the taxpayer;
- accounting to Parliament for NHSBT's performance and the effectiveness of the health and care system overall.

### ***The Principal Accounting Officer and NHSBT's Accounting Officer***

- 4.2. The Department of Health's Permanent Secretary is the Principal Accounting Officer (PAO) and so is accountable in Parliament for the general performance of the health and care system in England, including NHSBT. This requires him or her to gain assurance that NHSBT is discharging its statutory duties and meeting the objectives set out in the strategic planning summary provided annually to the Department. In this way the PAO is able to report to Parliament on DH's stewardship of the public funds it distributes and for which it holds overall accountability.
- 4.3. The Department's Permanent Secretary, as the Department's Principal Accounting Officer, has appointed NHSBT's Chief Executive as its Accounting Officer (AO). The AO may be called to Parliament to account for the performance of NHSBT. The PAO can also be held to account in Parliament since the PAO's oversight should allow him or her to assess the adequacy of NHSBT's stewardship of public funds and discharge of its duties. This assessment includes making judgments about whether NHSBT is operating to adequate standards of regularity, propriety, feasibility and value for money (assessed for the Exchequer as a whole).
- 4.4. The PAO's oversight of NHSBT's performance relies upon the provision of information and processes to enable both parties to review performance.
- 4.4.1. The information provided to the Department by NHSBT includes (not an exhaustive list):
- The NHSBT monthly Board performance report, which measures:
    - progress against its strategic targets and key projects
    - operational KPIs covering safety, supply, service delivery and productivity etc.
    - financial performance
  - A full set of Board papers in advance of each Board meeting every two months
  - Formal financial reporting to the Department (quarterly monitoring reports etc.)
  - Reports in support of Cabinet Office and Departmental spending controls

- 4.4.2. The processes in place to enable the Department and NHSBT to review performance include:
- Quarterly accountability reviews chaired by the SDS, or a representative, and involving the NHSBT Chair, Chief Executive and other relevant executive directors (as determined by the Chair). The focus of these meetings is on strategic issues, any issues regarding delivery that are of concern to the SDS, including compliance with the framework agreement, and any requests for assistance which the NHSBT Chair believes appropriate to bring to the meeting. The sponsor team works with NHSBT to establish the agenda and identify the specific items for discussion prior to the meeting. These meetings support the shared principles and are structured to promote openness, constructive challenge and the identification and resolution of strategic issues. Representatives of the other UK Health Departments are invited to attend all accountability review meetings
  - A representative of the SDS attends all NHSBT Board meetings and representatives of the other UK Health Departments are also invited
  - Annual accountability review, similar to the above but including a full review of NHSBT performance in the prior year and a review of the effectiveness of the Department/NHSBT partnership.
  - As required, meetings between DH and the NHSBT Chair, Chief Executive and other executive directors
  - Submission and review of the summary NHSBT strategic plan and annual budget as part of the Department's annual planning process
  - Attendance by a representative of the SDS at the Governance & Assurance Committee
- 4.5. NHSBT publishes an Annual Report and Accounts setting out how it has exercised its functions during the year. Drafts of the report are shared with the Department and the other UK Health Departments and are audited by the Comptroller & Auditor General. The final report is sent to the Secretary of State, with copies laid before Parliament and also the Scottish Parliament (Scotland Act 1998).
- 4.6. NHSBT is responsible for the delivery of its objectives and the Department limits the circumstances in which it will intervene in its activities. The following constraints do, however, apply:
- 4.6.1. All funds allocated to NHSBT must be spent on the statutory functions of NHSBT. If any funds are spent outside the statutory functions of the NHSBT the Department could seek adjustments to the subsidy.
- 4.6.2. The Secretary of State may terminate the tenure of the non-executive Chair or a non-executive member in the circumstances set out in Statutory Instrument 2005 No. 2531, as amended.
- 4.6.3. In the event of unresolved concerns regarding how NHSBT is carrying out its functions, the Secretary of State is able to direct NHSBT. If NHSBT fails to comply with such Directions, the Secretary of State, in consultation with the

other UK Health Ministers where appropriate, could either discharge relevant functions himself, or make arrangements for other bodies to do so on his behalf.

- 4.6.4. As NHSBT has performance accountability to the Northern Ireland, Scottish and Welsh Health Departments, all practical steps will be taken to involve them in these performance review processes.

## 5. The NHSBT Board

- 5.1. NHSBT is governed by its Board. The role of the board is as described in the corporate governance code for central government departments<sup>9</sup> and includes: establishing and taking forward the strategic aims and objectives of NHSBT, consistent with its overall strategic direction and within the policy and resources framework determined by the Secretary of State; holding its executive management team to account; and ensuring the organisation is able to account to Parliament and the public for how it has discharged its functions.
- 5.2. The Board is led by a non-executive Chair, who is responsible to the Secretary of State for ensuring that NHSBT's affairs are conducted with probity, and that NHSBT's policies and actions support it in the discharge of its functions and duties efficiently and effectively and meet NHSBT's objectives, including those set out in its business plan. The Senior Departmental Sponsor ensures that there is an annual objective setting and review process in place for the Chair.
- 5.3. NHSBT's Chair and non-executive members are appointed by the Secretary of State. Appointments are transparent, made on merit, and are regulated by the Commissioner for Public Appointments. NHSBT's Chair and members may appoint one of the non-executive members to be the Deputy Chair.
- 5.4. The Chief Executive reports to the Chair of NHSBT and is accountable to the NHSBT Board. The responsibilities of the Chief Executive are:
- Safeguarding the public funds and assets for which the Chief Executive has charge;
  - Ensuring propriety, regularity, value for money and feasibility in the handling of those funds;
  - The day-to-day operations and management of NHSBT;
  - Ensuring that NHSBT is run on the basis of the standards (in terms of governance, decision-making and financial management) set out in *Managing Public Money*, including seeking and assuring all relevant financial approvals;

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<sup>9</sup> The corporate governance guidelines (available at <https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments>) 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".

- Together with the Department, accounting to Parliament and the public for NHSBT's financial performance and the delivery of its objectives;
  - Accounting to the Department's Permanent Secretary, as Principal Accounting Officer for the whole of the Department of Health's budget, and providing a line of sight from the Department to NHSBT;
  - Reporting quarterly to the PAO on performance against NHSBT's objectives, to be discussed at the formal quarterly accountability meetings chaired by the Senior Departmental Sponsor.
- 5.5. The responsibilities of the Board as a whole include supporting the Accounting Officer in ensuring that NHSBT exercises proper stewardship of public funds, including compliance with the principles laid out in *Managing Public Money*; and ensuring that total capital and revenue resource use in a financial year does not exceed the amount specified by the Secretary of State.
- 5.6. The Board ensures that effective arrangements are in place to provide assurance on risk management, governance and internal control. The Board has set up a Governance & Assurance Committee, chaired by an independent non-executive member with significant experience of financial leadership at board level. The internal and external auditors must be able to attend all meetings and be provided with all papers.
- 5.7. The Board has ultimate responsibility for the delivery of services which meet the required standards of quality and safety for patients and donors. The Board provides leadership in driving a safety culture through the organisation, underpinned by structures designed to ensure optimal governance and clinical effectiveness. The role of the Board in relation to other organisations which also have responsibility for safety policy is outlined in **Annex E**.

## 6. Partnership working

- 6.1. The Department of Health and NHSBT have agreed to a set of shared principles.
- Working together for patients, people who use services and the public, demonstrating our commitment to the values of the NHS set out in its Constitution.
  - Respect for the importance of autonomy throughout the system, and the freedom of individual organisations to exercise their functions in the way they consider most appropriate
  - Recognition that the Secretary of State is ultimately accountable to Parliament and the public for the system overall. NHSBT will support the Department in the discharge of its accountability duties, and the Department will support NHSBT in the same way
  - Working together openly and positively. This will include working constructively and collaboratively with the other UK Health Departments and organisations within and beyond the health and social care system.

- 6.2. The Department and NHSBT work together, and with the Department's other arm's length bodies, and the other UK Health Departments, in the interests of patients, people who use services and the public to maximise the health and wellbeing gain for the population, working to the values set out in the NHS Constitution. To support this, NHSBT and the Department follow an 'open book' approach. In the case of issues with an impact on the development or implementation of policy, the Department can expect to be kept informed by NHSBT. In the same way, the Department will seek to keep NHSBT apprised of developments in policy and Government. There are likely to be some issues where the Department or NHSBT will expect to be consulted by the other before the Department or NHSBT makes either a decision or a public statement on a matter. The Department and NHSBT will make clear which issues fall into this category in good time. The sponsor team will be responsible for ensuring that this works effectively.
- 6.3. The Department will support NHSBT in the delivery of its work programme through providing guidance on how to access and influence resources from across the UK health network and facilitating the approval of its key business cases through the Department and the Cabinet Office.
- 6.4. To support the Secretary of State and the Principal Accounting Officer in the discharge of their accountabilities, the Secretary of State has the power to direct NHSBT to disclose to him or her such information as he or she feels necessary to fulfil their duties with respect to the health system. In addition, NHSBT shall have regard to any guidance issued by the Secretary of State. It is therefore expected that the Department will, when required, have full access to NHSBT's files and information. If necessary, the Senior Departmental Sponsor's team will be responsible for prioritising these requests for information.

### ***Emergency preparedness, resilience and response***

- 6.5. NHS England's Emergency Preparedness Framework 2013 requires all NHS funded organisations to comply with the principles of the Civil Contingencies Act 2004. The Act places statutory duties upon a defined group of "Category One responders" (which includes all acute hospitals) to maintain and exercise effective and appropriate emergency response plans. Although NHSBT does not itself have statutory responsibilities under the Act, as critical supplier to NHS hospitals, NHSBT will work with the Department, NHS England, PHE and the NHS to ensure support for the effective emergency response plans that are in place, take part in national exercises, and coordinate responses as necessary.
- 6.6. In support of this, NHSBT will comply with the terms of its SLA with the Department on emergency preparedness. In addition, NHSBT will comply with the relevant core standards in NHS England's *Core Standards for Emergency Preparedness Resilience and Response* and provide an annual statement of compliance to the EPRR Partnership Group. The Secretary of

State has cross-government responsibility to provide assurance on all aspects of the health system's emergency preparedness.

### ***Public and Parliamentary Accountability***

- 6.7. The Department and its ALBs share responsibility for accounting to the public and to Parliament for policies, decisions and activities across the health and care sector. Accountability to Parliament will often be demonstrated through parliamentary questions, MPs' letters and appearances before parliamentary committees. Accountability to the public may be through the publication of information on NHSBT's website, as well as through responses to letters from the public and responses to requests under the Freedom of Information Act.
- 6.8. The Department and its Ministers remain responsible to Parliament for the system overall, so often have to take the lead in demonstrating this accountability. Where this is the case, NHSBT supports the Department by, amongst other things, providing information for Ministers to enable them to account to Parliament. In its turn, the Department will provide leadership to the system for corporate governance, including setting standards for performance in accountability.
- 6.9. NHSBT, however, has its own responsibilities in accounting to the public and to Parliament, and its way of handling these responsibilities has been agreed with the Department. In all matters of public and parliamentary accountability the Department and its ALBs will work together considerately, cooperatively and collaboratively, and any information provided by NHSBT will be timely, accurate and, where appropriate, consistent with information provided by the Department. To facilitate this, the Department and NHSBT have agreed a public and parliamentary accountability protocol that sets out how they will work together to secure the confidence of the public and Parliament, and to maintain the service levels that MPs and the public have come to expect.

## **7. Transparency**

- 7.1. NHSBT is an open organisation that carries out its activities transparently. It demonstrates this by proactively publishing on its website its Annual Report and Accounts and key information including pay, diversity of the workforce, performance, the way it manages public money and the public benefits achieved through its activities. NHSBT will support those who wish to use the data by publishing the information within guidelines set by the Cabinet Office<sup>10</sup>. NHSBT holds open board meetings in line with the Public Bodies (Admission to Meetings) Act 1960. The annual report includes a governance statement, which is reviewed by the Senior Departmental Sponsor.

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<sup>10</sup> The guidance is available on the Gov.UK website:  
<https://www.gov.uk/government/topics/government-efficiency-transparency-and-accountability>

- 7.2. To underpin the principles of good communication, ‘no surprises’ and transparency, NHSBT and the Department have put in place arrangements for managing communications. Further details are provided in **Annex C**.
- 7.3. NHSBT’s executive and non-executive board members operate within the general principles of the corporate governance guidelines set out by HM Treasury (see footnote 8, page 9). They also comply with the Cabinet Office’s Code of Conduct for Board Members of Public Bodies<sup>11</sup> and with the rules on disclosure of financial interests contained in Statutory Instrument 2005 No. 2531.
- 7.4. NHSBT operates in accordance with the NHS Code of Conduct, which includes rules on conflicts of interest, and its code of conduct for all staff complies with the principles in the Cabinet Office’s model code for staff of executive non-Departmental public bodies<sup>12</sup>.
- 7.5. NHSBT takes all necessary measures to ensure that:
- patient, personal and/or sensitive information within its care and control is well managed and protected through all stages of its use, including through compliance with the Data Protection Act
  - it provides public assurance in respect of its information governance practice by completing and publishing an annual information governance assessment using an agreed assessment mechanism
  - it meets its legal obligations for records management, accountability and public information by compliance with relevant standards, including government and NHS codes of practice on confidentiality, security and records management.
- 7.6. NHSBT’s Senior Information Risk Owner and Caldicott Guardian work together to ensure that both patient and other personal information are handled in line with best practice in government and the wider public sector.

## ***Sustainability***

- 7.7. As a major public sector body, NHSBT has a key role to play in driving forward the government’s commitment to sustainability in the economy, society and the environment. As a minimum, NHSBT should comply with the Greening Government Commitments<sup>13</sup> that apply to all government departments, executive agencies and non-departmental public bodies, set out in the action plan for driving sustainable operations and procurement across government. Reporting is via the Department (including the consolidation of relevant information in the Department’s annual resource account), and the Department ensures that NHSBT is aware of the process for this.

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<sup>11</sup> <http://www.bl.uk/aboutus/governance/blboard/Board%20Code%20of%20Practice%202011.pdf>

<sup>12</sup> [http://www.civilservice.gov.uk/wp-content/uploads/2011/09/5\\_public\\_body\\_staffv2\\_tcm6-2484.pdf](http://www.civilservice.gov.uk/wp-content/uploads/2011/09/5_public_body_staffv2_tcm6-2484.pdf)

<sup>13</sup> <http://sd.defra.gov.uk/documents/Greening-Government-commitments.pdf>

## **Whistleblowing**

- 7.8. NHSBT, as with the Department and all its ALBs, has whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and best practice guidance<sup>14</sup>. It will prohibit the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest.

## **8. Audit**

- 8.1. The Comptroller and Auditor General audits NHSBT's Annual Report and Accounts. Assuming a satisfactory audit, the Comptroller and Auditor General will provide an audit certificate and audit report in time for NHSBT to lay the Annual Report and Accounts before Parliament, and the Scottish Parliament, in accord with published timetables.
- 8.2. The Comptroller and Auditor General may also choose to conduct a value-for-money audit of any aspect of NHSBT's work: NHSBT cooperates fully with the NAO in pursuing such audits, and give them full access to all relevant files and information.
- 8.3. The NHSBT Board is responsible for establishing and maintaining internal audit arrangements in accordance with the Public Sector Internal Audit Standards. NHSBT's internal audit function should report to its Governance and Assurance Committee, and should consider issues relating to NHSBT's adherence to its business plan. The Department's Audit and Risk Committee remit includes risk management, corporate governance and assurance arrangements in all its subsidiary bodies and so NHSBT's Governance and Assurance Committee should work closely with the Departmental committee. In support of this the representative of the Sponsor attends meetings of the NHSBT Governance and Assurance Committee (GAC). In case of any issues with the conduct of the GAC, or NHSBT executives, the representative of the sponsor will raise these, in the first instance, with the NHSBT Chair and NHSBT Chief Executive respectively.

## **9. Delegations and financial management**

- 9.1. Details of NHSBT's financial arrangements, including funding allocation, in-year reporting, preparation of accounts, and the accounting officer's responsibilities in relation to financial management and NHSBT's accounts, are provided in **Annex B**.

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<sup>14</sup><http://www.nhsemployers.org/EmploymentPolicyAndPractice/UKEmploymentPractice/RaisingConcerns/Pages/Whistleblowing.aspx>

- 9.2. NHSBT's delegated authorities are issued to it by the Department, including those areas where NHSBT must obtain the Department's written approval before proceeding. NHSBT will adhere to these delegated authorities.
- 9.3. NHSBT must demonstrate that it is delivering its functions in the most efficient manner, and must provide timely returns to the Department where these are required either by it or by other departments within central government.
- 9.4. NHSBT, as with all public bodies and government departments, must operate within any relevant set of efficiency controls. These controls may affect areas of spend such as information communications technology (ICT), marketing and advertising, procurement, consultancy, the public sector estate, recruitment, major projects or strategic supplier management. The Department will ensure that NHSBT is kept informed of any efficiency controls in operation.
- 9.5. As part of the government's approach to managing and delivering public service at a reduced cost base, NHSBT, as with all other arm's length bodies and the Department, is expected to receive its back office support, including finance and accounting, HR, payroll, procurement and ICT, through a shared or standardised service approach. Details of the services between NHSBT and the service provider will be set out in contract or where appropriate a service level agreement (SLA). The NHSBT Board will need to assure itself that any shared service solution meets its stated detailed business and operational requirements.
- 9.6. A shared or standardised value for money approach also applies to the use of estate. NHSBT will comply with guidance on property and asset management, as set out in **Annex A** and the principles set out by the Department's Estate Strategy Optimisation Board.
- 9.7. With regard to blood components and specialist services, NHSBT recovers its costs in the prices that are charged to NHS hospitals in England and north Wales. Volumes and prices are agreed by the National Commissioning Group for Blood (chaired by a representative of the SDS from within the Department). NHSBT operates within a net zero income/expenditure position and aims to recover its costs through the prices that have been set.
- 9.8. Funding for organ donation and transplantation is provided by way of subsidy from the Department, as well as contributions provided by the other UK Health Departments (on a population basis). More information is at **Annex B**.

## **10. Risk management**

- 10.1. NHSBT will ensure that it deals with the risks that it faces in an appropriate manner, according to best practice in corporate governance, and develop a risk management strategy in accordance with the Treasury guidance

*Management of Risk: Principles and Concepts*<sup>15</sup>. It will adopt and implement policies and practices to safeguard itself against fraud and theft, in line with HM Treasury guidance<sup>16</sup>. It should also take all reasonable steps to appraise the financial standing of any firm or other body with which it intends to enter into a contract.

- 10.2. The primary governance of NHSBT's performance rests with the NHSBT Board. NHSBT has put in place a reporting process to assure its Board of financial and operational performance against the business plan at its meetings (held six times per year). This includes a comprehensive monthly performance report (more detail at 4.4.1) which contains information on NHSBT's key risks and is shared with the Department to enable the Department to assure itself on performance and risk management. The Board's Governance and Audit Committee (GAC) is accountable for ensuring that NHSBT's risk management process is fit for purpose, working effectively and is managed in accordance with the Treasury guidance mentioned above. The overall assurance structure and process is captured within NHSBT's Integrated Governance Framework.
- 10.3. NHSBT and the Department will agree a process and trigger points for the escalation of risks to the DH Audit and Risk Committee (ARC), where those risks will have a potentially significant impact on NHSBT, DH or the wider system that requires a co-ordinated response.
- 10.4. Risks to the wider system that arise from NHSBT's operations, identified by NHSBT, DH or another body, are to be flagged in the formal quarterly accountability meetings chaired by the SDS. Such risks may also be flagged by NHSBT's Board and escalated to the DH ARC for consideration. It is the responsibility of NHSBT and its sponsor to keep each other informed of significant risks to, or arising from, the operations of the ALB within the wider system.
- 10.5. NHSBT will have effective and tested business continuity management (BCM) arrangements in place to be able to respond to disruption to business and to recover time-critical functions where necessary. In line with Cabinet Office guidelines, the BCM system should aim to comply with ISO 22301 Societal Security – Business Continuity Management Systems.
- 10.6. As part of its work, NHSBT undertakes and supports clinical trials and research and development projects for the benefit of NHS patients and the broader health system. To the extent that these are not covered by existing arrangements with the NHS Litigation Authority, the Department undertakes to enter into an on-going liability for any legal or other costs that may arise from such work. Each year, and taking account of the risks identified above, the Department and NHSBT will review the contingent liability represented by

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<sup>15</sup>[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220647/orange\\_book.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220647/orange_book.pdf)

<sup>16</sup> [http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/managing\\_the\\_risk\\_fraud\\_guide\\_for\\_managers.pdf](http://webarchive.nationalarchives.gov.uk/20130129110402/http://www.hm-treasury.gov.uk/d/managing_the_risk_fraud_guide_for_managers.pdf)

this undertaking and amend as necessary the Minute that has been presented to Parliament to describe the undertaking.

## **11. Human resources**

- 11.1. NHSBT is responsible for recruiting staff, but will comply with any departmental or government-wide recruitment controls. The Department will ensure that NHSBT is made aware of any such controls. Very senior managers in NHSBT are subject to the Department of Health pay framework for very senior managers in arm's length bodies, and may be subject to additional governance as specified by the Department. The Department will ensure that NHSBT is aware of any such requirements or restrictions.
- 11.2. NHSBT's staff are paid according to NHS terms and conditions. NHSBT must obtain the approval of the Secretary of State in respect of any new or additional policies relating to remuneration, pensions, allowances or gratuities.
- 11.3. Very senior manager remuneration is subject to the recommendations of the Senior Salaries Review Body.
- 11.4. In relation to pensions, the organisational pension scheme is the NHS Pensions scheme, which is administered by the NHS Business Services Authority and has rules set down in legislation.
- 11.5. As with all departments and arm's length bodies, NHSBT is required to follow any requirements for disclosure of pay or pay-related information.
- 11.6. Subject to its financial delegations, NHSBT is required to comply with the Department's and HM Treasury's approval processes in relation to contractual redundancy payments. All novel or contentious payments require the Department's and HM Treasury's approval. Special severance payments are always considered novel or contentious (this includes any proposal to make a payment as a result of judicial mediation).

### ***Equalities***

- 11.7. The public sector Equality Duty<sup>17</sup> requires NHSBT (as a public body) to have due regard to the need to:
  - Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
  - advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
  - foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

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<sup>17</sup> As set out in Section 149 of the Equality Act 2010

- 11.8. The specific duties require NHSBT, as a public body, to:
- Annually, publish information to demonstrate compliance with the public sector Equality Duty. This information must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees (provided the organisation has 150 or more employees) and other persons affected by its policies and procedures.
  - Prepare and publish one or more objectives<sup>18</sup> it thinks it should achieve to meet the public sector Equality Duty.

## 12. Relations with the Department's other arm's length bodies

- 12.1. NHSBT works in partnership with the Department and its other arm's length bodies, in the interests of patients, people who use services and the public, to maximise the health and wellbeing gain for the population, and working to the values set out in the NHS Constitution.
- 12.2. The Department and its arm's length bodies have complementary but distinct roles within the system to ensure that service users receive high quality services which deliver value for public money. **Annex D** describes the key relationships that NHSBT has with other bodies across the UK health system. As a manufacturer of biological products and related clinical services to the NHS the primary relationship between NHSBT and the DH family is that of a regulated entity under relevant legislation. In this regard NHSBT is inspected by the Care Quality Commission, Human Tissue Authority and the Medicines and Healthcare Products Regulatory Agency. In its role as a supplier to the NHS, NHSBT will also work with NHS England to implement any revised commissioning arrangements in support of the services that it provides.

## 13. Review

- 13.1. As described in section 3.3, NHSBT reviews and updates strategies for each of its strategic operating units on a periodic basis as appropriate. Each year, as part of the Department's annual planning process, the strategies and the related targets and plans are summarised and reported to the Department. This includes the annual plan/budget for the following year. In April each year NHSBT publishes a five year summary of its strategic plans for the benefit of all employees and stakeholders.
- 13.2. The Department regularly reviews NHSBT's performance at formal quarterly accountability meetings. In addition, the Department will undertake an in-depth review of NHSBT as well as its other arm's length bodies on at least a triennial basis.

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<sup>18</sup> This was required by 6 April 2012, and is required every four years thereafter

- 13.3. NHSBT is established by the *NHS Blood and Transplant (Establishment and Constitution) Order 2005*. Any change to its core functions or duties, including mergers, significant restructuring or abolition would therefore require further legislation or directions. If this were to happen, the Department would then be responsible for putting in place arrangements to ensure a smooth and orderly transition, with the protection of patients being paramount. In particular, the Department will ensure that NHSBT has procedures that will provide the Department with assurance on key transactions, financial commitments, cash flows, HR arrangements and other information needed to handle the transition effectively and to maintain the momentum of any on-going and / or transferred work.
- 13.4. This agreement will be reviewed every three years, or sooner upon request of either party.