

Board Assurance Framework

The BAF records the status of the principal risks that could impact on NHS Blood and Transplant (NHSBT) ability in achieving its strategic objectives or statutory obligations.

1. Principal Risk Status Summary

Reference	Principal Risk Title	Risk Appetite Level	esidual Score v sk Appetite Current Score (Residual)	Previous Score
P-01	Donor & Patient Safety	Minimal	Tolerable risk position (6 to 8)	8
P-02	Service Disruption	Minimal	Risk Limit (15 to 25)	12
P-03	Change Programme scale & pace	Open	Judgement Level (16 to 20)	20
P-04	Donor Numbers & Diversity	Open	Optimal Score (10)	12
P-05	Finance	Open	Tolerable risk position (12 to 15)	12
P-06	Inability to access and monitor clinical outcomes of patients	Open	Tolerable risk position (12 to 15)	12
P-07	Staff Capacity / Capability / Recruitment / Retention	Open	Judgement Level (16 to 20)	16

Reference	Principal Risk Title	Risk Appetite Level	Residual Score v Risk Appetite	Current Score (Residual)	Risk Movement	Previous Score
P-08	Leaders and Managers	Open	Judgement Level (16 to 20)	16	•	16
P-09	Regulatory Compliance (Primary Regulators)	Cautious	Judgement Level (12 to 15)	12	•	12
P-10	Service Disruption - Loss of Critical ICT	Minimal	pool pool pool pool pool pool pool pool			
P-11	Reputation	Open	DOG BOTTON TO THE PROPERTY OF			
P-12	Commercial Exposure	Open	DO DO DE DE LA COLLEGA DE LA C			
P-13	Governance Failure	Minimal	DO Impact			

Section 2. Principal Risk Detail

This section of the report provides detail of the principal risks and the contributory risks influencing the score. The section provides detail against the following areas:

Principal Risk Detail Risks that could significantly affect the achievement or performance of NHSBT's priorities / strategic obligations.

Contributory risks Dynamic risk level consisting of current directorate level risks which are influencing the status of the principal risk areas

Detail of risks recorded within the Risk Limit

Provides detail of risks recorded at the Risk Limit

Risk Appetite Detail

			Appetite Range		
• •	Low Risk (considered low risk and managed as such)	•		risk which requires	Risk Limit (Risk level which cannot be accepted or tolerated)
Minimal	1 to 3	4	5 to 8	9 to 12	15 to 25
Cautious	1 to 6	8	9 to 10	12 to 15	16 to 25
Open	1 to 9	10	12 to 15	16 to 20	25

2.1. Principal Risk - P-01 Donor and Patient Safety

Principal Risk Detail

	Risk Description				Risk Score (Residual)	Current Appetite Status No. of Child Risks at Risk Limit		Trend
	here is a risk that harm occurs to a donor or patient owing to failure to control the safety of NHSBT clinical activities				8	Tolerable risk position (6 to 8)		
Linked NHSBT Obligation					T Strategy Modernise NHSBT's operations			SBT's operations
Managed By	Clinical Risk Manager	Responsible Executive	Chief Medical Officer	Oversight Committee			Date Assessed	06-Jun-2023

Responsible Manager	Original principal risk has been simplified and the contributory elements have been identified as separate risks contributing to the principal risk score.
Summary	Contributing risks have not been approved outside Clinical Services, this is a work in progress. Further clarity on the scope of Clin-05 is required, including
	further identification of controls, assurance and mitigating actions.

		Creation Date	Impact	Likelihood		Date Assessed		Monitoring Committee
Clin-01	Clinical Safety	22-May-2023	4	2	8	06-Jun-2023		Clinical Governance Committee
Clin-02	Technology limitations	23-May-2023	4	2	8	06-Jun-2023	•	Clinical Governance Committee
Clin-03	Transmission of disease by a previously unidentified agent	22-May-2023	5	1	5	06-Jun-2023	•	Clinical Governance Committee
Clin-04	Known complication of transfusion or transplantation	22-May-2023	4	2	8	06-Jun-2023		Clinical Governance

								Committee
Clin-05	Advice and education	22-May-2023	4	2	8	06-Jun-2023	•	Clinical Governance Committee

2.2. Principal Risk - P-02 Service Disruption

Principal Risk Detail

	Risk Description				Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit		Trend
	There is a risk that NHSBT is unable to deliver safe and effective products and services caused by a disruption to one or more of NHSBT's critical activities resulting in an adverse impact to patient care.				16	Risk Limit (15 to 25)	1	1	
Linked NHSBT Obligation	Establishment & Constitution Order 2005 Linked NHSE			BT Strategy	Modernise NHSBT's operations				
Ву	Assistant Director, Risk Management & Business Continuity	Responsible Executive	Director of Quality	Oversight Committee	Risk Managem	isk Management Committee		29-Jun-202	23

Responsible Manager	Activity on power failure is being driven by joint actions led by DHSC with other Arms Length Bodies. Pandemic responses will be reviewed when national
Summary	lessons learned results in new guidance from DHSC. Severe weather includes high temperatures as well as the more historic cold weather, ice and snow.
	Work on the Southampton roof response is ongoing, but is now being managed as business as usual.

		Creation Date	Impact	Likelihood	Residual Score	Date Assessed	Monitoring Committee
BC-01	Pandemic Disease.	01-Mar-2023	5	1	5	28-Jun-2023	Risk Management Committee
BC-02	Severe Weather.	01-Mar-2023	4	2	8	04-Jul-2023	Risk Management Committee
BC-03	Power Failure.	01-Mar-2023	5	2	10	28-Jun-2023	Risk Management Committee
BS-02	Shortage of Blood Components /Inability to meet hospital demand	22-Mar-2023	4	3	12	19-May-2023	Blood Operational

								Leadership Team (BOLT)
MO-09	Irradiation Enforcement Notice	06-Oct-2017	4	4	16	17-Jul-2023		Blood Operational Leadership Team (BOLT)
PEOPLE-08	Industrial Action	05-Oct-2022	2	3	6	30-Jun-2023	•	People Committee

Detail of Contributory Risk Recorded at the Risk Limit

Risk Title		Creation Date	Impact	Likelihood		Date Assessed	Monitoring Committe
MO-09	Irradiation Enforcement Notice	06-Oct-2017	4	4	16	17-Jul-2023	Blood Operational Leadership Team (BOLT)

Risk	There is a risk that NHSBT will be unable to supply products from Hospital Services either locally or nationally, caused by not complying with the permit conditions as defined by
Description	the regulations for Irradiation (EPR 2016, IRR17), resulting in an enforcement notice being issued by the Environment Agency, Health and Safety Executive, MHRA or Counter
	Terrorism Police, the permit being revoked and the enforced closure of Irradiation procedures.

	Mitigating Control	Effectiveness	Gap In Control
	The ISO22301 compliant system for Business Continuity as laid out in various MPDs, certified by BSI (under UKAS criteria) and certified annually.	Fully Effective	
	 All staff working with Irradiators are trained to the appropriate processes and safety guidelines. Regional Hospital Services Managers trained in dose mapping 	Partially effective	Training for Regional Hospital Services Managers currently ongoing.
Management	1. Minimum of one Radiation Protection Supervisor on site at any one time. 2. NHSBT employ an Irradiation advisory service from UK Health and Security Agency. This is part of the Irradiation policy management structure. They are required to advise on Irradiation regulatory compliance. All sites with Irradiators are visited annually and reports produced. 3. Duty Hospital Service Managers are also trained as Radiation Protection Supervisors. DHSMs are also on call. 4. Quarterly Irradiation Management Group - Multi disciplinary and includes	Fully Effective	

representation from all other UK blood services and hospitals. Chaired by Principal Irradiation Protection Supervisor for NHSBT.	•	
CEO signed off EPR2010 management document. A system to assure the standard and regulatory compliance of processes, products and services Policies in place to ensure compliance with Irradiation regulations.	effective	Identification of possible non-conformances and correct these. Ensure Irradiation Policy is correct in terms of governance and safety processes.

	Source of Assurance	Effectiveness	Gaps in Assurance
	BSI Report - NHSBT ISO22301 Business Continuity Report for GAC Governance Statement 2018 Management Review 2017 BSI ISO22301 Certificate 2016 MPD701 and all associated documents Task Based Training Records	Substantial	
Assurance	Task Based Training Records	Moderate	Awaiting TBTRs for Regional Hospital Services Managers in dose mapping.
7.000.000	 MPD701 and all associated documents POL269 and recorded annual visits and reports. On Call rotas and records Attendance, actions and minutes of each meeting recorded by NHSBT. 	Substantial	
	POL269 Irradiation Regulatory Management and Safety Policy MPD701 Irradiation	Moderate	Indentification of possible non-conformances and correct these. Ensure Irradiation Policy is correct in terms of governance and safety processes. Irradiation documentation and process review to be conducted

	Action Title	Action Status	Due Date	Assigned to
	Set Up Health Safety and Wellbeing internal audits to support operational team	Assigned	<u> </u>	Lead Specialist Technical & Scientific Development (Manufacturing & Logistics)
Treatment (Action)	Identification of possible non-conformances (new booklet) and correct these.	Assigned	•	Lead Specialist Technical & Scientific Development (Manufacturing & Logistics)
	Ensure Irradiation Policy is correct in terms of governance and safety processes.	Assigned	•	Lead Specialist Technical & Scientific Development (Manufacturing & Logistics)
	IRR17 Risk Assessment Review, Updates and Training	Assigned		Lead Specialist Technical & Scientific Development

			(Manufacturing & Logistics)
Compliance with mandatory training - Irradiation Safety Awareness	Check Progress	15-Aug-2023	Lead Specialist Technical & Scientific Development (Manufacturing & Logistics)
Contingency rehearsals - Development of Scenario, Implementation and Confirmation	Assigned	31-Oct-2023	Lead Specialist Technical & Scientific Development (Manufacturing & Logistics)
Additional Lead Specialist to be trained in irradiation	Completed	31-Jul-2022	Projects Manager Operations
Irradiation documentation and process review to be conducted	Assigned	30-Sep-2023	Projects Manager Operations
Train Regional Hospital Services Managers in dose mapping	In Progress	31-Aug-2023	Projects Manager Operations
Confirm process for clinical queries with Clinical Lead	Completed	31-Jan-2023	Projects Manager Operations

2.3. Principal Risk - P-03. Change Programme - Scale and Pace

Principal Risk Detail

Risk Description				Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit		
	There is a risk that implementation of our strategy will be delayed because the scale and pace of our change programme is insufficient to realise benefits				16	Judgement Level (16 to 20)	0	•
Linked NHSBT Obligation	Corporate Strategy Linked NHSE			BT Strategy	Strategy Drive Innovation			
Managed By	Assistant Director Transformation Portfolio Management	Responsible Executive	Deputy Chief Executive	Oversight Committee	I Strategy and Transformation I		Date Assessed	21-Jul-2023

Responsible Manager	A review of this risk remains ongoing, with revised detail to be added to the next summary
Summary	

Risk Title	Creation Date	Impact	Likelihood	Date Assessed	Monitoring Committee

2.4. Principal Risk - P-04. Donor Numbers & Diversity

Principal Risk Detail

Risk Description				Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit		Trend	
	There is a risk that NHSBT does not attract the right number and diversity of donors due to failure to engage the public effectively, resulting in the worsening of the supply demand gap for our products				9	Optimal Score (10)	0	•	
Linked NHSBT Obligation	NHSBT Establishment & Constitution Order 2005 Linked NHSE			BT Strategy	Gro	ow and diversify	NHSBT's	donor base	
	Risk Manager (OTDT & Donor Experience)	Responsible Executive	Director of Donor Experience	Oversight Committee	I Donor Experience Sivil		Date Assessed	05-Jun-20	23

Responsible Manager	There has been no change to any risks related to P-04, all risks continue to be monitored and reviewed when necessary with the relevant stakeholders.
Summary	

		Creation Date	Impact	Likelihood		Date Assessed	Monitoring Committee
DX-01	Changing Donor Behaviour	19-Nov-2021	2	2	4	12-Jul-2023	Risk Management Committee
DX-04	Changing Donor Expectations	20-May-2019	2	3	6	22-Nov-2022	Risk Management Committee
DX-19	Social License to Operate	22-Nov-2022	3	3	9	04-May-2023	Risk Management Committee
DX-20	Changing Donor Motivations	22-Nov-2022	4	2	8	20-Jan-2023	Risk Management Committee

DX-21	Staff Capacity & Capability	29-Nov-2022	2	3	6	27-Mar-2023	Risk Management Committee
DX-22	Financial Planning / Unexpected Costs	29-Nov-2022	3	3	9	28-Mar-2023	Risk Management Committee
DX-23	Failure of Donor Facing Technology	29-Nov-2022	4	2	8	05-Apr-2023	Risk Management Committee
DX-24	Risks Associated with DX&C Data	29-Nov-2022	4	2	8	12-Jul-2023	Risk Management Committee

2.5. Principal Risk - P-05. Finance

Principal Risk Detail

		Risk Descrip	tion		Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	Trend
	ere is a risk that NHSBT is unable to maintain long term financial sustainability caused by insufficient nding or unexpected cost increases resulting in NHSBT being unable to meet expectations or obligations				12	Tolerable risk position (12 to 15)		
Linked NHSBT Obligation	T Achieving and maintaining Financial balance Lir				BT Strategy		Covers all St	rategic priorities
Ву	Financial Services Manager & Local Counter Fraud Specialist	Responsible Executive	Chief Financial Officer	Oversight Committee			Date Assessed	20-Apr-2023

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Responsible Manager							
Summary							

Risk Title		Creation Date	Impact	Likelihood	Residual Score	Date Assessed	Monitoring Committee
F-01	capability, reliability, and security of our systems leads means we are unable to complete financial processes leading to a loss of financial control and an inability to complete financial transactions.		4	3	12	13-Apr-2023	Risk Management Committee
F-02	cash position deteriorates to an extent that we are unable to meet our liabilities (e.g. payroll)	13-Apr-2023	4	2	8	13-Apr-2023	Risk Management Committee
F-03	Failure in NHSBT operational processes leads to us unable to make our payments in a timely way (including payroll)	13-Apr-2023	4	2	8	13-Apr-2023	Risk Management Committee

F-04	Income/Funding insufficient to to deliver against our obligations leading to a failure to deliver key requirements	13-Apr-2023	3	3	9	13-Apr-2023	_	Risk Management Committee
F-05	Loss of reputation for sound Financial Control (due to fraud, error, or improbity) leading to reduced willingness to invest in NHSBT services, lower delegations, and more external scrutiny	13-Apr-2023	3	3	9	13-Apr-2023	-	Risk Management Committee
Fin 05	There is a risk that a failure in our operational processes leads to us unable to make our payments in a timely way (including payroll)	17-Jul-2023						
Fin 06	There is a risk that we fail to provide efficient and effective financial management (budgeting, forecasting, reporting) leading to over/underspends and/or poor vfm	19-Jun-2023	2	1	2	19-Jun-2023	-	
Fin 07	There is a risk that we fail to recruit and retain an effectively, motivated, diverse and capable team leading to a low performing function	19-Jun-2023	3	3	9	19-Jun-2023	-	

2.6. Principal Risk - P-06. Clinical Outcome of Patients

Principal Risk Detail

		Risk Descrip	tion		Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	Trend
products and information sy	nere is a risk that NHSBT will be unaware and fail to monitor clinical outcomes in patients receiving our oducts and services caused by an inability to access data sets in a timely manner due to incompatibility of formation systems and lack of engagement with Trusts and other bodies holding significant datasets, eventing us from identifying and driving forward opportunities for improvement.				12	Tolerable risk position (12 to 15)		
Linked NHSBT Obligation	Linked NHSBT Safety & quality of NHSBT activities Linked N				BT Strategy	Drive Innov		nnovation
Managed By	Clinical Risk Manager	Responsible Executive	Chief Medical Officer	Oversight Committee			Date Assessed	07-Jun-2023

Responsible Manager	Risks relating to ability to access data in order to monitor outcomes of stem cell and apheresis patients in order to drive improvement in technology and
Summary	processes have been identified, mitigating workplans are at early stages of development. The risk regarding outcome of transfusion recipients requires further
	discussion and identification of the mitigating workplans. Formulation of an equivalent risk for organ and tissue recipient patients is in progress.

Risk Title		Creation Date	Impact	Likelihood	Residual Score	Date Assessed	Monitoring Committee
	Innovation in therapeutic apheresis and peripheral blood stem cell collection	07-Jun-2023	4	3	12	07-Jun-2023	Clinical Governance Committee
Clin-07	Opportunities to improve clinical outcome for stem cell patients	07-Jun-2023	4	3	12	07-Jun-2023	Clinical Governance Committee
Clin-08	Blood Usage	07-Jun-2023	3	4	12	07-Jun-2023	Clinical Governance Committee

Clin-09	Transplantation outcomes	14-Jun-2023	4	2	8	14-Jun-2023		Clinical Governance Committee
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2.7. Principal Risk - P-07. Staff capacity, capability, recruitment & retention

Principal Risk Detail

		Risk Descrip	tion		Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	
					16	Judgement Level (16 to 20)	0	•
Linked NHSBT Obligation	Establishment & Constitution Order 2005 Linked NHS			Linked NHSE	BT Strategy Invest in people and culture			ople and culture
Managed By	Assistant Director - HS&W	Responsible Executive	People Director	Oversight Committee	People Senior L Team (SLT)	Leadership Date Assessed 27-Apr-2023		

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Responsible Manager							
Summary							

		Creation Date	Impact	Likelihood	Residual Score	Date Assessed		Monitoring Committee
PEOPLE-01	Lack of Succession Planning	23-Jan-2017	3	3	9	19-Jun-2023		People Committee
PEOPLE-02	Occupational Health Service	23-Jan-2017	3	3	9	28-Apr-2023	1	People Committee
PEOPLE-06	Staff Capacity / Capability / Recruitment / Retention	26-Jul-2022	4	4	16	27-Apr-2023		People Committee
PEOPLE-07	Recruitment Team Capacity and Instability	03-Aug-2022	4	2	8	27-Apr-2023		People Committee

PEOPLE-09	Workforce Information	07-Oct-2022	3	3	9	27-Apr-2023	1	People Committee
PEOPLE-11	People Business Plan Performance Risk	07-Jun-2023	4	4	16	07-Jun-2023		People Committee

2.8. Principal Risk - P-08. Managers skills and capability

Principal Risk Detail

	Risk Description				Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit		
	There is a risk that NHSBT lack the skills and capabilities for leaders and managers required in today's NHS to create a high-performing, inclusive environment, and to deliver our strategic priorities				16	Judgement Level (16 to 20)	0	-	
Linked NHSBT Obligation	E			tion Order 2005	Linked NHSE	BT Strategy	gy Invest in people and culture		
Managed By	Assistant Director - H	S&W	Responsible Executive	People Director	Oversight Committee			Date Assessed	02-Feb-2022

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Responsible Manager	
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		Creation Date	Impact	Likelihood	Residual Score	Date Assessed		Monitoring Committee
OTDT-19	Leadership skills and capabilities	19-Jan-2023	3	3	9	19-Jan-2023		ODT Senior Management Team (SMT)
PEOPLE-05	Leaders and managers lack the skills and capabilities	20-Jun-2022	4	4	16	02-Feb-2023	1	People Committee

2.9. Principal Risk - P-09. Regulatory Compliance (Primary Regulators)

Principal Risk Detail

	Risk Description			Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	Trend	
in NHSBT be the ability of N It also has the (CQC = Care	ere is a risk that NHSBT will become non-compliant with current or emerging regulations which could result NHSBT being subject to significant regulatory action and/or licences being revoked. This would impact on a ability of NHSBT to provide critical services and products and/or have a serious impact on patient safety. Its ohas the potential to significantly, and detrimentally, affect the reputation of the organisation. QC = Care Quality Commission / HTA = Human Tissue Authority / MHRA = Medicines & Healthcare adducts Regulatory Agency)			12	Judgement Level (12 to 15)	0		
Linked NHSBT Obligation	Establishment & Constitution Order 2005 Linked NHSE			BT Strategy Covers all Strategic prior		rategic priorities		
Managed By	Lead Quality Specialist	Responsible Executive	Director of Quality	Oversight Committee	()Hality Assurance SMI		Date Assessed	10-May-2023

Responsible Manager	4 contributory risks were agree
Summary	at the optimal risk score, with the
	impact. 1 risk exists in the jude

4 contributory risks were agreed at Quality SMT in April and May 2023. 3 contributory risks have been reviewed fully with the relevant stakeholders, 2 remain at the optimal risk score, with the other contributory risk (Quality Resource) requiring addition review on 12/07 with stakeholders to determine the primary risk impact. 1 risk exists in the judgement zone, with a review scheduled being completed with stakeholders on 13/06 and approval from Quality SMT to be sought in July 2023

		Creation Date	Impact	Likelihood	Residual Score	Date Assessed	Monitoring Committee
QA-01	Quality Management System	19-Feb-2021	4	2	8	19-Apr-2023	Risk Management Committee
QA-02	Regulatory Horizon Scanning	19-Feb-2021	4	2	8	06-Jul-2023	Risk Management Committee

QA-03	Quality Resource	27-Apr-2023	4	3	12	27-Apr-2023	7	Risk Management Committee
	Compromised patient/donor safety as a result of an unsupported eQMS and fragmented governance system	03-Aug-2022	5	2	10	04-Aug-2022	•	Risk Management Committee

2.10. Principal Risk - P-10. Service Disruption - Loss of Critical ICT

Principal Risk Detail

	Risk Description				Current Appetite Status	No. of Child Risks at Risk Limit	
	There is a risk of full or partial loss of functionality in NHSBT's critical IT systems, caused by multiple elements, resulting in interruption to the delivery of NHSBTs objectives					0	
Linked NHSBT Obligation	NHSBT Establishment & Constitution Order 2005			BT Strategy		Covers all St	rategic priorities
Managed By	Responsible Executive Chief Digital and Information Officer			Digital, Data an Services (DDTS	٠.	Date Assessed	

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Responsible Manager						
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I	Risk Title		Impact	Likelihood	 Date Assessed	Monitoring Committee
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2.11. Principal Risk - P-11 Reputation

Principal Risk Detail

	Risk Description	Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	Trend	
the failure to a organisation of	At that NHSBT loses the trust and confidence of it's staff, the public and stakeholders eatisfy and demonstrate the correct behaviours and expectations of a post of the public, employees and stakeholders resulting in negative publicity, recrudems, reduced donor attendance and difficulties in maintaining the effective paservices					
Linked NHSBT All corporate and strategic obligations and objectives Cobligation Linked NHSB				Strategy Covers all Strategic priorities		
Managed By	Responsible Executive	Oversight Committee			Date Assessed	

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2.12. Principal Risk - P-12/ Commercial Exposure

Principal Risk Detail

Risk Description	Risk Score (Residual)	 No. of Child Risks at Risk Limit	
There is a risk that NHSBT fails to remain competitive in the wider business environment, caused by the business model and approach of competitors that provide similar products and services, resulting in a failure to secure wider business opportunities with a reduced market footprint			

Linked NHSBT Obligation	Corporat	e Strategy	Linked NHSB	T Strategy	Covers all St	rategic priorities
Managed By	Respons Executiv		Oversight Committee		Date Assessed	

Responsible Manager	•	 •	 -		
Summary					

2.13. Principal Risk - P-13. Governance Failure

Principal Risk Detail

	Risk Description		Risk Score (Residual)	Current Appetite Status	No. of Child Risks at Risk Limit	
There is a risk that NHSBT fails to understand, implement and control effective organisational processes, caused by absence, or ineffective monitoring arrangements, lack of leadership engagement, and the inadequate analysis of assurance, resulting in a failure to deliver organisational objectives, increased external scrutiny, unplanned financial expenditure, loss of staff, public, patient and stakeholder confidence						
Linked NHSBT All corporate and strategic obligations and objectives United NHSE Obligation Linked NHSE		BT Strategy		Covers all St	rategic priorities	
Managed By	Responsible Executive	Oversight Committee			Date Assessed	

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Responsible Manager	
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