Standard Operating Procedure for the interim management of Research compliance following the formation of Bristol NHS Foundation Trust (BFT)

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Document Control	
Document Type:	SOP
Version:	1.0
Effective From/Date of Approval:	01-Jul-2026
Review Date:	01-Jan-2027
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Approval Authority (Committee/ Group Executive Meeting):	Trust Research Group
Keywords:	Research, MHRA, HRA, trials, sponsor, studies.

Contents

1. Executive Summary / Introduction

UHBW and NBT collectively sponsor and host in excess of 1,000 research studies, including CTIMPs, CIMDs and ATIMPs. On 1st July 2026 a new organisation, Bristol NHS Foundation Trust (BFT), will be formed through the acquisition of NBT by UHBW. Throughout this process, it is imperative that there is ongoing compliance with all research related regulations and that there is minimal disruption to effective research delivery.

The safety of research participants and the integrity of research data remain paramount. Accordingly, continued compliance with all relevant regulatory frameworks and guidance must be maintained, including but not limited to:

- The Medicines for Human Use (Clinical Trials) Regulations (as amended)
- ICH Good Clinical Practice E6(R3)
- The UK Policy Framework for Health and Social Care Research

- The Human Tissue Act
- Data Protection legislation

This document sets out the interim operating procedure for all functions of Research & Development including;

- Grant development
- Sponsorship and Governance
- Commercial and non-commercial (hosted) Research
- Research Delivery Workforce
- Governance oversight and escalation
- R&D Systems and data management

A change process to merge the two core R&D departments will be carried out within the first six months of day one of the new organisation (day 1). The period between day 1 and the new R&D structure is the transition period.

A pragmatic and proportionate approach to management and oversight of research will be taken for the transition period. Processes related to the functions described above will be aligned as the two R&D departments become integrated into a single department.

Clear interim processes to describe R&D activities will be put in place during the transition period. They will ensure appropriate ongoing management and oversight of research to assure continuity of safe, effective research delivery, while maintaining the highest standards of participant safety and data integrity and all other aspects of regulatory compliance.

This SOP is intended to be in place for the duration of the transition period and will be reviewed at the latest at six months post-acquisition. If required, it will be amended and/or extended. Once a single organisational structure and a single Quality Management system with a unified set of R&D processes for Bristol NHS Foundation Trust are established, this interim guidance will be retired.

Alongside this SOP, *BRDG_001 Interim R&D Operating Arrangements for BFT* has been developed to support staff within R&D. It provides detailed information on interim operational processes. It is expected that this guidance document will evolve as the teams, systems and procedures work towards alignment; new BFT procedural documents will ultimately replace it.

2. Purpose and Scope

2.1 Purpose

The purpose of this document is to define the interim operating procedures for Research and Development (R&D) of the newly formed Bristol NHS Foundation Trust (BFT) following the acquisition of North Bristol NHS Trust (NBT) by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) prior to the introduction of a single Quality Management System (QMS).

NBT and UHBW are well-established research active hospital Trusts with their own suites of SOPs to cover the entire research pathway which are compliant with all applicable regulations. The very short timeline between confirmation of acquisition of NBT and the date of the legal merger make having a single combined Quality Management System for research unachievable as the workload would be dis-proportionate to the safety, data and regulatory risk. Therefore, existing SOPs from each organisation will continue to operate until superseded by BFT SOPs. Where effective and safe delivery of research may be impacted by running two parallel quality management systems this SOP identifies where alternative processes will be implemented for the interim period.

During the interim period, this SOP will:

- Clearly define which SOPs will be utilised for each function within R&D
- Define clear routes of escalation in the interim period
- Act as the authoritative SOP for R&D to describe interim arrangements for processes prior to the implementation of BFT research SOPs
- Support ongoing compliance with all applicable regulatory, legal and policy requirements
- Ensure safe and effective research delivery with minimal disruption

2.2 Scope

This SOP includes all core R&D functions and applies to:

- All R&D staff within Bristol NHS FT (BFT)
- All research delivery staff supporting studies hosted or originally sponsored by UHBW and NBT
- All research activities (including sponsored and hosted studies) conducted at BFT during the transition period
- Chief Investigators and Principal Investigators
- Clinical staff supporting research conducted within BFT.

The SOP applies for the duration of interim arrangements at BFT until a single quality management system is in place and supersedes all UHBW and NBT SOPs and therefore this SOP. It is anticipated this will be by April 2027 however this will be kept under review.

This SOP does not replace existing UHBW or NBT Standard Operating Procedures (SOPs) in full. Existing SOPs will remain in use unless explicitly superseded by this document. Where differences exist, this document defines the agreed interim approach to ensure consistent and compliant practice across both organisations.

For the remainder of this document, hospital sites that were previously UHBW and NBT are referred to as Hospital Operating Units (HOUs). If it is necessary to distinguish between the two locations, they are referred to as 'formerly UHBW' and 'formerly NBT'.

3. Definition of Terms

ATIMP	Advanced Therapy Investigational Medicinal Product, including gene therapies, somatic cell therapies, and tissue-engineered product
Bristol NHS Foundation Trust (BFT)	The organisation formed following the acquisition of North Bristol NHS Trust (NBT) by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW), effective from 1 July 2026.
Capacity and Capability (C&C)	The formal confirmation by an organisation that it has the resources, expertise, and facilities required to deliver a research study.
CIMD	Clinical Investigation of a Medical Device.
CTIMP	Clinical Trial of an Investigational Medicinal Product, as defined by the Medicines for Human Use (Clinical Trials) Regulations.
CWOW	Combined Ways of Working
Data Controller	The organisation that determines the purposes and means of processing personal data, in accordance with data protection legislation.
Data Processor	An organisation or individual that processes personal data on behalf of the Data Controller.

EDGE	The research management system used to record and manage research activity, including study set-up, approvals, and performance reporting.
HOU	Hospital Operating Unit
Hosted Study	A research study where the organisation participates as a delivery site but is not acting as Sponsor.
HRA	Health Research Authority.
ICH GCP E6(R3)	International Council for Harmonisation Good Clinical Practice guideline, defining standards for the design, conduct, recording, and reporting of clinical research.
Legacy Studies	Research studies initiated prior to the formation of Bristol NHS Foundation Trust under UHBW or NBT governance structures.
Transition Period	The defined period following acquisition during which interim arrangements are in place until full integration of R&D functions is achieved.
NBT	North Bristol NHS Trust.
Pharmacovigilance	Activities relating to the detection, assessment, understanding, and reporting of safety events in research.
REDCap	A secure electronic data capture system used for research data management and safety reporting.
SAE	Serious Adverse Event
SMT	Senior Management Team
Sponsored studies	A study whereby NBT, UHBW or from 01/07/26 BFT, takes on the responsibility of sponsor as defined in the UK Policy Framework Agreement for Health and Social Care Research, ultimately taking responsibility for that study.
SUSAR	Suspected Unexpected Serious Adverse Reaction
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust.

4. Roles and Responsibilities

Roles and Responsibilities are clearly defined within the HOU SOPs that will continue to operate during the interim period. There are additional roles and responsibilities required to ensure continuity of safe, effective, and compliant research activity during the transition period. All roles will operate in accordance with the principles of ICH GCP E6(R3), the UK Policy Framework for Health and Social Care Research, and applicable legislation, with participant safety and data integrity as the primary consideration.

Key additional roles and responsibilities for oversight, decision-making, and operational delivery under the interim arrangements are defined below.

(i) BFT R&D Senior Management Team (BFT SMT)

The BFT R&D Senior Management Team (BFT SMT) consists of senior staff from each HOU R&D department as defined in Appendix 1, which will remain in effect until the R&D restructure is complete and a newly formed SMT has been established. The following specific responsibilities of the BFT SMT fall under this SOP:

- Providing strategic oversight of the implementation of interim arrangements and transition plans
- Making decisions on harmonised processes and future operating models for the integrated R&D function
- Acting as the escalation point for complex, high-risk, or cross-organisational issues
- Ensuring that risks to participant safety, data integrity, and regulatory compliance are appropriately identified and managed
- Monitoring performance and progress against organisational objectives
- Reporting to Trust senior leadership on transition progress, risks, and mitigations

(ii) Senior R&D Management Teams based at each HOU

Alongside the responsibilities outlined in existing HOU SOPs the HOU Senior R&D Management Teams will also be responsible for the following during the interim period:

- Implementing interim processes at their HOU and ensuring alignment across HOUs
- Supporting day-to-day management of HOU-based R&D functions during the transition
- Escalating complex or high-risk issues to the BFT SMT where required
- Ensuring staff are appropriately supported, informed, and trained on interim arrangements
- Contributing to the development of future unified processes and SOPs

(iii) All R&D staff across both HOUs

All R&D staff will work within the parameters of their existing job descriptions until the change process for the integration of the two departments is complete. The roles outlined in the specific roles and responsibilities section for existing HOU-specific SOPs for will continue to operate and retain the same responsibilities. During the transition period all R&D staff will also be expected to:

- Follow the interim arrangements outlined in this SOP and any associated procedural documents until they are superseded

Additional responsibilities for specific R&D roles in this interim operating procedure are as follows:

- Senior representatives from the grants teams must ensure that research grants are reviewed and developed in line with HOU practice and processes. In addition, this may require escalation to BFT SMT for approval to proceed in the case of CTIMPs, ATIMPs and any studies that are deemed to pose a risk as per the process outlined in *BRDG_001 Interim R&D Operating Arrangements for BFT.*

- Senior representatives from sponsorship teams must ensure any requests for sponsorship received after 1st July 2026 are reviewed against *BRDG_001 Interim R&D Operating Arrangements for BFT* for agreement in principle to sponsor. This may require escalation to BFT SMT for approval to proceed in the case of studies meeting pre-defined criteria. Full detail of which studies must be escalated can be found in *BRDG_001 Interim R&D Operating Arrangements for BFT*.

- Sponsor representatives for CTIMPs and CIMDs must ensure regulatory authorities have been duly notified of change of legal entity (in the case of NBT) and name change (in the case of UHBW) in line with national processes. Communications to all trials units and updates to required systems (including portals for SUSAR submissions and CWOW) must be carried out to ensure there is no disruption to reporting requirements.

- Research Management Facilitator/Research Facilitator Team Leaders must follow *BRDG_001 Interim R&D Operating Arrangements for BFT* on study allocation for new study approval requests made after 1st July 2026 and ensure all facilitation team members are appropriately trained in any updated procedures including naming conventions, filing, EDGE workflow updates and communications with sponsors.

- Research Information Officer and Digital Transformation Lead will lead on developing a plan for migration of EDGE data and reviewing and amalgamating all R&D systems (e.g. SAE and breach reporting). They are responsible for ensuring continued

compliance with regulations during any system integrations and minimising service disruption.

- Research Infrastructure Manager will lead on oversight and management of access arrangements requests for BFT.

(iv) All Research Delivery Staff

All staff involved in research delivery across both HOUs are responsible for adhering to existing SOPs for each HOU until these SOPs are superseded. If any processes change they will be documented at that time in new guidance. Escalating risks, issues or uncertainties will continue to be raised through existing governance routes until a new R&D departmental structure is in place.

5. Procedures

This section sets out the interim operational arrangements for the management of R&D activities during the transition period. The procedures are structured by functional area and governance activity to provide clarity on how core R&D processes will be delivered across the HOUs until a single, unified operating model is established.

The intention of this section is to:

- Define how key R&D functions will operate during the transition period
- Ensure consistency in approach across the HOUs where processes differ
- Provide clear guidance on decision-making pathways, escalation routes, and oversight mechanisms
- Maintain compliance with applicable regulatory and governance requirements

Unless explicitly stated within this document, existing HOU SOPs remain in place. Where differences in process exist, this section outlines the agreed interim approach to ensure safe, effective, and compliant delivery of research activities.

Each functional area sets out:

- The interim approach to managing activities
- Any agreed variations from current practice
- Governance and oversight arrangements, including escalation where required

These arrangements will be reviewed regularly by members of the BFT SMT throughout the transition period to ensure they remain appropriate, proportionate, and aligned to regulatory expectations, the developing organisational structure and future state.

Contracts and Agreements

Contracts and agreements will be signed as per Trust's standing financial instructions and scheme of delegation.

5.1 Research Grant management (including collaboration agreements and vendor selection)

The following SOPs related to the research grants function will remain in place for each HOU until a unified BFT set of research SOPs has been implemented:

UHBW SOPs	NBT SOPs
SOP_003 Developing and Designing your study UHBW v2.2 22.04.26	RD/QMS/SOP/008: Writing a Protocol for CTIMPS V4.1
SOP_004 Writing a Research Protocol UHBW_V2.1 23.04.26	RD/QMS/SOP/016: R&D Vendor Selection and Management V2.1
SOP_016 Research Contracts and Vendor Selection v4.0 20.01.26	R&D - (P06) Research Misconduct Policy V1.0
P002_Research Misconduct Policy v1.0 21.02.25	R&D - (P07) Safeguarding Research Policy V1.0

5.1.1 Research Development, Grants and Contracts management interim arrangements

The following outlines variation from the SOPs for interim arrangements until a unified set of BFT research SOPs related to the grants function are in place:

- High-risk, complex, or cross-organisational contracts will be escalated to the BFT SMT for approval to proceed
- Where applicable, R-D (P07) Safeguarding Research Policy as described in the above table will be applied across both HOUs in the absence of an equivalent policy at UHBW

- All new grant applications from 01/07/26 will be brought to BFT SMT as a report for ongoing oversight and where required (as described in *BRDG_001 Interim R&D Operating Arrangements for BFT)* any grants requiring escalation for review.

5.2 Sponsorship and Governance

The following SOPs and policies related to the sponsorship and governance functions will remain in place for each HOU until a unified BFT set of research SOPs has been implemented:

UHBW SOPs	**NBT SOPs**
P001_Research Policy V1.13 21.10.25	RD/QMS/SOP/001: Preparation of Research Standard Operation Procedures V3.4*
SOP_001 Production and Management of Research Procedural Documents Developed by Research and Development V4.0*	RD/QMS/SOP/007: Applying for NBT Sponsorship V3.1
SOP_002 Research Sponsorship at UHBW_v6.0 13.01.26	RD/QMS/SOP/007b NBT Terms & Conditions of Sponsorship V2.0
SOP_004 Writing a Research Protocol UHBW V2.1 23.04.26	RD/QMS/SOP/007c Delegation of Responsibilities V2.0
SOP_006 Management of Investigational Medicinal Products UHBW v3.0 20.01.26	RD/QMS/SOP/008: Writing a Protocol for CTIMPS V4.1
SOP_008 Investigator Oversight of Research UHBW v4.0 14.01.26	RD/QMS/SOP/009: Periodic Reporting to Regulatory Authorities V5.2
SOP_009 Research Safety Reporting UHBW v13.0 14.01.26	RD/QMS/SOP/011: R&D Closing Suspending and Terminating Research V3.0
SOP_010 Monitoring Oversight of Research UHBW_v5.1 11.11	RD/QMS/SOP/012: R&D Managing Breaches of GCP or the Protocol V2.2
SOP_011 Validation and backup of computer systems UHBW v2.3 07.01	RD/QMS/SOP/013: R&D Safety Reporting CTIMPS V5.0

SOP_012 Study data UHBW_v3.1 22.04.26	RD/QMS/SOP/014: R&D Monitoring V3.1
SOP_014 Essential Research Documents UHBW_v2.5 22.04.26	RD/QMS/SOP/015: R&D Computer System Validation & Backup V2.0
SOP_018 Management of Breaches in Research UHBW v3.0 15.01.26	RD/QMS/SOP/017: R&D Data Management V2.2
SOP_019 UHBW Sponsored Research Modifications v3.0 28.11.25	

*These SOPs apply to all R&D SOPs and functions but have been listed here within the governance section.

To note, audit and inspection readiness will be maintained throughout the transition period, with appropriate documentation and evidence of sponsor oversight retained in line with regulatory requirements as outlined in the existing SOPs listed above. All SOPs, as per standard practice, are available on each HOU websites which will continue to exist post 01/07/26. If in the period covered by this SOP a new BFT website is developed and the previous domains superseded, all SOPs will be moved to the new domain and the new location disseminated as applicable.

5.2.1 Sponsorship and Governance Interim arrangements

The following outlines variation from the SOPs outlined above for interim arrangements until a unified set of BFT research SOPs related to sponsorship and governance are in place:

- Additional sponsorship studies oversight meetings will be put in place with applicable staff from each HOU working on HOU sponsored studies as described in *BRDG_001 Interim R&D Operating Arrangements for BFT*
- New sponsorship requests received after 1st July 2026 will be reviewed against *BRDG_002 Research Sponsorship Guidance* to determine appropriateness to proceed through sponsorship. The team based at the HOU where the CI is located will usually handle the sponsorship application. If it is not clear (i.e. the CI works across both HOUs) this will be flagged at the additional sponsorship studies oversight meetings described above for a decision or escalation as required.
- Sponsorship requests deemed low risk (and in accordance with the *BRDG_002 Research Sponsorship Guidance*) will be reviewed and agreed in applicable sponsorship meetings and only certain types of sponsorship applications escalated for BFT SMT review as outlined in *BRDG_001 Interim R&D Operating Arrangements for BFT*

- Any significant risks, issues, or non-compliance identified for sponsored studies at either HOU will be escalated to the BFT SMT for review
- Combined oversight of safety reporting for sponsored CTIMPs or CIMDs will be managed through BFT SMT as described in *BRDG_001 Interim R&D Operating Arrangements for BFT*
- Combined oversight of breaches in sponsored studies or serious breaches for hosted studies will be managed through BFT SMT as described in *BRDG_001 Interim R&D Operating Arrangements for BFT*
- Naming conventions including local reference numbers will follow *BRDG_001 Interim R&D Operating Arrangements for BFT*
- Within the QMS at each HOU, any updates required to procedural documentation during the interim period which are unrelated to the acquisition will be reviewed by each HOU quality lead to determine a) whether it is an urgent update and will need to follow current HOU SOPs for procedural document changes or whether b) it can wait to be updated as part of the newly formed procedural documents for BFT. A shared working space will be utilised to track BFT specific procedural documents as outlined in *BRDG_001 Interim R&D Operating Arrangements for BFT*
- Any new BFT procedural documents developed in the interim period will use different prefixes in order to provide clear distinction. The prefixes used are outlined in *BRDG_001 Interim R&D Operating Arrangements for BFT.*

5.3 Commercial and non-commercial (hosted) Research

The following SOPs related to commercial and non-commercial (hosted) research function will continue to be in place for each HOU until a unified BFT set of research SOPs has been implemented:

UHBW SOPs	NBT SOPs
SOP_008 Investigator Oversight of Research v4.0 14.01.26	RD/QMS/SOP/002: Obtaining R&D Confirmation for Research to Start V4.2
SOP_013 Research Study Samples UHBW v3.0 07.01.26	RD/QMS/SOP/003: Research Study Modifications V5.0
SOP_015 Archiving of Research Records UHBW v3.0 19.01.26	RD/QMS/SOP/006: Honorary Research Contract Letters of Access V4.2
SOP_017 Capacity and Capability review UHBW_v3.4 28.11.25	RD/QMS/SOP/010: Archiving V4.0

SOP_020 UHBW Hosted Research Modifications v2.0 15.01.26	
SOP_021 UHBW review of ATMPs v3.3 22.04.26	
SOP_024 Setup and Management of Phase I Trials UHBW v1.4 09.01.26	

5.3.1 Commercial and non-commercial (hosted) research interim arrangements

The following outlines variation from the SOPs outlined above for interim arrangements until a unified set of BFT research SOPs related to the commercial and non-commercial (hosted) research are in place:

- A new single numbering system for BFT and interim filing arrangements will be implemented for studies received after 01/07/2026 for capacity and capability assessments
- *BRDG_001 Interim R&D Operating Arrangements for BFT* outlines mechanisms implemented to avoid duplication of study set up across HOUs.
- Escalation of any issues in study allocation or complex study arrangements that are unable to be addressed through current HOU escalation pathways will be further escalated to BFT SMT.
- UHBW-NBT framework agreement as described in *SOP_017 Capacity and Capability Review UHBW* will become obsolete for any new studies received for confirmation of capacity and capability post 01/07/26. Any legacy studies operating under the framework will continue as agreed and any funding arrangements will be dealt with through internal funding transfers rather than via invoicing routes previously outlined in the agreement. As clinical services come together, funding arrangements will be reviewed.
- All procedural documents (i.e. templates for C&C, amendment email templates) from both HOUs which are referenced within the above SOPs will be updated during the transition period to include the new Trust name of Bristol NHS Foundation Trust where applicable. Further detailed information can be found in *BRDG_001 Interim R&D Operating Arrangements for BFT*.
- Where new studies (received post 01/07/26) involve both HOU sites, coordination between contracts teams will be required to ensure:
    - Inconsistent contractual terms are resolved
    - Alignment of risk allocation and responsibilities
    - A lead HOU team will be identified where necessary to coordinate contract negotiations.

- Where applicable, *SOP_024 Set up and management of phase I trials_UHBW* as described in the above table will be applied across both HOUs in the absence of an equivalent policy at NBT.

- *RD/QMS/SOP/006: Honorary Research Contract Letters of Access* will apply across both HOUs with the Research Infrastructure Manager (at 'formerly NBT') site taking the lead on management and oversight.

5.4 Research Delivery Workforce

The following SOPs related to Research Delivery Workforce function will remain in place for each HOU until a unified BFT set of research SOPs has been implemented:

UHBW SOPs	NBT SOPs
SOP_007 Research Training UHBW v2.0 12.11.25	RD/QMS/SOP/018: R&D Management of Fridges & Freezers V3.0
SOP_008 Investigator Oversight UHBW v4.0 14.01.26	RD/QMS/SOP/020: Management of healthy volunteers in research. V1.1
SOP_027 Informed Consent for Research Purposes UHBW_v2.0 20.01.26	RD/QMS/SOP/021: R&D Informed Consent in Adult Research Setting. V1.1
SOP_028 Source_ Data_Documentation_v1.3 27.04.26	
SOP_029 Dose escalation in research studies at UHBW v1.1 10.12.25	
SOP_030 Management and Use of USB Devices v1.0 15.01.26	

5.5 Research Delivery Workforce interim arrangements

- Existing organisational structures and line management arrangements will remain in place during the interim period.

- Research training provision across both HOU's will remain unchanged during the transition period. A single approach will be developed for implementation that aligns with the new R&D structure.

5.6 Governance Oversight and Escalation

Overall oversight of R&D activities will be maintained through existing governance structures as outlined in each HOUs procedural documents. However, the BFT SMT in addition will provide:

- Oversight of transition arrangements
- Oversight for escalation of cross HOU issues
- Executive decision-making authority on cross HOU issues
- Executive decision making on escalated issues relating to patient safety or data integrity

Further information including the frequency and structure of the meetings can be found in*BRDG_001 Interim R&D Operating Arrangements for BFT* and within the BFT SMT Terms of Reference.

5.7 R&D Systems and Data Management

In addition to the arrangements and SOPs as described in 5.2 the following outlines the interim arrangements of R&D systems and data management.

(i) EDGE

- EDGE (currently used by both HOUs which is a validated system for research management) will be updated at each HOU to ready for eventual migration into one instance of EDGE. All required updates (e.g. to minimise duplication, align data fields and workflows etc) will be documented as per *BRDG_001 Interim R&D Operating Arrangements for BFT*.
- To support continued reporting and to minimise potential migration issues, a standardised naming convention for fields will be implemented where required. This is outlined in *BRDG_001 Interim R&D Operating Arrangements for BFT*
- Forms, fields, and workflows across both systems will be reviewed to inform the design of the future BFT configuration. Following EDGE migration, legacy forms, fields, and workflows will be superseded by a unified structure.
- Reports from EDGE will be aligned to ensure consistent Key Performance Indicator management and will run in parallel.

The risk of running two parallel EDGE systems has been assessed as minimal and is the most pragmatic way to proceed until the migration has taken place due to the requirement of organisational structures to be agreed prior to migration.

Following migration of EDGE a single BFT EDGE system will be established, with agreed, standardised workflows, forms, and reporting structures. All new studies will be managed within the unified system, and legacy records will be maintained in line with data governance and reporting requirements.

(ii) REDCap

Both HOUs currently use REDCap for pharmacovigilance and breach management. Both REDCap systems will continue to be used during the interim period. However, a phased migration from NBT to UHBW version of REDCap will be implemented with full implementation expected by 01.12.26. This will include a transfer of legacy studies, and the process will be fully documented. NBT REDCap will eventually become obsolete.

(iii) External systems

To support ongoing reporting requirements for sponsored studies (e.g. use of ISCR portal for SUSAR submission, CWOW for approval and modification submissions and MedDRA reporting) all systems will be reviewed and applicable log in and organisation updates implemented.

(iv) Email:

BFT intends to migrate all email accounts to nhs.net in Autumn 2026. All generic email accounts, including those in use for safety reports, will be reviewed and *BRDG_001 Interim R&D Operating Arrangements for BFT* updated with the new email name. Communications will be sent to all external parties to ensure correct email addresses are used. Where required HOU SOPs will be updated to include updated email addresses.

• Monitoring and Compliance

What is Monitored	Monitoring/ Audit method	Monitoring responsibility *(individual/group/ committee)*	Frequency of monitoring	Reporting arrangements *(committee/group the monitoring results are presented to)*	How will actions be taken to ensure improvements and learning where the monitoring has identified deficiencies
Compliance against interim arrangements	Routine reports	Research Operation Managers	Monthly	BFT SMT	Follow standard research breach reporting processes as outlined in applicable HOU SOPs

• Associated Documents and References

P001_Research Policy

SOP_001 Prod & Mgmt of Proc Docs UHBW v4.0 12.01.26

SOP_002 Research Sponsorship at UHBW_v6.0 13.01.26

SOP_003 Developing and Designing your study UHBW v2.2 22APR2026

SOP_004 SOP_004 Writing a Research Protocol UHBW_V2.1 23.04.26

SOP_006 IMPs UHBW v3.0 20.01.26

SOP_007 Research Training UHBW v2.0 12.11.25

SOP_008 Investigator Oversight UHBW v4.0 14.01.26

SOP_009 Research Safety Reporting UHBW v13.0 14.01.26

SOP_010 Monitoring Oversight of Research UHBW_v5.1 11.11

SOP_011 Validation and backup of computer systems UHBW v2.3 07.01

SOP_012 Study data UHBW_v3.1 22.04.26

SOP_013 Research Study Samples UHBW v3.0 07.01.26

SOP_014 Essential Research Documents UHBW_v2.5 22.04.26

SOP_015 Archiving of Research Records UHBW v3.0 19.01.26

SOP_016 Research Contracts Vendor Selection v4.0 20.01.26

SOP_017 Capacity and Capability review UHBW_v3.4 28.11.25

SOP_018 Management of Breaches in Research UHBW v3.0 15.01.26

SOP_019 UHBW Sponsored Research Modifications v3.0 28.11.25

SOP_020 UHBW Hosted Research Modifications v2.0 15.01.26 SOP_021 UHBW review of ATMPs v3.3 22.04.26 SOP_024 Setup MGNT of Phase I Trials UHBW v1.4 09.01.26 SOP_027 Informed Consent for Research Purposes UHBW_v2.0 20.01.26 SOP_028 Source_ Data_Documentation_v1.3 27.04.26 SOP_029 Dose escalation in research studies at UHBW v1.1 10.12.25 SOP_030 Management and Use of USB Devices v1.0 15.01.26
RD/QMS/SOP/001: Preparation of Research Standard Operation Procedures RD/QMS/SOP/002: Obtaining R&D Confirmation for Research to Start RD/QMS/SOP/003: Research Study Modifications RD/QMS/SOP/004: Maintenance of Research Equipment SOP RD/QMS/SOP/005: Research Staff Training RD/QMS/SOP/006: Honorary Research Contract Letters of Access RD/QMS/SOP/006a External Researcher Information Form RD/QMS/SOP/007: Applying for NBT Sponsorship RD/QMS/SOP/007b NBT Terms & Conditions of Sponsorship RD/QMS/SOP/007c Delegation of Responsibilities RD/QMS/SOP/008 : Writing a Protocol for CTIMPS RD/QMS/SOP/009 Periodic Reporting to Regulatory Authorities RD/QMS/SOP/010 : Archiving RD/QMS/SOP/011: R&D Closing Suspending and Terminating Research RD/QMS/SOP/012 : R&D Managing Breaches of GCP or the Protocol RD/QMS/SOP/012a : ICH GCP NonCompliance Report Form RD/QMS/SOP/012c : Protocol Deviation Review & Analysis Form RD/QMS/SOP/013 : R&D Safety Reporting CTIMPS RD/QMS/SOP/014 : R&D Monitoring RD/QMS/SOP/015 : R&D Computer System Validation & Backup RD/QMS/SOP/016 : R&D Vendor Selection and Management RD/QMS/SOP/017 : R&D Data Management RD/QMS/SOP/018: R&D Management of Fridges & Freezers R&D - P06 Research Misconduct Policy R&D P07 Safeguarding in Research Policy
BRDG_001 Guidance document for interim arrangements for research in BFT

BRDG_002 Research Sponsorship Guidance
• The Medicines for Human Use (Clinical Trials) Regulations (as amended) The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 • ICH Good Clinical Practice E6(R3) ICH E6 Good clinical practice - Scientific guideline | European Medicines Agency (EMA) • The UK Policy Framework for Health and Social Care Research UK Policy Framework for Health and Social Care Research - Health Research Authority • The Human Tissue Act 2004 Human Tissue Act 2004 • UK Data Protection Act 2018 Data Protection Act 2018

• Document History

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
JUN 26	1.0	Research Operations Manager	Original	N//A

Appendix 1 – Members list of BFT SMT

Deputy Directors of Research/Heads of Research and Development Research Operation Managers Commercial Research Manager Deputy Director of Research Nursing Research Infrastructure Manager Research Matrons Research Development and Grants Manager Research Grants Manager
Director of Research is invited to join BFT SMT but not mandatory to make quorate.