Research Governance Service – Team Roles and Responsibilities

Research & Innovation SOP G-7007

University Hospitals of Leicester NHS
NHS Trust

Trust Reference: B11/2026

1. Introduction and Who Policy Applies to

This Standard Operating Policy (SOP) outlines the roles, responsibilities, and expectations of the Research & Innovation (R&I) Core Governance Team (Corporate Team) and the departmental governance teams within renal, oncology and respiratory services, which operate separately from the Core Team, but undertake equivalent governance functions. It aims to support a cohesive, efficient, and regulatory-compliant approach to research governance, with a particular focus on strengthening Capacity and Capability (C&C) processes and ensuring alignment with UHL R&I corporate policies and procedures. The SOP also seeks to reduce duplication, improve study start-up timelines in line with Department of Health and Social Care (DHSC) national metrics, and promote collaboration, transparency, and consistency across all governance teams, while maintaining compliance with UK regulations, SOPs, and UHL policies.

This SOP applies to all research conducted at UHL and includes but is not limited to;

- Study set-up including C&C assessment
- Management of research modifications and study close-outs
- Use of shared research systems (e.g., EDGE, IRAS, Florence)
- Communications, reporting, training, and quality improvement
- Oversight and management of compliance with all regulatory requirements, addressing instances of non-compliance, with specific emphasis on readiness for Medicines and Healthcare products Regulatory Agency (MHRA) inspections

2. Guideline Standards and Procedures

2.1 Roles and responsibilities of the Core R&I Governance Team

- Lead on regulatory and institutional compliance, SOPs, and national metrics reporting.
- Provide oversight and quality assurance for C&C reviews.
- Maintain and coordinate use of EDGE, Florence, IRAS, and related systems.
- Provide core R&I datasets and performance information for each clinical specialty.
- Manage sponsor communication and institutional risk assessments.
- Deliver standardised training and professional development pathways for governance staff.
- Coordinate performance reporting and monitor achievement against relevant local and national KPIs.

- Provide guidance on contractual and financial governance in partnership with the core contracting and finance team.
- Communicate key national and local governance updates via the trust wide Research Governance Committee.
- Proactively resolve or escalate internal or external performance issues as appropriate to the Directors.
- Authorise all requests for confirmation of C&C, and research modifications.

2.2 Roles and responsibilities of departmental governance teams

- Conduct study-specific feasibility assessments, process C&C reviews (for studies and research modifications) in accordance with core Research & Innovation (R&I) Standard Operating Procedures (SOPs).
- Ensure local SOPs, policies, and procedures are aligned to core R&I governance SOPs, policies, and procedures, to minimise risk of contradiction and ensure consistency.
- Liaise directly with clinical teams, support departments, Principal Investigators (PIs), and study sponsors to facilitate timely and accurate study setup.
- Maintain accurate and timely data entry in EDGE and all mandated systems, using the same trust-wide platforms and adhering to all relevant core policies and procedures.
- Participate fully in training and professional development programmes provided by the core R&I team to ensure consistency and regulatory compliance.
- Engage in regular reporting and quality assurance audits as part of a continuous improvement and accountability process.
- Proactively escalate capacity, risk, or compliance concerns to the core R&I team for timely support and resolution.
- Ensure a Research Support Officer or equivalent representative attends the weekly core performance review meeting to provide updates on study progress, status, and emerging issues.
- Avoid maintaining research data or records outside of approved systems such as EDGE and Florence, to support centralised performance monitoring and compliance with national metrics and to prevent data integrity issues.
- Ensure studies approaching or exceeding their planned end date are appropriately managed in accordance with core R&I policies and procedures.
- Have a representative at the Research Governance Committee who disseminates key information across their team as appropriate.
- Proactively resolve or escalate internal or external performance issues as appropriate to the Directors.
- Engage and contribute to the trust-wide quality working group.

3. Education and Training

Governance staff are expected to complete all mandatory Trust training and any role-specific research governance training deemed necessary for their role.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Compliance with governance processes and effectiveness of governance arrangements	Review of: • governance incidents • delays or failures in study set-up and C&C approvals • instances of non-compliance with governance processes • performance or capacity concerns escalated to Director • data quality or integrity issues identified in approved research systems. Trends and recurring issues will be reviewed to identify opportunities for improvement.	Director of Research Operations	In accordance with the approved R&I audit schedule.	Reported to relevant manager, with significant concerns escalated to R&I Directors as appropriate
Performance against timeliness targets	Review of performance dashboards and reports from EDGE and other approved systems against local and national metrics	Director of Research Operations	Weekly R&I Performance Meetings	Reported to relevant manager, with significant concerns escalated to R&I Directors as appropriate
Data Quality and System Compliance	Data quality audits of EDGE and Florence, including completeness, accuracy, timeliness and use of approved systems	Director of Research Operations	In accordance with the approved R&I audit schedule.	Reported to relevant manager, with significant concerns escalated to R&I Directors as appropriate

5. Equality Analysis Assessment

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs. As part of its development, an Equality Analysis of this policy has been undertaken and its

impact on equality have been reviewed. No detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

6. Supporting references

None

7. Key Words

Governance, roles and responsibilities, Capacity and Capability

CONTACT AND REVIEW DETAILS	
Guideline Lead Jen Boston Deputy Director of Operations	**Executive Lead** Nigel Brunskill R&I Director
Details of Changes made during review: N/A, new SOP	