

JOINT RESEARCH GOVERNANCE COMMITTEE

TERMS OF REFERENCE

1. CONSTITUTION

1.1. The Joint Research Governance Committee (JRGC) is established by agreement of the Norfolk & Norwich University Hospitals NHS Foundation Trust (NNUH) and the University of East Anglia (UEA).

1.2. Its purpose is to:

- Provide oversight of regulated and high risk trials and studies sponsored by NNUH or UEA.
- Provide assurance to NNUH and UEA that effective systems and processes are in place to manage studies well and in compliance with legal and regulatory requirements.
- Provide assurance to NNUH and UEA that the studies are being conducted in compliance with legal and regulatory requirements and any issues arising are being addressed in a timely manner.
- Inform NNUH and UEA of any particular risks or issues either organisation should be aware of.

2. AUTHORITY

2.1. The JRGC has no executive powers other than those specified in these Terms of Reference. The JRGC is authorised to investigate any activity within its Terms of Reference.

3. MEMBERSHIP

3.1. Core membership of the Joint Research Governance Committee shall comprise:

- ❖ Chair
- ❖ Deputy Chair
- ❖ NNUH Director of Research Operations
- ❖ NNUH Associate Medical Director for Research
- ❖ NNUH Research Services Manager
- ❖ NNUH Research Governance Coordinator
- ❖ NNUH Research Governance Administrator
- ❖ NNUH Medical Advisor to Research and Development Office
- ❖ NNUH Lead Research Nurse – CRN Operations
- ❖ NNUH Lead Research Nurse – Strategic Partnerships and Commercial
- ❖ NNUH Senior Research Nurse (on a rotational basis- determined by Research Matron)
- ❖ NNUH Clinical Trials Pharmacist
- ❖ UEA Sponsor representative, Research and Innovation Services

- ❖ UEA Health Sciences Research representative
- ❖ UEA MED representative
- ❖ NCTU Director/Deputy Director
- ❖ NCTU Senior Operations Team representative
- ❖ Clinical Director Quadram Institute CRF
- ❖ Quadram Institute Bioscience representative
- ❖ Biorepository representative
- ❖ NNUH Divisional Research Leads or representatives (including but not limited to Consultants or senior professionals) from:
 - ❖ Medicine and emergency services
 - ❖ Surgery
 - ❖ Women and children
 - ❖ Clinical support services
- ❖ NNUH Junior Member

3.2 The Chair and Deputy Chair of the Committee will be approved by NNUH Research Oversight Board and UEA Faculty of Medicine and Health Sciences Research Executive. The role of Chair will rotate every three years, with the Deputy Chair becoming the Chair by agreement of JRGC and Research Oversight Board. Previous Chairs may continue as members with the agreement of the Research Oversight Board. If the Chair is unable to attend, the meeting will be Chaired by the Deputy Chair or other deputy nominated by the Committee.

3.3 Only members of the Committee are entitled to be present at its meetings. The Committee may however invite non-members to attend its meeting or part thereof as it considers necessary. In particular, the Chief Investigator (CI) of the trials and studies may be invited to attend to address any particular issues.

3.4 The NNUH Research Oversight Board and UEA Faculty of Medicine and Health Sciences Research Executive will review the membership of the JRGC annually to ensure that it meets the requirements of the Trust and UEA. Members will be required to attend at least one of the JRGC meetings in any one year.

4. SUPPORT ARRANGEMENTS

4.1. The Director of Research Operations will arrange for appropriate administrative support to be provided to the Committee.

5. MEETINGS AND QUORUM

5.1. Meetings will be held a minimum of quarterly (every three months).

5.2. In principle, to be quorate at least half the members of the Committee must be present. However, to ensure effective functioning of the Committee, quoracy is at the discretion of the Chair who may decide that there are members with sufficient expertise to conduct a meeting. If this is not the case final decisions on specific items may be deferred to a subsequent meeting.

5.3. If any member is unable to attend a meeting of the Committee they may arrange for a substitute to attend in their place, with the agreement of the Chair of the Committee, and their deputy shall be counted for the purposes of quoracy.

5.4. Responsibility for calling meetings of the Committee shall rest with the Chair.

6. DUTIES

The duties of the Joint Research Governance Committee are:

6.1. Oversee compliance of all NNUH and UEA sponsored regulated trials and high risk studies with all relevant UK and European legislation. This includes the UK Policy Framework for Health and Social Care Research (2017), or its successor, The Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments), the Medical Devices Regulations 2002 (and amendments) and the Human Tissue Act 2004.

6.1.1. Ensure that appropriate quality assurance and quality control systems are in place to monitor, audit and review the conduct of approved research.

6.1.2. Ensure adequate provision of Good Clinical Practice (GCP) and related research regulatory training for Trust and UEA staff.

6.1.3. Oversee and approve the development and maintenance of the NNUH UEA Joint Standard Operating Procedures.

6.1.4. Ensure that effective mechanisms are in place for pharmacovigilance in health care research.

6.1.5. To receive and review reports, or other documentation, on, Serious Adverse Events, Serious Adverse Reactions, Suspected Unexpected Serious Adverse Reactions, Serious Breaches and other notifiable events. To ensure expedited reporting occurs, as appropriate, to the MHRA and HRA/REC in relation to Trust Sponsored CTIMPs.

6.1.6. To monitor submission of regulatory reports.

6.1.7. Ensure that the corrective and preventative actions arising from any external or internal inspection, monitoring or audit of relevant healthcare research are fully implemented in a timely manner.

6.2. When requested, advise NNUH and UEA about decisions on whether or not to take on sponsorship and associated risks for particular trials.

6.3. Ensure referral of issues concerning research governance/ breaches of GCP to the NNUH Research Services Manager, Director of Research Operations and the Research Manager, Faculty of Medicine and Health Sciences.

6.4. Report issues of concern either with individual research projects or with the quality assurance or quality control systems to the NNUH Research Oversight Board and to UEA's Faculty of Medicine and Health Sciences Research Executive.

6.5. To raise with NNUH Research Oversight Board and to UEA Faculty of Medicine and Health Sciences Research Executive issues relating to resourcing of relevant research.

6.6. At the request of Trust or UEA staff, to review issues identified in project specific risk assessments of relevant research sponsored by either NNUH or UEA.

6.7. Undertake annual review of the performance and function of the Joint Research

Governance Committee and its satisfaction to these Terms of Reference.

7. REPORTING

- 7.1. The Minutes of the meeting will be provided to the Research Oversight Board and the UEA Faculty of Medicine and Health Sciences Research Executive
- 7.2. The Chair of the Joint Research Governance Committee shall draw to the attention of the NNUH Research Oversight Board and to UEA Faculty of Medicine and Health Sciences Research Executive any activities, issues or risks that require its attention or action.
- 7.3. The Committee will provide an annual report of its activities to the NNUH Research Oversight Board and the UEA Faculty of Medicine and Health Sciences Executive.

8. PROCESS FOR MONITORING EFFECTIVENESS OF THE JOINT RESEARCH GOVERNANCE COMMITTEE

- 8.1. The JRGC will report to the Research Oversight Board annually on the outcome of its annual review. The annual report will include information concerning compliance with the required attendance at meetings and the reporting arrangements for its committees. It will also include information on the planned work of the JRGC in the year ahead.
- 8.2. The Terms of Reference of the Committee will be reviewed annually by the Committee and any proposed changes submitted to the Research Oversight Board for approval.

9. DECLARATIONS OF INTEREST

- 9.1 All members must declare any actual or potential conflicts of interest relevant to the work of the Committee/Group, which shall be recorded in the minutes accordingly. Members should exclude themselves from any part of a meeting in which they have a material conflict of interest. The Chair will decide whether a declared interest represents a material conflict.

10. REPORTING COMMITTEES

- 10.1 The following committees or working groups have been established to report to the Committee/Group:
 - Research Governance Operational Group
 - Standing Operating Procedures Focus Group

11. ASSOCIATED POLICIES

- 11.1 The Committee/Group has delegated authority to approve and oversee implementation of the following policies:
 - Standing Operating Procedures

12. RELATIONSHIP WITH DIVISIONS AND GOVERNANCE SUB-BOARDS

- 12.1 For the avoidance of doubt, it should be noted that the structural position and operation of the Committee/Group is to be consistent with the existing governance and leadership arrangements through the Divisions and Governance Sub-boards. The Chair of the Committee/Group will ensure that in its operation and effect the Committee/Group supports the existing clear lines of escalation, responsibility and accountability through Divisions and Governance Sub-boards.

Date adopted by the Joint Research Governance Committee: 30th March 2022

Date for next review: February 2023

Date Approved by the NNUH Research Oversight Board: 3rd February 2022

**Date Approved by UEA Faculty of Medicine and Health Sciences Executive:
7th February 2022**

Appendix to Joint Research Governance Terms of Reference - Current membership March 2022

Role	Name	Institution	Appointed	Due for rotation (if applicable)
NCTU Deputy Director Chair	Matt Hammond	UEA	February 2022	January 2024
Deputy Chair	Jon Lartey	NNUH	February 2022	January 2024
NNUH Associate Director for Medical Research	Kris Bowles	NNUH		
NNUH Director of Research Operations	Jenny Longmore	NNUH		
NNUH Research Services Manager	Julie Dawson	NNUH		
NNUH Research Governance Coordinator	Basia Brown	NNUH		
NNUH Research Governance Administrator/minuting	Jackie Orford	NNUH		
NNUH Medical Advisor to the R&D office	Marcus Flather	UEA		
NNUH Lead Research Nurse - CRN Operations	Melissa Cambell-Kelly	NNUH		
NNUH Lead Research Nurse – Strategic Partnerships and Commercial	Louise Coke	NNUH		
NNUH Senior Research Nurse	rotational basis- determined by Melissa Cambell-Kelly	NNUH		
NNUH Clinical Trials Pharmacist	Gail Healey	NNUH		
UEA Sponsor representative, Research and Innovation Services	Sarah Ruthven	UEA		
UEA Health Sciences Research representative	Jane Cross	UEA		
UEA MED representative	Lee Shepstone	UEA		
NCTU Director	Ann Marie Swart	UEA		
NCTU Senior Operations Representative	rotational basis determined by Matt Hammond	UEA		
Clinical Director Quadram Institute CRF	Vacant	NNUH		
Quadram Institute Bioscience representative	Antonietta Hayhoe	QI		
Biorepository representative	Rachael Stanley	NRP Biorepository		
NNUH Divisional Research Leads or representatives (including but not limited to Consultants or senior professionals) from:				
Emergency and Urgent Care	Ian Pope			
Medicine	Vacant			
Surgery	Adrian Chojnowski	NNUH		
Women and children	Paul Clarke	NNUH		
Clinical support services	Vacant	NNUH		