Health Research Authority

RESEARCH GOVERNANCE FRAMEWORK STEERING GROUP

TERMS OF REFERENCE

1. Introduction

1.1. The Department of Health is currently responsible for the Research Governance Framework (RGF) in England and is available here https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf.

1.2. Separate frameworks are held by the Health Departments for the Devolved Administrations (DAs):

1.2.1. Northern Ireland - http://www.dhsspsni.gov.uk/research_governance_framework.pdf

1.2.2. Scotland - http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf

1.2.3. Wales - http://wales.gov.uk/docs/dhss/publications/governance/090929researchen.pdf

1.3. The Health Research Authority (HRA) will take responsibility for issuing guidance for research in England, in place of the RGF, when it becomes a Non Departmental Public Body (NDPB) as part of the Care Act 2014. The Care Act sets out the HRA's main functions as:

1.3.1. functions relating to the co-ordination and standardisation of practice relating to the regulation of health and social care research

1.3.2. functions relating to research ethics committees

1.3.3. functions as a member of the United Kingdom Ethics Committee Authority

1.3.4. functions relating to approvals for processing confidential information relating to patients

1.4. The HRA and DAs have committed not to just update this as a document, but to fundamentally review the whole framework with an ambition to have a single UK wide framework for research.

1.5. There is UK wide agreement that the HRA lead this work now, ahead of actually getting responsibility and a commitment to a UK wide framework (that may though have to set out differences as well as commonality across the four nations).

1.6. The current version of the RGF will be withdrawn upon a new framework being published.

2. Purpose

2.1. To review the current version of the RGF and produce a new common framework which is compatible on a UK wide basis through a programme of work involving the following key projects:

	Project title	Lead
1.	What research can the NHS support?	Amanda Hunn
2.	Social Care	Amanda Hunn
3.	What are the risks to research because of perceived risks of research?	David Montgomery / Catherine Blewett
4.	Risk in Research: Serious breach notifications and safety reporting	Catherine Blewett
5.	Are ethics committees, and ethics committee perception of research as a risky activity, a risk to research	Catherine Blewett / Stephen Tebbutt
6.	Proportionate consent processes	Clive Collett

2.2. The Steering Group (SG) will aim to put in place a common framework across the UK where possible. The common framework will be developed as a set of high level principles which will allow compatibility across the four nations.

2.3. The SG will consider the following:

2.3.1. Scope – how much of the research journey is covered and should be included

2.3.2. Compatibility – how the framework will successfully function in and between each country

2.3.3. Patient and Public Involvement – how patients and the public are engaged to ensure the replacement framework reflects patient and public views about the balance of protecting and promoting their interests

2.3.4. Communication – how the findings and recommendations are reported and the new framework consulted upon

2.3.5. Design – what the new framework should look like and its functionality

2.3.6. Implementation – how the framework will be implemented successfully across the UK and its timing

3. Membership and Chairing

3.1. Membership for the SG will largely be internal plus representatives from each of the Devolved Administrations (DA) and an observer from the Department of Health (DH).

3.2. The Chief Executive will chair the SG.

3.3. The Board Secretary and Chief Executive Business Manager will programme manage the work and provide secretariat support to the SG.

3.4. Membership will be as follows:

3.4.1. Janet Wisely, HRA (Chair)

3.4.2. Stephen Tebbutt, HRA (Programme Manager and Secretariat)

3.4.3. Hugh Davies, HRA

3.4.4. Catherine Blewett, HRA

3.4.5. Shaun Griffin / Gordon Harrison, HRA

3.4.6. Janet Messer, HRA

3.4.7. Jim Elliot, HRA

3.4.8. HRA Policy lead (once appointed)

3.4.9. Amanda Hunn, HRA (until completion of projects)

3.4.10. David Montgomery, HRA (until completion of project)

3.4.11. Janice Baillie, Health and Social Care Research & Development

3.4.12. Mike Stevens, Chief Scientist Office

3.4.13. Alex Newberry, National Institute for Social Care and Health Research

3.4.14. Bill Davidson, Department of Health (Observer)

3.5. In the absence of the Chief Executive, the group may elect any other member to act as chair for that meeting.

3.6. Other colleagues or stakeholders may attend by invitation for specific items or be co-opted as required with agreement of the Chair.

4. Quorum

4.1. A quorum shall be five members including the following:

4.1.1. 3 representatives from the HRA

4.1.2. 2 representatives from the DAs (at least 1 from 2 countries)

5. Responsibilities

5.1. The SG will be responsible for ensuring a framework is ready for full consultation upon the HRA receiving NDPB status.

5.2. The SG will be responsible for the design and functionality of the new framework.

5.3. The SG will receive oversight of the key projects relating to the programme of work and be kept informed of progress and receive and log any risks or issues which arise.

5.4. The SG will be responsible for agreeing the scope and implementation of the programme.

5.5. The SG will ensure the findings from the above projects are communicated suitably and at an appropriate time.

5.6. The SG will be responsible for reviewing the findings to distinguish what outcomes relate to the high level principles of the framework and what outcomes could be considered more operational details to be considered elsewhere.

5.7. Comments from a range of stakeholders in all countries will be sought on the findings / recommendations before a revised framework is developed.

5.8. The SG will hold a risk register for the programme which will feed into the combined corporate and directorate risk registers for the HRA.

5.9. The HRA will be responsible for allocating resources to the SG to ensure the programme is appropriately resourced.

5.10. The Chair or Programme Manager will report to the HRA Executive Management Team on a regular basis regarding the progress of the programme.

5.11. Governance for the programme of work will be provided through the HRA EMT, the HRA Board and through established sponsorship accountability meetings.

5.12. Consultation on the new framework will take place separately for each DA with comments to be fed into the UK assessment.

6. Frequency of meeting

6.1. The SG will meet every 2 to 3 months. Meeting dates will be confirmed to coincide with important stages of the programme.

6.2. Meetings may be held face to face, via videoconference or teleconference.

6.3. Ad-hoc meetings may be held by agreement of the Chair as and when required.

6.4. Meetings may, exceptionally, be cancelled by the Chair.

7. Papers

7.1. The deadline for receipt of agenda items and related papers by the Secretary is seven (actual) days before the meeting.

7.2. The Secretary will circulate the agenda and papers five (actual) days before the meeting.

8. Reporting

8.1. Draft minutes of each meeting will be circulated within five working days of the meeting for comment to all and will provide a clear record of decisions reached and actions agreed.

8.2. Minutes will be formally approved at the subsequent meeting.