UK compatibility and cross-border working

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Wales – Support & Delivery

Support & Delivery

- Develop study
- Apply for funding
- Select sites
- Gain approvals
- Set up study
- Deliver study
- Analyse data
Welsh Government
Performance management of NHS R&D and the Support Centre

Support & Delivery

NHS R&D Offices including research delivery workforce
- Strategic planning of NHS allocations and research delivery resources
- Individual NHS organisation and collective decision making
- Delivery of research study targets through a skilled research delivery workforce
- Increase the quality and quantity of people-centred research in Wales

Managed by Welsh Government against key performance indicators outlined in the NHS R&D Delivery Framework

Support Centre
- Facilitates the implementation of Welsh Government policies by providing centralised support functions and support services for the health and social care research community in Wales
- One Wales-wide organisation hosted by Powys Teaching Health Board
- Managed by Welsh Government against a set of key performance indicators
Scotland
NHS Research Scotland (NRS)

- Partnership between Chief Scientist Office & NHS Health Boards in Scotland
- Ensures the operational efficiency and effectiveness of NHS research offering
- Works through existing R&D Structures
- Strategy and Policy agreed at monthly NRS Board meetings
Regional working

- 4 hubs
  - Ethics, R&D Permissions
  - Biorepositories
  - Safe Havens
- SHARE
- CMT
- Topic Networks and SGs

North
NRS Permissions coordination

East
NRS Governance and national SOPs

South
NRS Contractual issues and training

West
IT lead
Operational Efficiencies

• Contracting:
  • Single costing and contract negotiation for all Scotland
  • mCTA accepted as standard
  • Accept NIHR Template costs

• Scotland-wide R&D Approvals
  • Non-commercial - median 12 working days NHS contact time
  • Commercial - median 12 working days NHS contact time
Contract cycle times

NRS Partner data
Health Science Scotland – academic collaboration
Northern Ireland
Northern Ireland – funded R&D Infrastructure

PHA R&D

5 HSC Trusts: Research project support and permissions.

HSC Research Gateway (permission portal for multicentre projects)

Study support: NICTU, NICTN, NICRN, HSC Innovations

STUDY DELIVERY
PHA R&D Office
Co-ordinates, funds and supports research activity within the HSC

HSC Permissions

HSC R&D Offices
- Gateway coordinates cross order project permissions and is embedded in the Western HSC Trust
- All Trusts work together to manage permissions through the gateway in Northern Ireland
- Collegiate working with a number of regional resources: e.g. Northern Ireland Cancer Trials Network (NICTN)
- Trust representation at all levels regionally and nationally.
- A regional focus on maximising opportunities for patients to participate in research regionally, nationally and internationally
- Managed through a number of committees that reflect a collegiate approach, with oversight through the Public Health Agency Research and Development Office

HSC Research Gateway
Facilitates the permissions process for multicentre projects that include Northern Ireland as a lead/participating site
- Regionally agreed process to ensure a seamless and speedy process for multicentre permissions
- Measured against agreed regional metrics
- Coordinates with the rest of the UK to share relevant information across nations
England
Health Research Authority

- Established 2011
- Protect and promote the interests of patients and the public in research
- Host for Research Ethics Service plus broader remit including provision of some functions for UK
- Consensus and collaboration on standards rather than inspection
UK-wide arrangements

Devolved administrations:
- RECs
- R&D coordination

HARP: UK-wide IT system

Research Ethics Service Assessment team
Technical Assurance team
Confidentiality Advice Team
HRA Approval Remit

• For research hosted by NHS in England
• CRN portfolio and non-portfolio
• Studies requiring UK Health Department REC review – using existing REC arrangements
• Studies not requiring UK Health Department REC review
• Other approvals eg MHRA remain separate, but HRA Approval only issued when all are in place
Cross-border working
Study-wide governance process
Site level Information

- Site Specific Information (SSI) forms will still be used for setting up NHS/HSC sites in the devolved administrations (DAs).
- This includes DA sites for studies that are sponsored/led from England.
- HRA will accept SSI forms for research studies which are sponsored/led from a DA with sites in England.
- For DA-led studies, the HRA Approval team will facilitate the completion of any additional information requirements in England.
- Sponsors from a DA should contact HRA at the earliest opportunity.
Study-wide governance review

- Applicant
  - Sites in one Devolved Nation
    - IRAS Application: Use a SSi for each site
  - Sites in England Only
    - IRAS application: Use schedule of activity and capability
  - Sites in Devolved Nations only
    - IRAS Application: Use a SSi for each site and follow guidance from lead nation.
  - Sites that Include both England and a Devolved Nation
    - IRAS Application: For all sites
      - England is lead nation
        - English Sites: Use Schedule and Statement (non-commercial only)
        - Devolved Nations: Use SSi
      - Devolved Nation is lead nation
        - Devolved Nations: Use SSi
        - English Sites: SSi sent to HRA to facilitate site set-up
Questions and Discussion
Summary of cross-border arrangements

• Each UK NHS Coordinating Function accepts centralised assurances from each other to reduce duplication and ensure consistency
• HRA is testing new approaches to local information in England
• Concerns have been raised at policy level about the impact on cross-border compatibility
• In the interim different arrangements are in place for site information in England in comparison to rest of UK
• Discussions continue between the 4 nations to address UK-wide compatibility issues
• 4 Nations are committed to review the information required at the local NHS site level