

Introduction to ORECNI and the NHS/ HSC Research Ethics Service

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Overview

- The NHS/HSC Research Ethics Service and the Office of Research Ethics Committees NI (ORECNI)
- What do RECs consider when reviewing research proposals?
- What happens in a REC meeting?







The NHS/HSC Research Ethics Service

- UK service managed by the Health Research Authority (HRA)
- 72 NHS RECs across the UK
- Strict legislative and policy requirements
 - e.g. UK Clinical Trails Regulations 2004; UK Governance Arrangements for Research Ethics Committees (GAfREC) 2020)
- Each REC audited every 2 years by HRA
- Work alongside other regulatory bodies







The NHS/HSC Research Ethics Service (2)

- Chair and vice-chair and up to 18 members
- Members independent; don't represent any interest group or organization
- Each UK REC has 10 meetings per year
- Proportionate Review Service (for low risk studies)
- Each head office (England; Scotland Wales and NI) accountable to relevant Health Department







About ORECNI

- Part of UK research ethics service
- Support 2 NI RECs (REC A and REC B)
- Aim
 - Protect research participants
 - 2. Facilitate research providing meaningful and valid results.



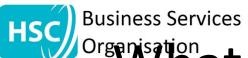






- HSC/ NHS patients/ users or their relatives/ carers usually needs approval
- Studies involving the collection of human tissue
- Adults who lack capacity to consent
- Residents in private nursing homes or residential homes in NI or Patients in independent health care facilities
- Not an exhaustive list! See HRA Decision tool for more information http://www.hra-decisiontools.org.uk/ethics/index.html





What issues do RECs consider? (1)

- Risks and benefits of research
 - Research procedures; withholding standard care; intrusion; confidentiality risk
- Vulnerable group
 - Children; Learning Disability; Adults Lacking Capacity; elderly etc.
- Equality and inclusion issues
 - -e.g. Non-English speakers; age; gender etc.







What issues do RECs consider (2)

- Recruitment
- Participant information
 - General readability and language; Format
- Consent process
 - Legal position (children and young people; Adults Lacking Capacity etc.)
- Patient Public Involvement (PPI)
- What happens after the research?
 - Publication of results





Business Services What happens at the REC meeting?

- 4 applications per meeting
- All REC members read applications before meeting
- Lead reviewer's summary and discussion
- Identify issues to discuss with the researcher
- Conversation with researcher
- Reach decision
 - Favourable opinion (subject to other necessary approvals)
 - Unfavourable
 - Provisional (REC needs more information/ changes)





Useful resources

- https://www.hra.nhs.uk/planning-and-improvingresearch/research-planning/prepare-study-documentation/
- https://www.hra.nhs.uk/planning-and-improving-research/bestpractice/informing-participants-and-seeking-consent/
- <u>Examples Consent and Participant information sheet preparation</u> guidance.
- https://www.hra.nhs.uk/about-us/committees-and-services/onlinebooking-service/
- https://www.hra.nhs.uk/approvals-amendments/amendingapproval/examples-of-substantial-and-non-substantialamendments/
- Putting people first embedding public involvement in health and social care research - Health Research Authority (hra.nhs.uk)
- UK Standards for Public Involvement (<u>UK Standards for Public Involvement (google.com)</u>)







Thank you!

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