

# 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 Trials Regulations 2004; UK Governance Arrangements for Research Ethics Committees (GAfREC) 2020)
- Each REC audited every 2 years by HRA
- Work alongside other regulatory bodies



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# 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



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# About ORECNI

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



# Examples of research needing ethical review

- 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>



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# 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.



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# 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



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# 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)
- Strict timelines for REC final opinion (60 days)



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# Useful resources

- <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>
- <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/>
- [Examples - Consent and Participant information sheet preparation guidance.](#)
- <https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/>
- <https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/>
- [Putting people first - embedding public involvement in health and social care research - Health Research Authority \(hra.nhs.uk\)](#)
- UK Standards for Public Involvement ([UK Standards for Public Involvement \(google.com\)](#))



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# Thank you!

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