What are the Current Challenges for NHS Ethics Committees

Developments in Ethics in Scotland
The Association of Research Ethics Committees

in partnership with University of Strathclyde
Regional Workshop 9th Feb 2011
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West of Scotland Research Office
What are Research Ethics Committees?

A group of people appointed to review research proposals to assess formally if the research is ethical.

Research must conform to recognised ethical standards including the dignity, rights, safety and well-being of the people who take part.
<table>
<thead>
<tr>
<th>WHY</th>
<th>The UK Health Departments provide for a Research Ethics Service so that the research proposals relating to their areas of responsibility can be reviewed by a research ethics committee.</th>
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</thead>
<tbody>
<tr>
<td>WHAT</td>
<td>The Research Ethics Service consists of research ethics committees and head offices that co-ordinate the development and management of their operations.</td>
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<tr>
<td>INDEPENDENT</td>
<td>Research ethics committees are independent of the researchers, the organisations funding the research and the organisations where the research will take place.</td>
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<tr>
<td>FUNCTION</td>
<td>The committee has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society</td>
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</table>
Governance Arrangements for Research Ethics Committees GAFREC

• A policy document of the UK Health Departments

• Describing what is expected from the research ethics committees and when review by these committees is required

• Includes: remit, composition, functions, management and accountability
GAFREC SCOPE

- Research involving users of services for which the UK Health Departments are responsible and where the law requires review by a REC

- In Scotland this applies to all research related to the NHS
Where GAFREC does not require review by a research ethics committee within the Research Ethics Service, review may be undertaken by research ethics committees established by universities and other institutions.
Exclusions

• REC are not expected to consider applications in respect of activities which are not research
  e.g. clinical audit, service evaluation, public health surveillance
When is NHS Research Ethics approval required?

Is it research?

NRES guidance ‘Defining Research’

http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/
### Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

<table>
<thead>
<tr>
<th>Research</th>
<th>Service Evaluation*</th>
<th>Clinical Audit</th>
<th>Surveillance</th>
<th>Usual Practice (in public health)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
<td>Designed and conducted solely to define or judge current care.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed to manage outbreak and help the public by identifying and understanding risks associated.</td>
<td>Designed to investigate outbreak or incident to help in disease control and prevention.</td>
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<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
<td>Designed to answer: “What standard does this service achieve?”</td>
<td>Designed to answer: “Does this service reach a predetermined standard?”</td>
<td>Designed to answer: “What is the cause of this outbreak?”</td>
<td>Designed to answer: “What is the cause of this outbreak?” and treat.</td>
</tr>
<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures current service without reference to a standard.</td>
<td>Measures against a standard.</td>
<td>Systematic, statistical methods to allow timely public health action.</td>
<td>Systematic, statistical methods may be used.</td>
</tr>
<tr>
<td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
<td>Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.</td>
<td>Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.</td>
<td>May involve collecting personal data and samples with the intent to manage the incident.</td>
<td>Any choice of treatment is based on clinical best evidence or professional consensus.</td>
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<td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.</td>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
<td>Usually involves analysis of existing data or administration of interview or questionnaire.</td>
<td>May involve analysis of existing data or administration of interview or questionnaire to those exposed.</td>
<td>May involve administration of interview or questionnaire to those exposed.</td>
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<tr>
<td>Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before audit.</td>
<td>Does not involve an intervention.</td>
<td>May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.</td>
</tr>
</tbody>
</table>

* Service development and quality improvement may fall into this category.
Is your project ..... 

| **Audit** | Measuring against a standard  
| | Is there a standard in place?  
| | All interventions are routine and determined by best clinical practice. No treatment allocations are involved. Outcome is normally of local relevance only, informing local planning of budgets, training etc. |
| **Service Evaluation** | May involve evaluating a new routine development in service.  
| | No randomisation involved or treatment allocation. Can involve feedback through questionnaires or interviews |
| **Research** | Can involve testing a new intervention, participants can be randomised to a treatment or intervention. Often there will be a control group involved. Outcome will have more general applicability. Can be published as research. |
What is the Remit of an NHS REC?

GAFREC

Governance arrangements for NHS Research Ethics Committees in Scotland July 2001 (to be replaced shortly)

- Patients or users of the NHS, including those under contracts with private sector
- Relatives or carers of NHS patients/users
- Access to the personal data or bodily material of NHS patients
- Foetal material and IVF involving NHS patients
- The recently dead in NHS premises
- The use of, or potential access to, NHS premises/facilities
- NHS staff recruited as research participants by virtue of their professional role
Legal requirements for REC review

• People who lack (or lose) the capacity to give informed consent
• Processing of confidential patient information without consent where this would otherwise breach confidentiality
• Human cells taken from the living or deceased *differences in Scotland
• Exposure to ionising radiation
• Medical devices that are not CE-marked or CE-marked devices that have been modified or being used for a new purpose
• Investigational medicinal products
Exceptions

• The Gene Therapy Advisory Committee (GTAC) takes responsibility for clinical trials involving novel gene therapy or cell derived from stem cell lines
NRES Regional Structure in Scotland

**NoSRES**
- NHS Highland
- NHS Grampian
- NHS Orkney
- NHS Shetland
- NHS Western Isles

**EoSRES**
- NHS Tayside
- NHS Forth Valley
- NHS Fife

**WoSRES**
- NHS Ayrshire & Arran
- NHS Dumfries & Galloway
- NHS Greater Glasgow & Clyde
- NHS Lanarkshire
- Special HB (Golden Jubilee)

**SESRES**
- NHS Lothian
- NHS Borders
NHS REC Structure in Scotland

4 Regions

WoSRES
NoSRES
SESRES
EoSRES

Edinburgh Independent

REC Governance

Health Board
NHS REC
CSO
UKECA
NRES
Scientific Officer

Research ethics enquiries

Committee Chairs

Local NHS R&D Departments

Local Data Protection Caldicott Guardian, Clinical Audit/Clinical Governance Departments

Co-ordinators

Scientific Officer
## Types of RECs

<table>
<thead>
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<th>Types of RECs</th>
<th>Subtypes</th>
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<tr>
<td>Recognised Type I</td>
<td>CTIMPs in healthy volunteers</td>
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<tr>
<td>Recognised Type III</td>
<td>CTIMPs</td>
</tr>
<tr>
<td>GTAC</td>
<td>Gene therapy or stem cell clinical trials</td>
</tr>
<tr>
<td>Adults with Incapacity</td>
<td>Adults lacking capacity to consent</td>
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<tr>
<td>Authorised</td>
<td>General or flagged</td>
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<tr>
<td></td>
<td>Human tissue banks</td>
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<td></td>
<td>Devices</td>
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<td></td>
<td>Children etc</td>
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Who can be a sponsor?

- Must be a legal entity
- Commercial studies are usually both funded and sponsored by the company involved
- Occasionally an academic funder e.g. MRC, CRUK or EORTC will also sponsor a study
- Usually academic studies are sponsored by an NHS Board or university or a co-sponsorship agreement
  - responsibilities depend primarily on who employs the chief investigator, responsible for the design, conduct and reporting of the trial.
Compliance and Enforcement

• If REC review is required, sponsors may not allow any research they are sponsoring to begin without a favourable REC opinion.

• RECs must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research, they are not responsible for enforcement if the research turns out to be unsafe or is not carried out as agreed. This responsibility rests with the relevant regulators, researchers employer and the care organisations where the research takes place.
Student Research
NRES R&D MHRA IRAS
NRSCC University REC
Proportionate Scrutiny

• REC review is proportionate to the scale and complexity of the research proposed. Research proposals that present no material issues of research ethics do not warrant consideration at a full meeting of a REC. They should be identified on receipt so that the ethical review may be undertaken by an executive sub-committee.
Proportionate Review Timeline

Application submitted by Researcher via local REC office → Application received and validated by REC → Proportionate Review Sub-Committee Meeting

- Favourable Opinion
- Favourable Opinion with conditions
- Provisional Opinion
- Unfavourable Opinion
- No Opinion (Ethical issues identified)

Further information required → Full REC review required → Decision letter sent to researcher

Favourable Opinion → Full REC meeting → Final Decision

14 Days Maximum

Proportionate Review Sub-Committee Meeting

Chair's Action Meeting

Further Information Favourable Opinion

Further Information Favourable Opinion (with conditions)

Provisional Opinion

Unfavourable Opinion

Decision letter sent to researcher

7 Days Maximum

60 Days Maximum

If the researcher refuses the next available REC meeting, the 60 day clock will be stopped.
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<tr>
<th>RESEARCH TYPE For Proportionate Review</th>
<th>Suitable for Proportionate Review?</th>
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<tbody>
<tr>
<td>I Research using data or tissue that is anonymous TO THE RESEARCHER</td>
<td>YES</td>
</tr>
<tr>
<td>II Research using existing tissue samples already taken with consent for research</td>
<td>YES</td>
</tr>
<tr>
<td>III Research using “extra tissue” (e.g. further blood taken at time of routine sampling or tissue taken at “clinically directed” operation)</td>
<td>YES</td>
</tr>
<tr>
<td>IV Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences</td>
<td>YES</td>
</tr>
<tr>
<td>V Research interview / focus group that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences</td>
<td>YES</td>
</tr>
<tr>
<td>VI Research surveying the safety or efficacy of established non drug treatments, involving limited intervention and NO change to the patients’ treatment</td>
<td>YES</td>
</tr>
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N.B: Research involving children may be considered for Proportionate Review where it meets the above criteria.