

Improving the evidence base for adult social care practice

School for Social Care Research

Workshop on Ethics & Governance and Social Care Research

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Why should social care research be subject to ethical review?



Dr Mark Sheehan
The Ethox Centre
University of Oxford

Ethics of social care practice and research

Ethics of Social Care Practice

- Ethical issues centre largely on balancing competing accounts of the individual's good
 - **Autonomy**: enabling the service user to make decisions that fit their personal life plan within the context of needing support
 - **Paternalism**: Act for the service user's good, irrespective of his wishes, preferences, or personal account of the good life

Ethics of social care practice and research

Social Care Research Ethics

- Ethical issues centre on balancing the individual's good and the good of future individuals
- Wearing the "practitioner's hat": Seeking to minimise risks and respecting the autonomy of people recruited as participants
- Wearing the "researcher's hat": Maximising the overall benefits within a piece of research

Navigating research ethics: 3 approaches

1. The libertarian “rights-based” approach

- Emphasises the value of research participants’ autonomy and freedoms
- Places focus on the validity of consent
- If consent has been obtained, the research is ethically justified to proceed
- Other considerations relating to harm or overall benefit are not seen as morally relevant
- If permission has been obtained, the research is justified to proceed

Navigating research ethics: 3 approaches

2. The paternalist “duty-based” approaches

- The emphasis is placed on the researcher’s duties to participants
- These duties give rise to rules that determine which actions are ethically justified, independent of consequences
- One rule might require that the participant is not exposed to a more than minimal risk of harm
- Valid consent cannot override the fulfilment of these duties
- Research that exposes participants to harm can never be justified

Navigating research ethics: 3 approaches

3. The utilitarian “consequence-based” argument

- The research is justified if the overall total good that can be done is maximised
- Emphasises that the value and quality of the research is a core ethical considerations
- Balances the benefits and harms to individual participants *and* people in the future
- Non-consensual research that harms participants is justified if it will lead to considerable future benefits

Which of these three approaches do
you find most satisfactory?

From ethics to governance

- Research ethics review recognises the importance of all three approaches. The focus is on:
 1. obtaining valid consent
 2. ascertaining the harms and benefits facing participants
 3. ascertaining the beneficial outcomes for individuals external to the research
- There are no right answers to how these considerations should be balanced when they pull in opposing directions that can be given in advance
- The emphasis is on researchers to argue for why their protocol is justified, and to defend their arguments under challenge

Gaining approval in a nutshell

1. Valid consent
 - Mediates #2?
2. Harms/benefits to participants
 - May overrule #1?
3. Benefits to society
 - The value/usefulness of the research
 - Scientific validity

The key question for the researcher: How are these concerns to be balanced or judged?

2 practical examples

1. Paying participants (beyond reimbursing expenses)

- Does payment invalidate consent?
 - Coercive?
 - Should we inform participants beforehand about the payment they will receive?
- Will payments benefit participants, or cause them harm?
- Are payments crucial to obtaining the benefits that the research has the potential to bring about?
- **Resolution:** Present an argument to the REC, and expect that argument to be challenged in light of opposing considerations

2 practical examples

2. Involving adults lacking the capacity to consent (LCC)

- How is the participation of adults LCC to be reconciled within an autonomy-based consent process?
- What additional duties to protect adults LCC are required?
- Does involving adults LCC lead to research that is less (or more) likely to produce useful and beneficial knowledge?

Resolution: Researchers need to work harder to justify including adults LCC, and to incorporate additional protections and procedures

And finally... why a REC?

- **Contestability:** The relevant ethical considerations are reasonably contested, and need to be worked through
- Researchers have a clear conflict of interest in this process of balancing the relevant considerations
- **Independent accountability:** relevant stakeholders who stand in relation to the ethical considerations are best placed to reason through the process of making appropriate judgements

Any questions?

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The Social Care Research Ethics Committee

**What RECs do –
and how to keep on the right side
of them**

**Deborah Rutter
REC convenor for SCIE**



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Some Key Principles of Ethics Review of Social Care Research in England

- * No investigator should have to seek ethics review from more than one REC.
- * Social care community accepts a wider definition of what constitutes research e.g. most service evaluations would be accepted as suitable for review by the Social Care REC.
- * Social care community may operate a different concept of 'risk' or potential damage from that pertaining to invasive health studies.



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Who decides if referral to REC for review is necessary?

- GAfREC (2011, amended Feb 2012) outlines legal and statutory requirements for review of particular types of research
- The chief investigator and/or the sponsor can decide if criteria for review are met – and if the case is uncertain, seek advice from NRES queries line or from Social Care REC
- Social Care REC does see borderline cases where there are motives for review: Chair can give formal opinion on need for review (contact coordinator)

Sources of ethical review in adult social care research

National Research Ethics Service (NRES):

- NRES RECs have own Governance Arrangements (GAfREC) & are funded by DH
- Key plank in NIHR funding & support for (mainly health) research in UK (UK a world leader)
- Social Care REC is an NRES specialist REC

University RECs (most HEIs should have one)

Local Authority Governance consortia



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Origins of the Social Care REC

Social care researchers dissatisfied with NRES provision – design, methods, contexts not understood

Funded by Department of Health via NRES

Social Care REC operates to all SOPs of National Research Ethics Service (NRES);

IRAS form version redesigned (within limits) to include SC REC

First monthly meeting held in June 2009: we meet 11 times per year, on first Friday of month (except August)

Developments of Social Care REC

1. Accredited by NRES as meeting their QA systems
2. Trained, and approved by Sec of State for Health to review research with adults lacking capacity (under Mental Capacity Act, 2005)
3. Enlarged our remit, into NHS (joint/integrated services or topics; social science methods in NHS settings)
4. While NRES has cut back number of its Committees 200 RECs (2004) to 81 (2011) in England, we have maintained the case for specialist social care provision



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What are RECs for? GAfREC

Governance Arrangements for Research Ethics Committees: a harmonised edition (May 2011, Dept of Health)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474

Harmonised as includes (with some exceptions) health *and social care services* covered by all UK health departments.



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What are NRES RECs?

“A research ethics committee is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.” (GAfREC, 2011, 1.1)



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What NRES RECs cover

Among other categories, research involving:

- (a) people identified from, or because of, their past or present use of the services for which UK Health Depts are responsible (including health & social care services provided under contract with the private or voluntary sectors),
- (b) potential research participants identified because of their status as relatives or carers of above.

GAfREC 2011

Note: research involving staff of services are **NO LONGER** automatically included in cover



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What makes a 'good' application?

1. Clarity of aims and process;
2. Accessible information and consent;
3. Thought-through strategy for recruiting people without offending Data Protection and confidentiality;
4. Consideration of how to impose least possible burden on participants;
5. Additional support/debriefing for participants;
6. Social inclusion in research for all those in a diverse community (including those with communication deficits);
7. Understanding of 'confidentiality' – deconstruct it!



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What else will help?

Being clear about ethical issues & difficulties – the REC will be reassured by your recognition of them.

Don't exaggerate the impact or benefit of the research – even in health, it is unusual for participants to benefit (though later ones may).

Fill in the IRAS form thoughtfully: it is long and comprehensive because it must describe your research aims, methods and arrangements to the members. This is your only opportunity to 'speak' with members, other than to clarify queries if you attend the meeting, or by mail if you cannot attend.



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Common deficiencies in applications

1. Information and consent not fit for purpose
2. Uncertain (illegal?) arrangements for recruiting people:
 - a. who has right to contact them?
 - b. 'opting out' recruitment is not normally acceptable strategy for frail people
3. Disproportionate burden on people (service users, carers, staff)
4. May need strategies for disclosure of abuse in information sheet;
5. May need further support for interviewee after data collection

More common deficiencies

6. Social inclusion in research: some topic areas particularly need translation/multilingual researchers
7. Confidentiality:
 - What is anonymisation?
 - When is data coded and linked or unlinked?
8. Lack of transparency, honesty, clarity for participant
9. No access to social care (only to health) record under s.251 of NHS Act without person's consent (joint records?)
10. NEVER assume staff will collect & anonymise data.
11. Student supervisors should review applications before signing!

REC review may be good for you!

- Statutory requirement (eg Mental Capacity Act) or requirement by funder (eg SSCR)
- Publication – journals may require it
- Host organisations may be reassured
- Your approach – eg to recruitment – will be thought through in detail (the forms!) and may even be improved

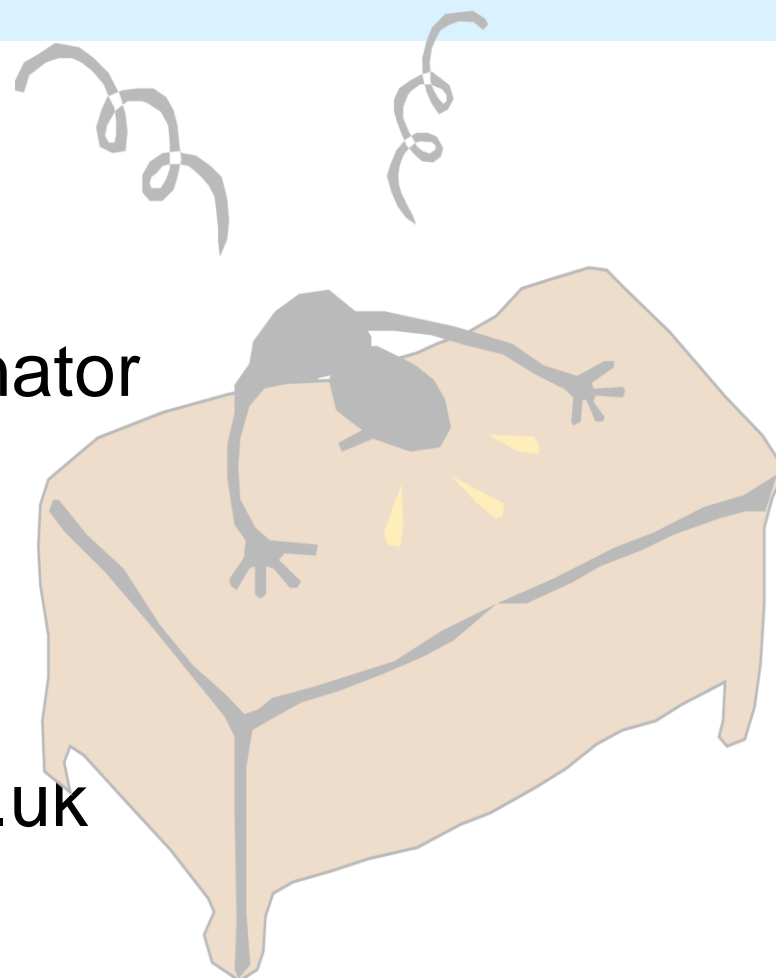
If you don't use us, you will lose us!



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Further information and help

- Barbara Cuddon :
Social Care REC Co-ordinator
- email screc@scie.org.uk
- www.screc.org.uk
- www.scie.org.uk
- Deborah.Rutter@scie.org.uk



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Coventry University

Research governance and ethics for adult
social care research in England - policies
practices and challenges

John Woolham
Research Fellow

Challenges for governance and ethics in adult social care research

Structure

- History & context
- Research governance in different settings
- Issues and challenges

Challenges for governance and ethics in adult social care research

History & context

- Three main sources of review - NHS/NRES, URECs, CSSRs
- Separate histories different structures and functions
- RGF 2001/2005 - Response to Alder Hey and subsequent Redfern Report - the catalyst for growth of RG committees - all have status of 'guidance'
- MCA (2005) - legal duties on researchers
- Academy of Medical Sciences (2011) - proposals to streamline clinical research -no mention of social care research

Challenges for governance and ethics in adult social care research

History & Context

- Concerns (2001-04) about the imposition of an NHS RGF on social care research - social scientists in universities also concerned. Key reasons
 - Time-consuming (bureaucratic delay)
 - Limited knowledge of social care research methodologies by NHS reviewers
 - Responses seen as high-handed & unsupportive (lack of recognition of constraints facing much social care research).
 - Lack of consistency in outcome of reviews between different RECs.
 - Process encouraged a 'mindset' that ethics review process an obstacle to overcome rather than a way of conducting research.
 - Local authorities were given longer to implement revised governance arrangements

Challenges for governance and ethics in adult social care research

Research governance in different settings

NHS

- Adhoc arrangements until 1991 & NHS Circular
- Responsible for *all* research in NHS settings
- Well resourced
- Standardised approach: IRAS 2008. Further efficiencies to review system
- Centralised approach - 'command and control'
- Independent

Challenges for governance and ethics in adult social care research

Research governance in different settings

Universities

- Responsible for research carried out by university staff and students
- Variety of different structures (committee, electronic, centralised, devolved. Some also have self-assessed triage arrangements by likely level of risk).
- All universities are likely to have RECs now - major funders won't fund and journals won't publish non-reviewed proposals

Challenges for governance and ethics in adult social care research

Research governance in different settings

Local authorities

- Some strong on research. Others less so: Many CSSRs have no in-house research capacity.
- In-house research often poorly resourced & not always a priority
- Wide range of 'research-like' activity - 'pure' research, audit, service evaluation & consultation
- Often focused on managerial issues & narrowly defined performance (less on 'best practice')

Challenges for governance and ethics in adult social care research

Issues and challenges

Is there a need for research governance?

RGF was a response to a scandal in the NHS rather than social care and the NHS already had RECs then.

Motives may be fear of litigation rather than ethical practice?

Two narratives: imposition of unwelcome bureaucracy that's undemocratic/stifles research or and opportunity to raise standards

- Can protect vulnerable people from 'bad' research
- Can help to raise standards
- Can co-ordinate activity locally and regionally (preventing unnecessary duplication, over-researching of local groups etc)
- Can help 'plug' research in so findings are accessible and are used.

'At no point are we going to forcibly inject dependent patients with irreversibly toxic green stuff. Why are we treated as if we were going to?'

Dingwall (2006) p.52

Challenges for governance and ethics in adult social care research

Issues and challenges

What *is* research anyway?

This is the current NRES guidance.

Are ethical issues *only* likely to be present if the study is described as 'research?'

NRES feel most local authority - and some University studies - are *not* research so don't need NRES review.

Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	SURVEILLANCE	USUAL PRACTICE (in public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	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.	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.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
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.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing data or administration of interview or questionnaire to those exposed.	May involve administration of interview or questionnaire to those exposed.
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.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to www.nres.npsa.nhs.uk/applications/apply/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

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

Challenges for governance and ethics in adult social care research

Issues and challenges

Where should researchers go to get their research reviewed?

Principles of the 'route-map for researchers'

- reciprocity
- Avoidance of double handling
- Proportionality
- Independence (from funder or research employer)
- Researcher led (researcher's responsibility)



Challenges for governance and ethics in adult social care research

Issues and challenges

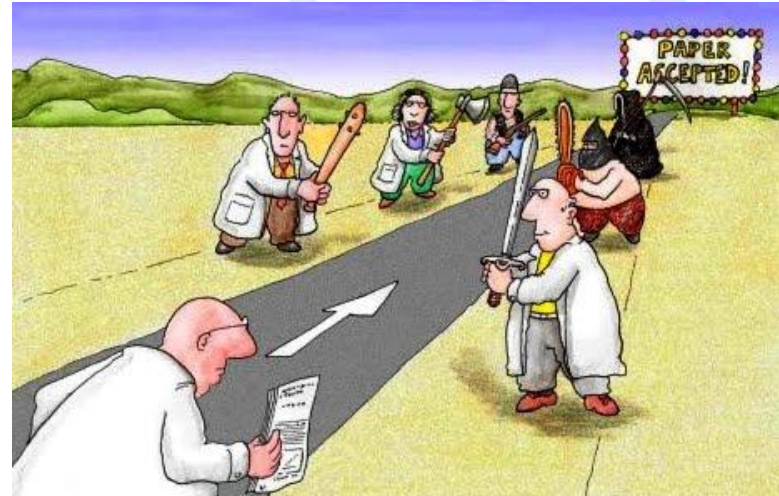
The problem with proportionality

Principle is of

- 'light touch' review for studies that are of low ethical risk.

Problems are

- How is this defined and by whom?
- How can a reviewer know if a research proposal is 'low risk' until he/she has read the whole application and all associated paperwork carefully?



Most researchers regarded the new streamlined ethics process as a great improvement.....

Challenges for governance and ethics in adult social care research

Issues and challenges

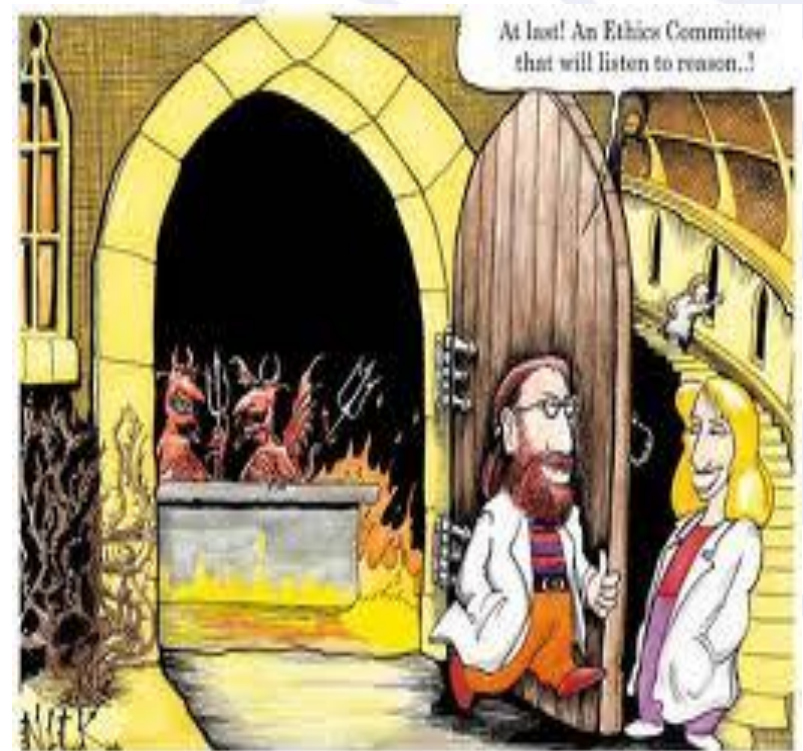
The problem of reciprocity and 'double-handling'.

Principle is that

- all research gets reviewed once

Problems are that

- Different sources of review don't accept the currency of another reviewing body - there is 'asymmetry' in the relationship between reviewing bodies.
- This lack of trust may be justified in respect of the quality of some reviewing activity



Challenges for governance and ethics in adult social care research

Issues and challenges

How independent are different sources of review?

- NRES. Independently funded, & removed from local operational management in NHS. Too early to say what impact HRA (replacing NRES) will have on structural independence.
- URECs. Some potential conflicts of interest - pressure to publish, bring in research income but reviewing activity protects departmental/faculty reputations.
- Local authorities. Independence likely to vary. Support from a senior manager 'champion' probably vital. Risks that RG leads may be invited to favourably review some studies or avoid review without sanction.



Challenges for governance and ethics in adult social care research

Issues and challenges

Researcher led?

- An unknown number of studies may evade scrutiny in local authorities - depending on whether research governance arrangements exist, local definitions of research, the robustness of reviewing arrangements and the support senior managers provide.
- Evasion from URECs probably less, due to other incentives and sanctions imposed by funders and publishers but quality of review may vary
- Compliance more likely in NHS settings as RECs are more deeply embedded in NHS culture, but definitions of research are problematic.



Challenges for governance and ethics in adult social care research

Issues and challenges

The scope of the review: what actually gets reviewed?

- Reviewers in some sectors may not receive or require all the paperwork. *(how can an assessment be made of a study, for example, if a proposal but no questionnaires are submitted for review?)*
- Lots of studies highly critical of the ethics review process, but there's almost nothing about the quality of submitted proposals.

Speed of response & workload /capacity of reviewing systems

'Applicants new to IRAS struggle with the idea of as much as with their actual use of it: the process is not yet, as is the case with most healthcare research, embedded in the organisational research culture of most of our applicants. Key sections in applications are not written in lay language, there are multiple typos, sections not completed, version numbers etc, not put on attached documentation; Information Sheets and Consent forms are inadequate, using language which is not written with the needs of the respondent in mind. Reviews of the basic science by e.g. university or organisational research committees are rarely included with applications'.

SCREC Annual Report (2011) p. 8

Challenges for governance and ethics in adult social care research

Issues and challenges

Knowledge, skills, & experience

a. Reviewers

- Do reviewers always have the required knowledge and skills?
- How much training and access to training do reviewers have?
- How much user/carer involvement on committees is there?

b. Researchers

- Is there a career structure?
- How does one learn to be a competent researcher? (everyone is inexperienced at some point).

‘...the majority of councils that provide services for adults do not have a workforce that is used to carrying out research.....This lack of familiarity with the conduct of research, combined with a tendency to proceduralise, generates an approach to research governance where all risks are managed through ever more detailed and precise procedural requirements. This is grounded in a belief that if the procedure is carried out then risk will be eliminated.

McLaughlin & Shardlow,
(2009) p. 16.

Challenges for governance and ethics in adult social care research

Concluding thoughts

Returning to the 'route map' principles

- Reciprocity limited by asymmetric relations and between different reviewing bodies
- Avoidance of double handling assumes basic levels of competence which if absent erodes trust
- Proportionality hard to achieve without self assessment of risk or a reviewer doing a full review
- Independence of RECs not always structurally guaranteed.
- People are probably better protected from bad research now than before RGF
- Price has been high for researcher time - systems still hard to navigate, still overlap & are still time consuming
- Reviewers also pointing to problems with the quality of applications
- Solutions likely to involve investment in training for researchers and reviewers
- Governance issues may reflect wider societal ambivalence towards risk and protection

Selected references

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The Social Care Research Ethics Committee

Obtaining Ethics Committee Approval from Social Care REC

**Barbara Cuddon
Co-ordinator**



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- **Role of the Co-ordinator**
- **The remit of the Social Care REC**
- **Application process**



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Role of the Co-ordinator

- Process applications
- Arrange and service all meetings
- Respond to researchers
- Support Chair and Committee
- Work with NRES
- Advice and support



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Social Care REC

- Specialist REC
- 14 Members
- Membership reflects the social care context
- Meets monthly in central London

Social Care REC Reviews

- Adult social care research study proposals
- Intergenerational studies involving adults and children or families
- Social care research that involves people lacking capacity in England and Wales which requires approval under the Mental Capacity Act 2005



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Social Care REC Reviews

- Social care studies funded by Department of Health e.g. NIHR School for Social Care Research
- Own account' research undertaken by Councils with social services responsibilities, where the Chief Investigator and/or sponsor feels there are substantial ethical issues
- Social care databases



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Social Care REC Reviews

- Studies taking place in NHS settings with NHS patients where the approach uses social science or qualitative methods, provided that the research does not involve any change in treatment or clinical practice
- Studies of integrated services (health and social care), provided that there is no clinical intervention involved



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Social Care REC Reviews

- Adult social care research involving changes in, or withdrawal of, standard care
- Studies not suitable for review by other NRES RECs, e.g. service user-led research
- Student research within the field of social care should ordinarily be reviewed by a UREC



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Application process

Online IRAS System –
www.myresearchproject.org.uk



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IRAS Sources of Support

- www.myresearchproject.org.uk
- www.nres.nhs.uk
- www.screc.org.uk



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IRAS Form

Fill in the IRAS form thoughtfully

- Filter questions
- Answer all the questions
- Lay language



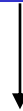
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IRAS FORM

- Supporting documentation e.g. Information Sheets and Consent Forms
- Complete the checklist
- Title of document, version number and date

Quick Guide for Submitting Applications to the Social Care Research Ethics Committee

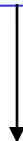
Researcher goes to www.myresearchproject.org.uk and completes online IRAS form



Researcher phones the Co-ordinator to book in the application

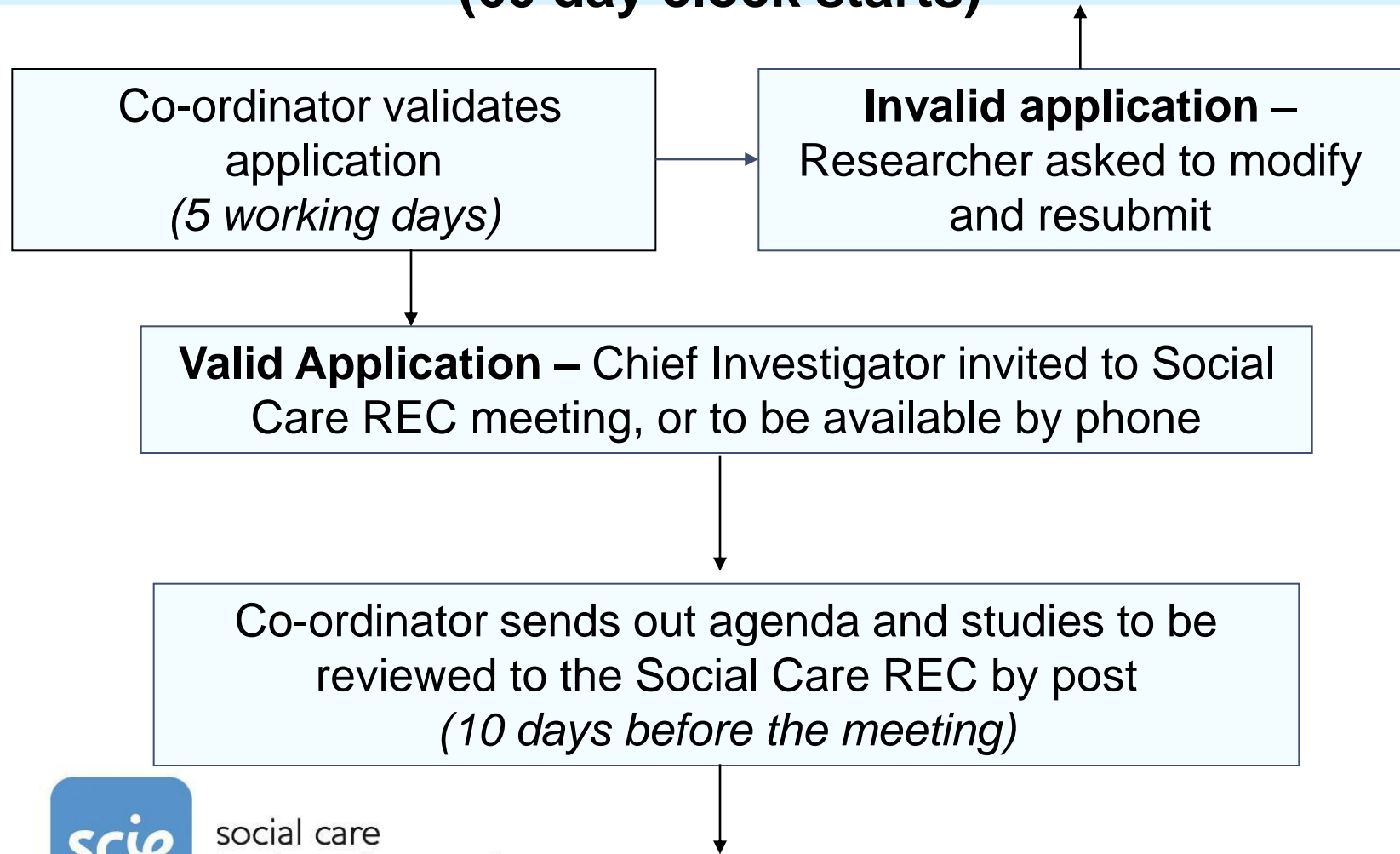


Researchers submits the IRAS form and supporting documentation direct to the Co-ordinator asap after booking



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Application received by the Social Care REC Co-ordinator (60 day clock starts)



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Format of Social Care REC Meeting

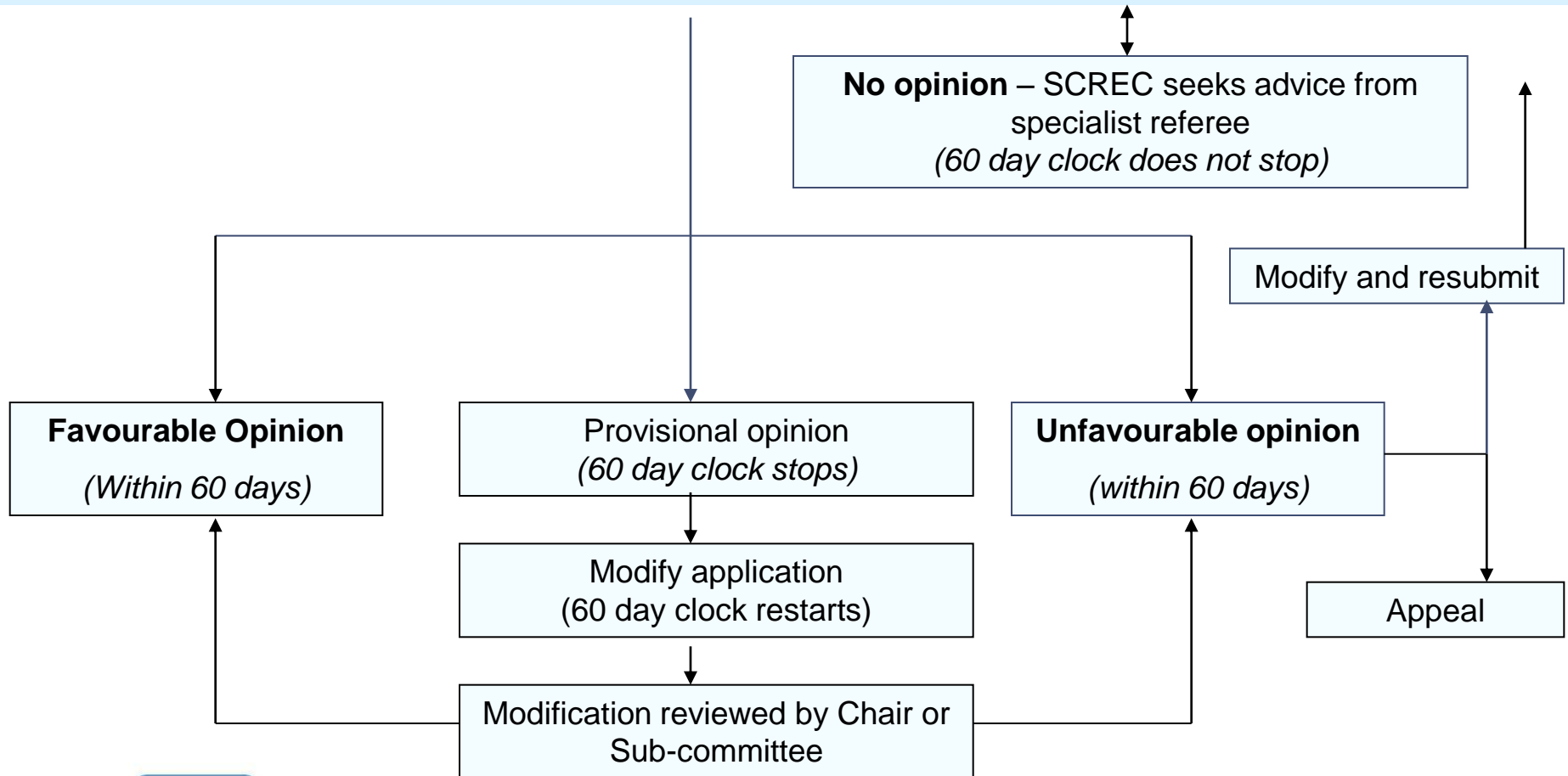


- Discuss each application in turn
- Invite applicant into meeting to answer question
- Consider applicants responses and confirm a decision
- Applicant informed in writing 10 working days after the meeting



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Application reviewed by the Social Care REC



Other Approvals

- ADASS Research Group
- NHS R&D Approval
- Local Authority Research Governance Approval www.researchregister.org.uk/governance.asp
- Other management permission



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Further Information and Help

- **Barbara Cuddon**
- **Social Care REC Co-ordinator**
- **Email: screc@scie.org.uk**
- www.screc.org.uk
- www.scie.org.uk



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Research and the Mental Capacity Act 2005



The Act applies to England & Wales only

David Stanley

Professor of Social Care, Northumbria University

Chair, national Social Care Research Ethics Committee

With acknowledgments to:

David Neal

Head of Policy & Deputy Director

National Research Ethics Service



Core principles of ACT (sec 1)

1. **People must be assumed to have capacity unless it is established that they lack capacity**
2. **Before treating people as unable to make a decision, all practicable steps to help them to do so must be tried**
3. **People should not be treated as unable to make a decision merely because they make an unwise decision**
4. **Acts or decisions on behalf of people who lack capacity must be in their best interests**
5. **Before any act or decision, the person responsible must consider whether the purpose could be achieved in a less restrictive way**

Assessing capacity (sec 3)

1. A person (P) lacks capacity in relation to a matter if *at the material time* P is unable to make a decision for themselves *in relation to the matter* because of an impairment of, or a disturbance in the functioning of, the mind or brain and as a result is unable to:
 1. Understand information relevant to a decision
 2. Retain the information
 3. Use or weigh the information
 4. Communicate their decision (by any means)
2. A lack of capacity cannot be established merely by reference to age, appearance, or a condition or an aspect of behaviour which might lead others to make unjustified assumptions about capacity



Capacity may depend on type of decision:

1. **Capacity must be assessed for each particular decision – because P might lack capacity to make a complex decision it should not be assumed that they do not have the capacity to make a less complex one**
2. **Researchers must be able to assess capacity when recruiting participants – or seek expert advice / input from other professionals where necessary.**



The MCA & research provisions:

1. Background:

- **Government agreed at Bill stage that there should be provision for strictly controlled research to avoid current legal uncertainty and inequity**
- **Clauses based on ethical norms**
- **Consistent with other statutes, human rights and international instruments**
- **Final provision aimed at balancing concerns to enable essential research whilst respecting and protecting vulnerable people**



Scope of research provisions:

1. Any 'intrusive' research - definition of intrusive
2. Wherever it is conducted, including eg:
 1. Prisons & police cells
 2. Residential care homes & day centres
 3. Drug & alcohol treatment centres
 4. Universities
 5. Private & NHS treatment settings
 6. Armed services including battle zones
 7. Social research (including censuses & surveys)
3. People aged 16 and over
4. CTIMPs (clinical trials) are excluded
5. HTA



The research provisions:

- **Sections 30-33 make it lawful to conduct intrusive research involving people who lack capacity**

Section 30: intrusive research

Section 31: requirements for approval

Section 32: consulting carers

Section 33: additional safeguards

There is also transitional provision (s 34) relating project s approved before the law came into force.



Section 30:

1. **Since 2007, under a statutory instrument for England, intrusive research involving a person who lacks capacity is unlawful unless it is approved by an ‘appropriate body’ (sometimes referred to as ‘section 30 approval’)**
2. **An appropriate body is in practice a research ethics committee recognised for these purposes under the Act by the secretary of state.**
3. **What are the appropriate bodies? In England - all NRES RECs including the national Social Care REC and NHS RECs. University RECs are not recognised as appropriate bodies**



Intrusive research:

- 1. Research is intrusive if it would normally be unlawful to do it without consent**
- 2. The requirement for consent is not limited to interventional studies and includes, for example any research involving access to personal data, questionnaires, interviews or observations which infringe the right to privacy**
- 3. Consent is not a legal requirement and therefore the MCA would not apply where research is limited to the use of: non identifiable data; identifiable data approved for process without consent by NIGB (formerly PIAG); non identifiable tissue from the living**
- 4. S 30 approval is not required for projects which are not 'research' (ultimately for research, employer, sponsor to determine)**



Section 31 approval criteria

- 1. Research must be connected with an impairing condition**
- 2. Research of equal effectiveness cannot be conducted if confined to people with capacity**
- 3. Must have the potential to benefit the participant without imposing a disproportionate burden OR provide knowledge of treatment for others with same condition and involve negligible risk (& other safeguards)**
- 4. Arrangements are in place to comply with sections 32 & 33**



Section 32: consulting carers

1. **Researcher must seek advice from a carer or another person (the 'consultee') on whether P should take part and what P's wishes and feeling would be**
2. **The consultee gives advice NOT consent**
3. **Under the MCA there is no 'consent' representing the presumed will of the participant**



Section 32:

Identifying a consultee

1. Researcher must take reasonable steps to identify a *personal consultee*
2. A personal consultee means a person who is a. engaged in caring for P (not professionally or for payment) or is interested in P's welfare and b. is prepared to be consulted
3. If no personal consultee can be found, the researcher may consult a *nominated consultee* ie a person independent of the project and appointed in accordance with DH guidance



Section 32:

- 1. The researcher must respect the advice of the consultee**
- 2. The consultee should be kept informed during the study and may advise at any time that P should be withdrawn**
- 3. It is good practice for the consultee to be provided with full information about the research and to attend during research procedures.**



Section 33: additional safeguards

- 1. Nothing must be done to which P appears to object, unless it is in their best interests**
- 2. If P indicates a wish to withdraw from the research this should be respected without delay**
- 3. Any advance statement by P must be respected**
- 4. P's interests must be assumed to outweigh those of society**



MCA Questions:

- **Q1 A Local Authority wishes to get feedback and suggestions on the domiciliary services it provides to older people in the Borough with a view to extensive re-design and re-commissioning. It has contracted a private research organisation to evaluate the existing scheme and seek suggestions for future services. A semi-structured interview conducted in the recipient's home has been designed. The team is worried that some of the older people contacted because they receive the service could have capacity problems.**



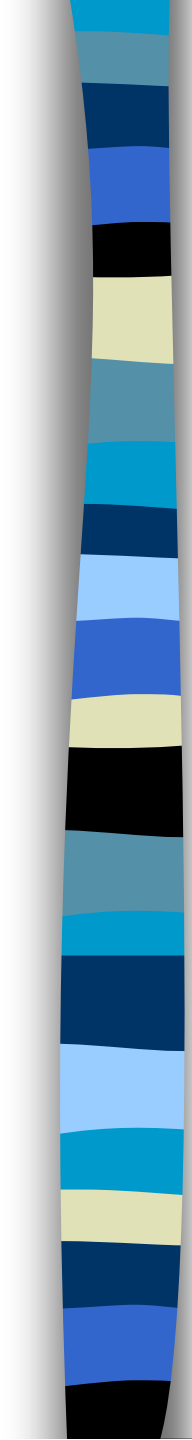
MCA Questions:

- **Q2.** A study wanted to interview partners of adults lacking capacity about their experiences of living with the ALC, but to exclude the ALC as a participant. Would it nonetheless be necessary to involve a consultee on behalf of the ALC? The ALC is not a participant so arguably it would not be necessary in relation to the MCA. Is that a reasonable interpretation? An ethical issue may or may not remain.



MCA Questions:

- Q3. If the ALC is a participant in the research, the best person to be (personal) consultee would be the partner. However the researcher might wish to include the partner in the study. The MCA research guidance says that a nominated consultee cannot be connected with the research, however it is silent on this matter regarding a personal consultee. It follows therefore that a personal consultee may be connected with the research – eg may also be a participant. Is that a reasonable interpretation?



DH advice (by extrapolation from MCA helpsheet) Q1

The research is not directly related to the condition causing the incapacity of these individuals, nor to the treatment of those with that condition, although it is related to their general care. It would however be difficult for the research team to demonstrate that the study could not be as effectively conducted only with those who had the capacity to consent. It is also unlikely that people lacking capacity to consent would be able to respond directly to the interview questions.

The study team establishes clearly from the outset that it does not intend to include people without the capacity to consent to participation. It attempts to screen out people lacking capacity from the initial mailshot (an introductory letter, explaining the study). It relies on people who are interested to 'opt-in' (volunteer), and includes a note in the letter for recipients and carers to the effect that participation is entirely voluntary, and they need take no further action if they cannot or do not wish to take part. (A separate study of carers' views is planned.)

NRES advice Q2

This is a particularly tricky issue which is not addressed in the Code of Practice. The question is whether the research is intrusive in relation to the person lacking capacity ("P"). Although not a participant as such, would the research intrude into their privacy in a manner that would involve a breach of the Human Rights Act or the Data Protection Act if done without their consent? It may depend on the circumstances and the research procedures to some extent. If the research team will not be holding or analysing identifiable personal information about P, one might argue there is no breach of privacy or confidentiality. But the researchers may well become aware of P's identity in the course of the interview, and personal matters relating to P could be discussed. In replying recently to a similar query from a researcher planning to interview relatives about the care of adults subject to Deprivation of Liberty Safeguards, we advised erring on the side of caution and treating the research as intrusive and subject to sections 30-33 of the MCA. This advice was actually welcomed as the researcher had been uneasy about proceeding without the protection of section 30 approval! But it is a borderline judgement. Ultimately it is a matter for the researcher and their sponsor, and they are free to seek their own legal advice.



NRES advice Q3

There is no *legal* obstacle to the consultee being connected with the research. The provision relating to nominated consultees is presumably designed to address the scenario where the consultee could have a vested interest in the research, e.g. as a collaborator or close colleague of the researcher. The Act does not appear to be concerned with personal consultees having their own interest in the research as participants. Whether this is an *ethical* problem is a matter for the REC. At training events we have discussed a case study involving interviews with both P and the nearest relative, who was also likely to be the personal consultee. Some delegates expressed concerns that the consultee could be unduly influenced by their own desire to take part, or their personal support for the research aims. However, the general view was that this was not a significant risk - most consultees could reasonably be expected to consider the interests of P as well as their own views. Also, a requirement to seek a separate consultee, e.g. another family member, would be artificial, onerous for the researcher and could lead to family tension. On balance, delegates considered it reasonable to allow the consultee to wear both hats, but the consultee information sheet should stress that this role requires them to put aside their own views and consider the wishes and feelings of P.



Additional information:

1. Applications for section 30 approval are made through the Integrated Research Application System (IRAS) advice is also available, at: www.myresearchproject.org.uk/
2. Clear guidance is provided in the Code of Practice for the Act at www.dca.gov.uk/legal-policy/mental-capacity/mca-cp-plain3.pdf
3. A help sheet for social scientists, which is applicable to other disciplines too, and which provides helpful definitions of some of the Act's terms, advice and case examples can be accessed at:
www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@pg/documents/digitalasset/dh_106217.pdf



Ethics in practice: Considering ongoing ethical issues in qualitative research

Workshop on Ethics and Governance in Social Care Research
University of Coventry, 17 September 2012

Kezia Scales, Sociology and Social Policy
kezia.scales@nottingham.ac.uk



UNITED KINGDOM • CHINA • MALAYSIA

Collaboration for Leadership in Applied Health Research and Care for Nottinghamshire, Derbyshire, and Lincolnshire (CLAHRC-NDL)

“...to foster the translation of research evidence
into practice in health and social care.”

A partnership of:



CLAHRC is a member of:



Overview

Ethics in practice: The sustained challenge of conducting ethically sound research that takes into account the rights, the safety, and the wellbeing of every person that is affected by the research.

- Informed consent
- Rapport
- Deception
- Confidentiality and anonymity
- Ethics in/of practice

... And ethically important moments.



Case studies

1. Challenging care: The role and experience of healthcare assistants in dementia wards



(http://www.sdo.nihr.ac.uk/files/project/SDO_ES_08-1819-222_V01.pdf)

2. Learning to care: Exploring the translation of person-centred care into practice in LTC

Ethical implications

Patients/residents:

- Privacy, dignity, autonomy
- Isolation, stigmatisation, loneliness, dependence

Healthcare assistants, care assistants, nursing aides:

- Majority of direct contact with care recipients
- Marginalised, devalued position
- Low pay; limited benefits, training & professional development; little mentoring or supervision
- Short-staffing and high turnover
- Emotionally and physically challenging work

Informed consent

Questions to consider in advance:

- Who will be asked for consent?
- What happens if/when the setting changes?
- How to ensure truly informed consent?

Consider: emergent design; time; power



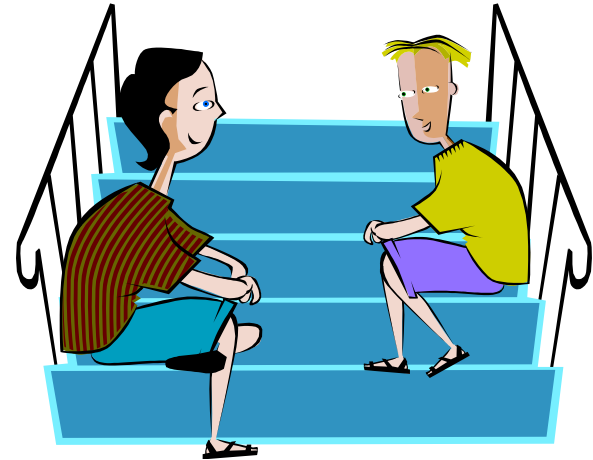
Informed consent is a “**relational and sequential process rather than a contractual agreement**” (Murphy and Dingwall 2007: 2226).

He asked if I was bank staff, [the nurse] explaining to him that I am doing the research project: “What’s it called?” she asked. I told him and [the HCA] said jokingly with her hand covering her mouth: “She’s the spy on the wall.” They joked about my noting them down and reporting them and I smiled, telling them I was only there to explore stress and coping in the job. “Yeah sure!” they laughed. I laughed along and it all seemed pretty light-hearted (or so I hoped!).

— Fieldnote, Project 1

Rapport

- Establishing rapport
- Maintaining boundaries
- “Faking friendship”?



The researcher's ethical responsibility is to maintain **“a fine balance between building sufficient trust to be able to probe participants for potential rich data, while at the same time maintaining sufficient distance in respect for the participant”** (Guillemin & Heggen 2009: 292).

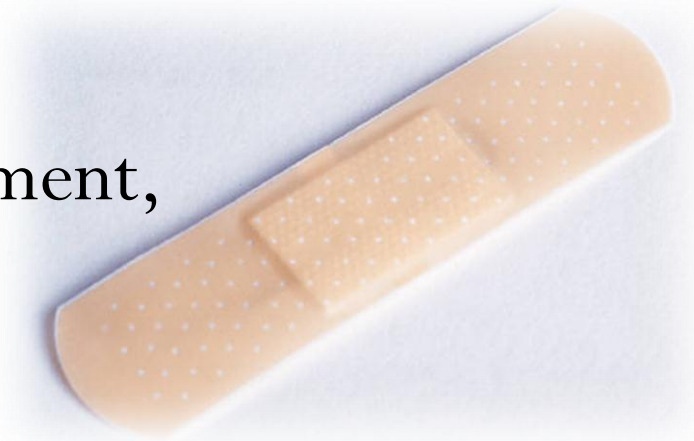
Confidentiality and anonymity

- Intentional breach of confidentiality?
- Accidental breach of confidentiality —
letting something slip



Risk and harm

- Social or psychological harm
- During the research: embarrassment, inconvenience, annoyance
- After publication:
 - Identification of the research site
 - Public embarrassment or humiliation
 - Unsympathetic treatment of findings by media
 - Professional or criminal investigations
 - Offense to participants



Ethics in/of practice

“In the event that the researcher observes examples of unsafe or unethical practices in the care context, she will address these on a case-by-case basis according to facility procedures, with guidance from her supervisors.”



Ruth was sat with a lap belt in one of the chairs across from the nurses' station till the end of the shift... When I came back later on from my break, Yolanda and Nadine were laughing and saying “do it again” as they watched Ruth do funny things with the blanket: she'd flip it up, hold it there over her head for a minute — “now watch!” they'd say, and she'd lower it as they both called “peekaboo!”.

— Fieldnote, Project 2

Ethically important moments

Ethically important moments: “The difficult, often subtle, and usually unpredictable situations that arise in the practice of doing research” (Guillemin & Gillam, 2004: 262).

... It is in these moments that “the researcher’s ethical competence comes to the fore. By this we mean the researcher’s willingness to acknowledge the ethical dimension of research practice, his or her ability to actually recognise this ethical dimension when it comes into play, and his or her ability to think through ethical issues and respond appropriately” (Ibid: 269).



Noel: ... we're getting very good feedback, like things that people aren't happy about, in terms of, waiting too long for their call light, um, even surprising is, sometimes um residents are saying that staff don't talk to them as nice as they would like. Do you see that at all?

Kezia: [pause] I would, I would say, I haven't seen any evidence of *unkind* interaction, I think maybe efficiency becomes abruptness, you know, so I've seen maybe tasks being done in an efficient way without a lot of —

N: Conversation.

K: - conversation, and I think that if you're more, alert — although I strongly believe even if you're not very alert, you're conscious of a lot of these kinds of signals — um, it might seem, not very warm, sometimes. And I think that varies a lot, um, so it's, you know—

N: Cause if you see that, I — I don't know if that would be a breach of your confidentiality, but I'd wanna know that if it's a particular person so that we could counsel them on how to do that better.

K: Yeah... okay. Well, I'll keep, I'll sort of, over the next little while, I'll keep an eye on that and see if there are any specific examples.

N: Okay.

K: Um, yeah, I'll, yeah, I'll keep that in mind. Um — but I think hearing from the residents is probably a good, that's a good way to learn about it.

- Interview, Project 2

Conclusion

1. Think through ethical implications in advance. How might you respond?
2. Remain conscientious and reflexive about ethical issues as they arise.
3. Be willing to compromise.
4. Be transparent about ethics decisions.
5. Ensure structured opportunities for dialogue, debriefing, and support.

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NatCen

Social Research that works for society

Ethical Issues in Quantitative Research

Soazig Clifton

9th March 2012



Overview

- About NatCen
- Case Studies
- Ethical Issues Throughout the Project Lifecycle
 - Informed Consent
 - Collecting Sensitive Information
 - Confidentiality vs Disclosure of Harm
 - Mental Capacity Act and Inclusivity
- Conclusions

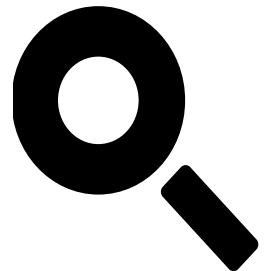


About NatCen Social Research

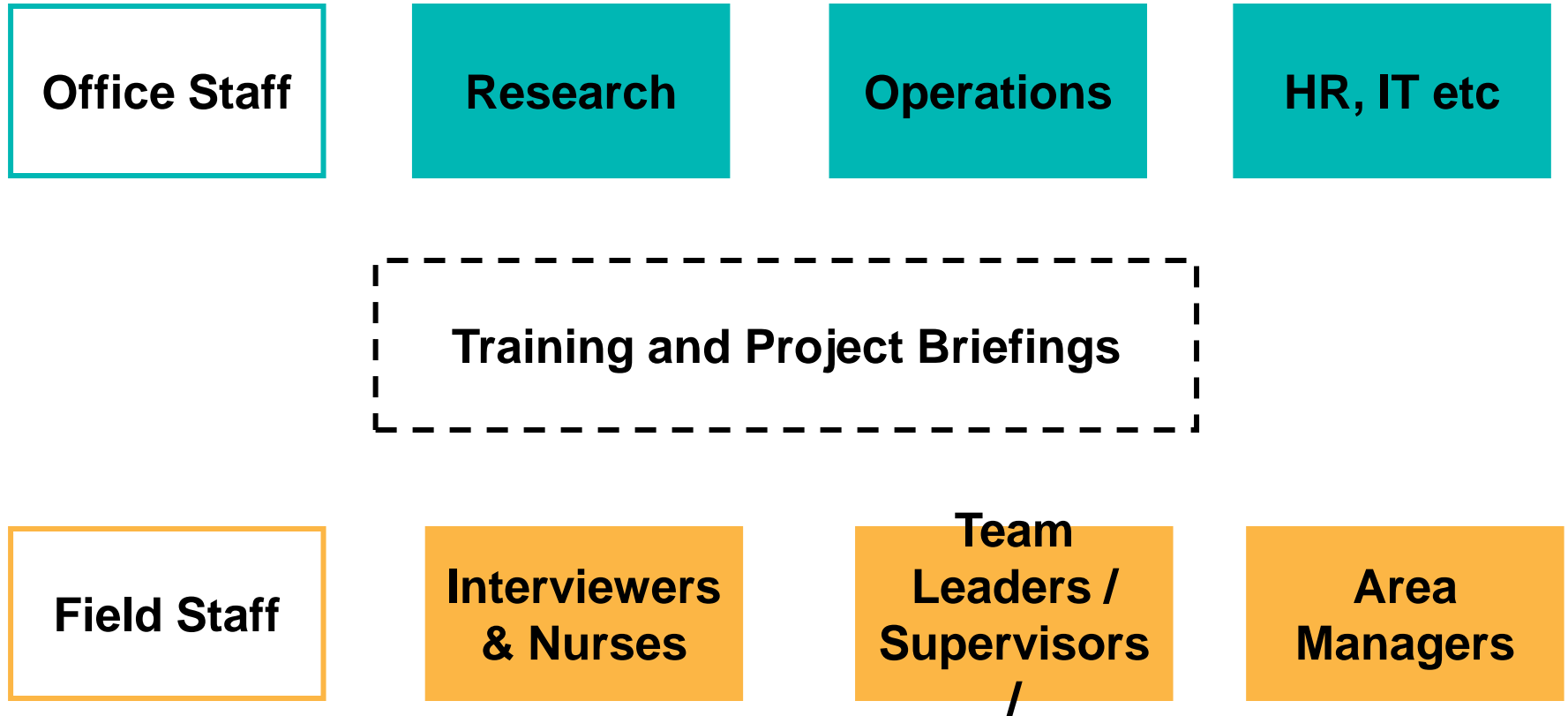
1

Social Research that works for society

We believe that social research has the power to make life better. By really understanding the complexity of people's lives and what they think about the issues that affect them, we give the public a powerful and influential role in shaping decisions and services that can make a difference to everyone. And as an independent, not for profit organisation we're able to put all our time and energy into delivering social research that works for society.



Organisation structure



A 'typical' interview



Ethical Approval

- NatCen REC
- MREC
- University RECs

Case Studies



2

Case Studies

- UK Study of Abuse and Neglect of Older People
- National Survey of Sexual Attitudes and Lifestyles (Natsal)
- English Longitudinal Study of Ageing (ELSA)

Ethical Issues Throughout the Project Lifecycle



3

Informed Consent

How much information to
give, and when?

Can too much information
be off putting?

Lewis J & Graham J.
Research participants' views
on ethics in social research:
issues for research ethics
committees. Research
Ethics Review 2007;3:73-9

Who should be given the
information?

Case Study: Natsal



Natsal
2010

- Britain's first, and largest, study of sexual behaviour
- 1 person aged 16-74 selected from each household
- Detailed questions about sexual experiences, as well as more general questions eg general health
- Urine and saliva samples collected

Asking difficult questions

Is it ok to ask people
about their sex lives?

What if the participant
gets upset about
something in the
interview?

Questionnaire design



Natsal
2010

- Neutral language
- Interviewer training
- Showcards and self completion methods
 - Reduce embarrassment
 - Maintain privacy

Test your questions first

Ensuring no harm comes to the participant

- Cannot predict what will upset participants
- Signpost participants to organisations who can help
- What support is available to the interviewer?

Disclosure of harm

What if an interviewer sees or hears something that worries them?

Can they pass on information about a participant when they have promised confidentiality?

What if a female participant in her 80s tells the interviewer that she thinks her son is stealing from her?

...A man aged 45 reports that he is having sex with a girl under the age of 16?

...A man in his 90s reports that he is
being bullied by his care worker?

...a 16 year old girl tells the interviewer that she is being sexually abused by a member of her family?

...there is a young child in the house, and the interviewer has a 'funny feeling' about the parents' behaviour. The conditions in the house are unsanitary, the parents' behaviour towards the child seems very passive, and the interviewer is worried about neglect?

Case Study: Elder abuse

- 1 person aged 66+ selected from each household
- Did not cover people living in institutions
- Measured prevalence of four types of abuse:
 - Psychological
 - Physical
 - Sexual
 - Financial
- Also measured neglect

NatCen's obligations

There is no statutory requirement for NatCen fieldworkers to disclose information to public bodies when they perceive a risk...

...BUT statutory law requires citizens to disclose information that could aid the detection of specific crimes

...AND fieldworkers are entitled, as an independent free agent, to disclose information.

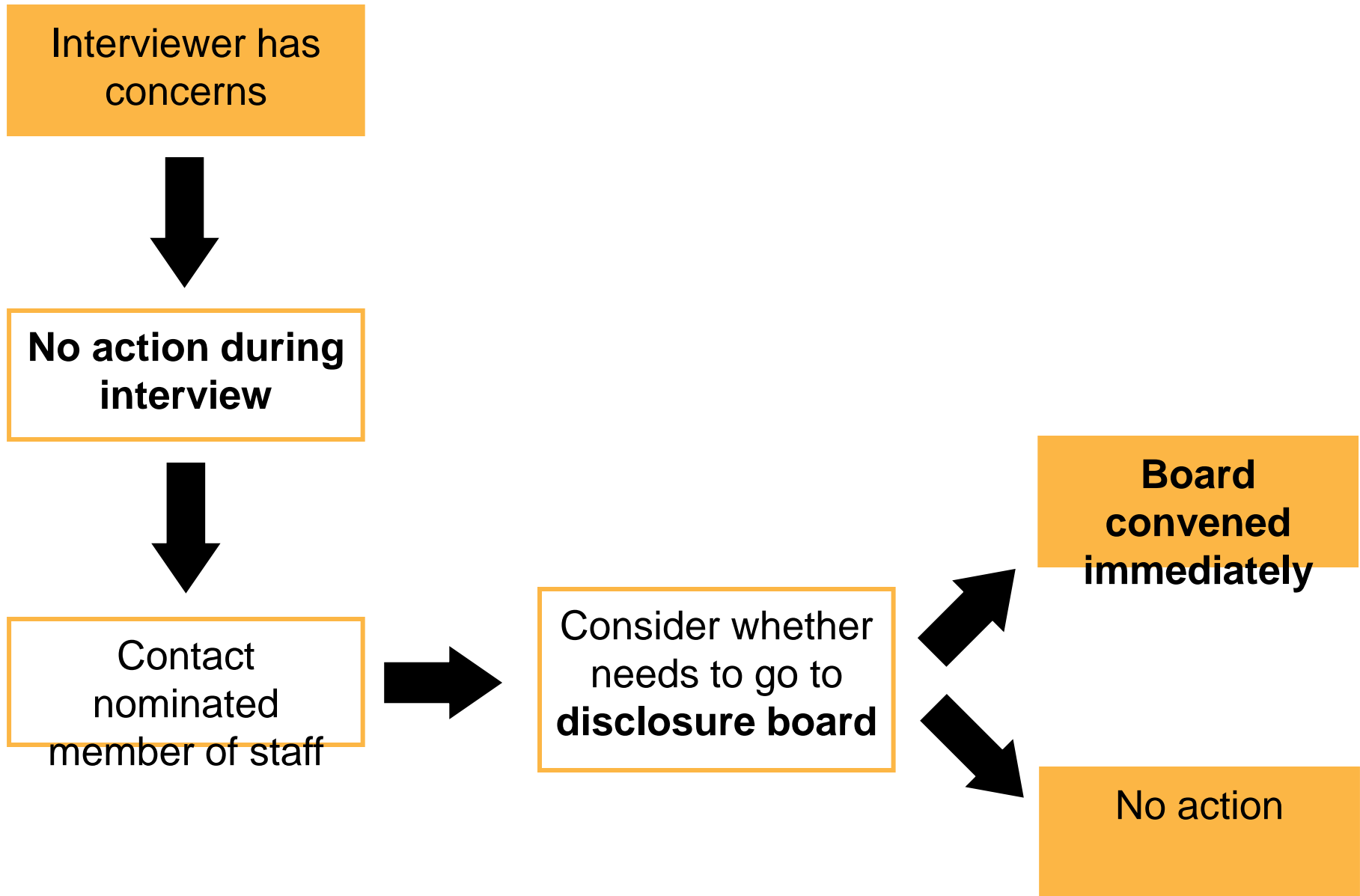
Risks

Participants make take civil action against interviewers if they believe an interviewer made a malicious false disclosure of information against them...



...Equally they can take civil action against an interviewer who perceived them to be in clear danger but failed to disclose

By requesting that the fieldworker informs NatCen of their concerns, **NatCen take on responsibility for the decision**



How does the board decide?

Seriousness of alleged harm or illegal behaviour

Strength of evidence

Ability of individual involved to help him or herself

Is the situation already known to support services / others capable of intervening?

Potential risks to individuals and to NatCen

Approvals previously given by NatCen or other Research Ethics Committees

Mental Capacity Act and inclusivity

Participants must have the mental capacity to make an informed decision about whether to take part

But it's important for our research to fully represent the population, including vulnerable groups

Case Study: ELSA

- Longitudinal Study of people aged 50+ and their partners
- Follow participants up every 2-4 years
- Interview + Nurse visit
- Long interview (1.5 hours)
- Range of topics covered including
 - Health
 - Finance
 - Psychosocial health
 - Biological / cognitive measures

Adaptations on ELSA

Interviews in institutions

Communication is key

Proxy Interviews

If respondent lacks mental capacity to make an informed decision, can do a proxy interview with partner / relative

Consider frailty

Find out best time of day
Break up interview into chunks
Skip sections

Conclusions



4

Conclusions

- In large-scale surveys, researchers will not have contact with participants
- Will be largely unaware of ethical issues that arise during fieldwork
- Preparation is vital
- Interviewers need training and clear guidelines
- Also need ongoing support

Thank you

If you want further information or
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NatCen

Social Research that works for society