Ethical considerations and data protection in evaluation

This document sets out the key ethical considerations and data protection aspects particularly relevant to evaluation in a fuel poverty and health context.

In general, researchers should respect the diversity of human society; where possible, evaluations should take account of age, disability, gender, sexual orientation, race, culture and religion. It is worth noting ten *questionable* practices in social research (including evaluation) according to Robson (2011[1]):

1. Involving people without their knowledge or consent
2. Coercing them to participate
3. Withholding information about the true nature of the research
4. Otherwise deceiving the participant
5. Inducing them to commit acts that may diminish their self-esteem
6. Violating rights of self-determination (e.g. in studies aiming to promote individual change)
7. Exposing participants to physical or emotional stress
8. Invading their privacy
9. Withholding benefits from some participants
10. Not treating participants fairly, or with consideration, or with respect

Ethical guidelines

Research ethics refers to the moral principles guiding research from inception through to publication. Research or evaluation which include people vary widely in the method and purpose, however basic ethical principles should be followed in each and carefully considered from the design stage[1]. Relevant ethical guidelines include:

- Research Councils UK Policy and Guideline on Governance of Good Research Conduct (2013)
- The British Psychological Society - Code of Human Research Ethics.
- Research Governance Framework for Health and Social Care, produced by the Department of Health attempts to bring together guidelines/ statutes in the field. The document includes a section on ethics (2.2) with guidance for protecting research participants' rights. This sets out the primary consideration for protecting the dignity, rights, safety and well-being of participants.
- The UK Government Social Research Unit published guidance on Ethical Assurance for Social Research in Government which details their five main ethical responsibility principles: Principle 1: Sound application and conduct of social research methods, and interpretation of the findings; Principle 2: Participation based on informed consent; Principle 3: Enabling participation; Principle 4: Avoidance of personal and social harm and Principle 5: Non disclosure of identity.

[1] Robson, C. (2011) Real World Research, third edition, pp.211, John Wiley & Sons Ltd, Chichester.

Ethics review process

You are likely to need to get ethics approval for an evaluation that involves contact with the health service. The ethics review flowchart can help you decide on necessary steps. Where NHS or social care ethics approval is required, further advice on the steps to follow is set out below. Meanwhile, continue to engage with partners and stakeholders to develop ideas about the evaluation while applying, because this will allow you to develop your proposal and actually see if people will play ball.

Applying for NHS ethics approval

If you are in one CCG area, check with your health partner whether they can set up data sharing protocols based around informed consent. Check if this is practically feasible in terms of CCG resources.

Then:

If you are getting a university to evaluate your project, get them to undertake the application.

Otherwise advice on applying can be found with the National Research Ethics Service (NRES), now part of Health Research Authority.

www.hra.nhs.uk/research-community/applying-for-approvals/

The Integrated Research Application System

The Integrated Research Application System (IRAS) needs to be used for obtaining ethical permission if you are working with NHS patients and/or in a NHS setting or wanting NHS data. It is a single online system for applying for permissions and approvals for health and social care/community research in the UK.

http://www.hra.nhs.uk/research-community/applying-for-approvals/#sthash.w3eYy7E7.dpuf

To use the system there is a free on-line module available

https://www.myresearchproject.org.uk/ELearning/index.html

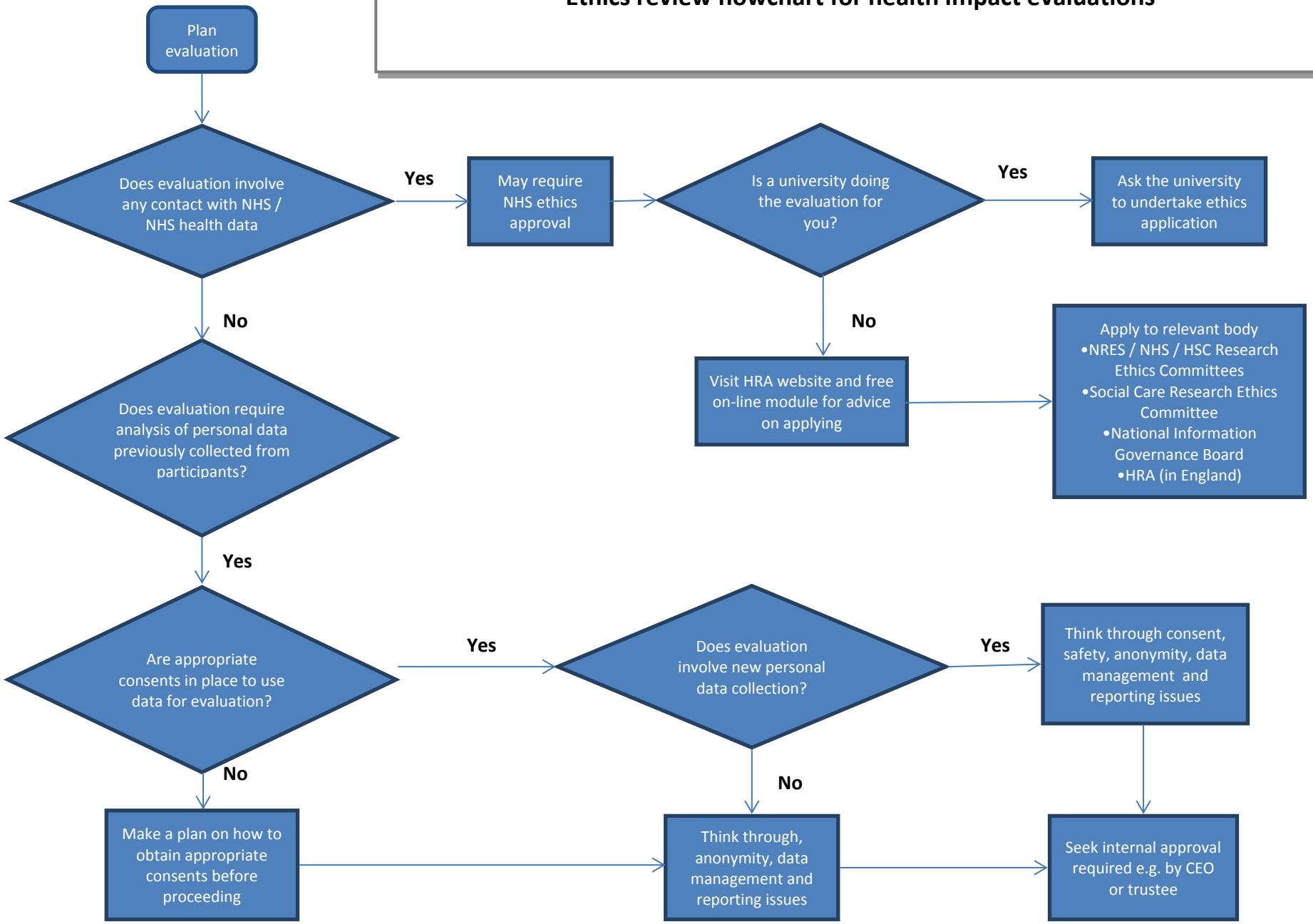
The three research governance bodies most pertinent to this area of work will be:

- NRES / NHS / HSC Research Ethics Committees
- Social Care Research Ethics Committee
- National Information Governance Board

For projects in England you can apply to HRA

www.hra.nhs.uk/resources/hra-approval-applicant-guidance/

Ethics review flowchart for health impact evaluations



Informed consent

Informed consent must be gained from participants in ethical research and evaluation. This includes the provision of clear participant information in written, verbal and/or pictorial form to participants and the provision of time for reflection and questions. When gaining consent from children, or vulnerable adults (with mental health problems or learning difficulties), arrangements must be made to ensure the relevant information is provided in a form which the participant can understand. ***Additional document 10, Booster Fund Questionnaires***, contains an example consent form. Homeless Link Ethics Toolkit includes a template consent form to receive consent from clients for use before seeking information from external bodies.

The Mental Capacity Act 2005 provides safeguards for people who lack capacity to provide consent; the researcher may be able to respect the person's previous wishes, or consult a carer who can take an independent view with consideration towards the person's interests, wishes and feelings. The Regulations under Section 60 of the Health and Social Care Act 2001 specify the very limited circumstances when identifiable patient information may be used for research without consent.

The NHS National Patient Safety Agency debates ethical procedures and publishes guidance on issues such as 'time to consent' and 'how Research Ethics Committees consider and decide about the inclusion or exclusion of participants in research who may have difficulties in adequate understanding of English?'

The Research Methods Knowledge Base includes general guidance on ethics, and background cases of the unethical human research which led to more stringent ethical guidance.

Data protection considerations

The Information Commissioner's Office has a guide to data protection.

The NHS has a general advice webpage on using confidential patient information. Under the Health Service (Control of Patient Information) Regulations 2002, confidential patient information may be processed *for medical purposes* without consent in certain circumstances, provided that the processing has been approved by the Health Research Authority through the Confidentiality Advisory Group (CAG). The NHS Act 2006 sets out the legislation the NHS must abide by in terms of working with local authorities and other partners, in addition to more general legislation.

The UK Data Archive has a Managing and Sharing Data best practice guide which includes information on the benefits of data sharing and the appropriate ways to arrange it. The guide provides advice on anonymising data for ethical purposes and the provision of access control.

The Research Ethics Guidebook includes a page on data storage and data security, which includes planning who will have access to the data and planning how they will access the data. This is in accordance the Data Protection Act 1998 which controls how personal information is stored and used. Files which contain personal or identifiable data must be either encrypted or password protected and only accessed by agreed members of the team; where data is anonymised it still needs to be held securely. In using shared computers and email, particular care needs to be taken.

Anonymisation

Guidance on anonymising data is provided by the UK Data Archive. Anonymising data ensures that individuals, organisations or businesses cannot be identified. A person's identity can be disclosed by either direct identifiers (names, addresses, postcodes, telephone numbers or pictures) or indirect identifiers (information on workplace, occupation or exceptional values of characteristics such as salary or age).

In quantitative data variables can be removed or aggregated to, again minimising the impact this has on the data analysis in terms of variable relationship analysis and where spatial references have value.

In qualitative data pseudonyms, replacement descriptors or vaguer terms can be used whilst ensuring the data is not distorted and the maximum content is maintained.

Homeless Link have produced an Ethics Toolkit which can assist evaluation staff with getting anonymization right.