

Research Governance Policy and Procedure

1st November 2011

DOCUMENT CONTROL

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1. Introduction

- 1.1 This policy, procedure and associated guidance on research governance affects all individuals (including any Council staff, any Council contractors, or any other individuals) who are undertaking, supporting or granting access for any research. This may also be applicable to consultation or non-financial audit activity which involves service users or staff, or information about them.
- 1.2 This policy is intended to:
- reflect best practice in research which involves users of Council services or information about them;
 - promote a quality research culture within Haringey Council; and
 - minimise risk to service users by aiming to forestall any research which is potentially unsafe or may generate unsound conclusions.
- 1.3 The principal driver for the original adoption of this formal policy in April 2008 was the development of the Department of Health's Research Governance Framework for Health and Social Care, commonly known as RGF. The RGF sets out standards for all research in health and social care, bringing together general principles of good practice which cover five main areas:¹
- ethics - safeguarding the dignity, rights, safety and well-being of participants as the primary consideration for all research studies;
 - science - checking that no unnecessary duplication takes place, and conducting appropriate independent review of all proposals by relevant experts;
 - information - ensuring free and comprehensive access to information on research in progress and on completed research findings;
 - health and safety - prioritising the health and safety of research participants, researchers and other staff at all times;
 - finance - ensuring financial probity, compliance with the law and with requirements for use of public funds.
- 1.4 The policy also reflects the Mental Capacity Act 2005 (which took effect on 1 October 2007), which includes substantial statutory requirements around research undertaken with people who lack capacity to consent². As the current version of the Department of Health's RGF was published before the Mental Capacity Act was passed, both documents need to be read alongside each other to understand the full requirements and expectations that now fall upon local authorities with social services responsibilities.

¹ Department of Health (2nd ed., 2005), 'Research Governance Framework for Health and Social Care', http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

² <http://www.legislation.gov.uk/ukpga/2005/9/contents>

- 1.5 This policy is not a replacement for Haringey Council's existing corporate requirements, procedures and guidance for public consultation activity³ and where applicable, must be read alongside the consultation toolkit.

2. Scope and definitions

- 2.1 The definition of research for this policy is:

An attempt to derive generalisable new knowledge, through addressing one or more clearly defined questions using specific method(s), which is not a routine part of providing a service to the individual(s) involved.

This can include consultation, other than routinely conducted service evaluation, and any non-financial audit that is not part of routine management practice.

- 2.2 This is based on the definition in the Department of Health's RGF⁴ and is intentionally broad. This is because activity that might be described as 'consultation', 'audit' and so on is not necessarily free from the risks associated with research, and it is not considered acceptable to be able to re-classify an activity specifically in order to avoid scrutiny of its methods or ethics.⁵

- 2.3 The policy applies to all research as defined above which involves studying any of the following:

(a) users of services provided or commissioned by Haringey Council and/or their carers, if they are accessed via or with the support of the service(s) in any way;

(b) any personal information held about individual users of services provided or commissioned by Haringey Council and/or their carers; or

(c) staff who work directly for the Council or indirectly for a contracted provider of services, in their professional capacity.

- 2.4 The current scope of the national RGF is research relating to the responsibilities of the Secretary of State for Health – that is the national health service and adult social care. Under the original RGF

³ Council staff can find the 'Consultation ToolKIT' in the 'Tools and Processes' section of Harinet.

⁴ DH, Research Governance Framework, p.3

⁵ Social Services Research Group (SSRG), Research Governance Framework Resource Pack 2nd edition April 2010, chapter 3 ssrg.org.uk/governance/files/rgf.pdf, p.67

proposals this would have included children's social care, which was the responsibility of the Secretary of State for Health until 1998 when it was moved to the Department for Education (DfE).⁶ Locally the extent of research governance can be wider than adult social care⁷ and some local authorities have extended their local RGF to include children's services or all Council services. In 2010 Haringey Council extended the scope of its RGF to include children's services. It is now extended again to cover all the Council's services, whether directly provided or commissioned.

3. Policy statement

- 3.1 Haringey Council is keen to promote evidence-based practice. The Council encourages research and research-related activity within services as a valuable tool for learning, user engagement and empowerment, and service improvement. However the Council also has a duty of care towards staff, service users and their carers.
- 3.2 Therefore all research and research-related activity which falls within the scope and definitions of this policy (see above) shall only commence when:
- sufficient information about the activity has been provided; and
 - Haringey Council is satisfied with the scientific, ethical, equalities and diversity and safety standards of the activity; and
 - written approval has duly been granted in accordance with the procedures set out in this document.
- 3.3 Where a piece of research or research-related activity is ongoing and repeated on a monthly or annual basis, written approval will only need to be obtained through these procedures on the first occasion, provided that no substantive changes are subsequently made to the activity.

4. Aims of this policy and procedure

- 4.1 Aims of this policy and procedure are:
- To promote **best practice** in research and research-related activity
 - To promote a **quality research culture** within Haringey Council.
 - To **avoid unacceptable risk**, including risk of:
 - harm (of whatever kind) to participants in the research, or the researchers;

⁶ In 2009 the DfE commissioned a review to look at the development of research governance in children's services. "Research Governance in Children's Services: the Scope for New Guidance" was published by the Department in 2010 after the election of a new government.

⁷ See Social Services Research Group (SSRG), Research Governance Framework Resource Pack 2nd edition April 2010, chapter 2 ssrg.org.uk/governance/files/rgf.pdf,

- generating unreliable or invalid results;
- going over the agreed budget;
- breaching data protection requirements.
- To **promote efficiency** and reduction of ‘consultation fatigue’, by avoiding duplication of research activity through central review and logging.
- To **improve dissemination** of current and future research findings.
- To contribute to genuinely **evidence-based policy**.
- To promote **equalities and diversity** (as almost by definition good research is inclusive research).
- To smooth compliance with **freedom of information and complaints requirements**, by ensuring relevant information about all research (including any problems and other information likely to be relevant to any complaint about the research) is readily available across the Council.
- To facilitate **greater political and public acceptance** where necessary for any research undertaken, by providing the opportunity to highlight the increased rigour brought about by the implementation of this policy.
- To **reduce any risk of litigation** relating to the findings of research projects.

5. Equalities and diversity

- 5.1 Equalities and diversity issues need to be taken into account by every one involved at each stage of the research process from design through approval to publication of findings. The equalities strands of Haringey Council’s Equal Opportunities Policy⁸; age, disability, gender reassignment, marriage and civil partnership, pregnancy maternity, race, religion or belief, sex (formerly gender), sexual orientation all need to be considered.
- 5.2 Particular care is needed on the part of researchers to ensure that research methods do not unintentionally discriminate. After taking any explicit sampling criteria into account, all reasonable steps should be taken to ensure that particular groups of people targeted in a study are not excluded from participation. For example, interpreters or translation services may be required for service users whose first language is not English or who normally communicate using BSL. Questionnaire design should be ‘disability friendly’ in design. Buildings chosen as venues for focus group work should be fully accessible to people with physical or sensory impairments. Advocates may be needed for people with mental health issues or learning difficulties.
- 5.3 All contracts for research must include specific mention of all equalities considerations especially the six key equalities strands.

⁸ Haringey Council Equal Opportunities Policy July 2007

- 5.4 All research needs to explicitly record what specific equalities groups said when they were consulted.
- 5.5 The composition of the Approval Panel should be reflective of diversity.
- 5.6 Overview and monitoring of research activity in equalities terms should be done at all stages of the process including:
- research design
 - equalities monitoring of researchers, research subjects and research
 - approvers
 - analysis and evaluation of completed research findings
 - identification of gaps in knowledge of particular equalities groups
 - the possibility of commissioning research to fill the knowledge gaps

6. Responsibilities of all staff

- 6.1 Staff retain the responsibility for the care of their service users while they are participating in research activity.⁹
- 6.2 Before allowing any researcher(s) to approach their service users or carers, staff (whether employed directly by Haringey Council or indirectly through a contractor) should satisfy themselves that the researcher(s) have the appropriate written approval from Haringey Council to do so. If in doubt, staff can ask the researcher(s) to show their proof of approval.
- 6.3 If any staff member becomes aware that a service user who is participating in any research study and who lacks capacity to provide or withdraw consent appears to wish to be withdrawn from the study (for example if they appear upset or distressed), they should inform the researcher(s) at the first available opportunity. The researcher(s) must then end the participation of that service user immediately. Staff should contact the Policy, Equalities and Partnership Team if they have any further concerns.

7. Procedure for researchers, part 1: Prior to submitting an application

- 7.1 The **Mental Capacity Act 2005** (sections 30-34) requires any research involving people who lack capacity to make their own decisions to be

⁹ DH, Research Governance Framework, p.41

approved by an “appropriate body”, it cannot be approved by a local authority or a university Research Ethics Committee. The Appropriate Body is an established ethics committee recognised as such by the Secretary of State for Health. In England this is the Social Care Research Ethics Committee (SCREC) based at the Social Care Institute for Excellence (SCIE). Therefore any proposals for research involving people who lack capacity (as defined by section 2 of the Act¹⁰) must first obtain approval from SCREC before they can be considered by Haringey Council. Proof of this approval must be submitted with the application to the Council.

7.2 Procedures for social care developed under the Research Governance Framework do not replace the existing standards on **multi-site research in social care**:

- research involving four or more different adult social care departments should first be approved by the Association of Directors of Adult Social Services (ADASS) Research Group.¹¹
- research involving four or more different children’s services departments should first be approved by the Association of Directors of Children’s Services (ADCS) Research Group.¹²

Proof of this approval must therefore be enclosed with applications for approval for any project which will involve four or more adult of children’s social care departments.¹³

7.3 If your research study will also require access through any **NHS organisation**, it is highly likely that that organisation will require you to apply for approval through their own research governance procedures. Research governance is much more established and resourced in the NHS than in social care, so any approval granted by Haringey Council will not generally have any effect on the need for NHS approval; however NHS approval may well simplify and/or shorten the process of approval by Haringey Council. In these cases researchers are therefore strongly advised to submit an application to the relevant NHS organisation(s) first before contacting Haringey Council.

7.4 The RGF is clear that “the decision whether or not to give permission for research in a care organisation rests with that organisation”.¹⁴ Therefore obtaining external approval in one of the ways detailed above is always in addition to, rather than instead of, the need for approval to be granted by Haringey Council.

7.5 It is a core requirement of the Research Governance Framework that all **external** research projects must have a **sponsor**. The sponsor is the organisation, or individual employee(s) of that organisation acting

¹⁰ Available at http://www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_2#pt1-pb2-l1g2

¹¹ SSRG, ‘Research Governance Framework Resource Pack’ April 2010, p.20

¹² ADCS Research Group <http://www.adcs.org.uk/research/research-guidelines.html>

¹³ Information on how to apply for this approval can be found at <http://www.adass.org.uk/>

¹⁴ DH, Research Governance Framework, p.42

with appropriate authority, which agrees to take on responsibility for confirming that there are proper arrangements in place to initiate, manage, monitor and finance the study.¹⁵ The sponsor is most likely to be either the researcher's employer or the main funder of the study. Confirmation of the sponsor's details must be provided on the External Research Study Proposal Form. If these details are absent or inappropriate Haringey Council cannot give approval for the study. For research projects by Middlesex University students, the University will be taken to be the sponsor.

- 7.6 All external researchers who are requesting one-on-one contact with vulnerable service users must be able to prove that they each hold current clearance from the **Criminal Records Bureau (CRB)** before Haringey Council will be able to give approval.
- 7.7 All researchers must ensure that they comply with the **Data Protection Act 1998** and the **Freedom of Information Act 2000**. Outline information on the key requirements of each is set out in appendix A to this document.

8. Procedure for researchers, part 2: Submitting an application

- 8.1 All would-be researchers need to submit a form outlining their proposal. Requirements vary as follows.
- 8.2 **Students at Middlesex University** undertaking their research projects within Haringey Council services should submit the University's "Application for Research Ethics Approval" form to the University as the University has advised them. They should complete the Haringey RGF application form and submit it to the Haringey Council RGF Panel with a copy of the letter from Middlesex University Ethics Committee confirming they have given their approval to the proposed research.
- 8.3 **Researchers who have already submitted an application form to an NHS organisation or to another local authority** may choose, in the first instance, to submit a copy of the same form to Haringey Council. The Council will aim to avoid unnecessary extra bureaucracy in these cases, but reserves the right to ask the researcher(s) for additional information if any questions from the Council's own form are not satisfactorily covered on the other organisation's form. If the additional information required is substantial, researchers may be asked to complete Haringey Council's form. Waiting for receipt of this further information may cause a delay in approval. In these circumstances researchers therefore always have the option of

¹⁵ Researchers and potential sponsors are strongly advised refer to pages 34-37 of the DH's Research Governance Framework where a more detailed description of the sponsor's responsibilities is provided.

completing and submitting Haringey Council's own RGF application form if they think their existing documentation / forms do not cover the information required by Haringey. .

- 8.4 Which ever forms students, researchers or staff are submitting you must ensure that it includes the following:
- a copy of your questions or questionnaire
 - the participant information sheet
 - the consent form for participants
 - if you have already had approval from a Research Ethics Committee, a copy of their letter of approval
 - if you are proposing to interview staff a letter from the relevant head of service saying they agree to their staff being involved
- 8.5 Haringey Council recognises that the external application process may be found something of a burden by less well resourced researchers, particularly from small voluntary and community sector organisations. Given that the Council does wish to encourage research, particularly where it will enhance knowledge on equalities and diversity researchers facing resource limitations may contact the Policy, Equalities and Partnership Team for a discussion if they are having particular difficulties with any aspect of the application process.
- 8.6 For internal applications the lead researcher should ensure they have permission from the Head of Service to carry out the research before submitting their application for research governance approval.

9. The approval process

- 9.1 Upon receipt of the completed form, the applicant will be sent an e-mail acknowledging receipt, and confirming the indicative timescale for a decision to be reached. In normal circumstances this will be **within 30 days**.
- 9.2 Clearly, not all proposed research projects will pose the same levels of risk. With some proposals it is likely to be clear after relatively brief consideration that there is minimal or no risk to participants, while with other projects there may be an initial reason for some concern which would warrant more detailed scrutiny and deliberation before giving approval.
- 9.3 Haringey Council has limited resources for research governance, and so it is important for time and resources to be focused upon the proposals which may potentially present the highest risk. The level of scrutiny applied will be based on an initial assessment of potential risk.

- 9.4 The initial assessment will be undertaken by the Policy, Equalities and Partnership Team, or a nominated representative from the Council's Research Governance Panel, on the level of risk to be assigned to each application.
- If the project is initially assessed as **level 1** the proposal will be sent to the core members of the Research Governance Panel for review and the decision for approval. Where possible this should include a senior manager with responsibility for the client group(s) who would be involved in the research project. After reviewing a proposal the members selected may agree a decision or choose to escalate the decision to the full panel. The RGF Panel may choose to make decisions on these proposals via e-mail correspondence, or hold face-to-face panel meetings as needed to make their decision.
 - If the project is initially assessed as **level 2**, the proposal will be escalated to the full RGF Panel for review and the decision for approval. The decision will be made by majority view and if necessary, the chair will make the final decision. The full panel will meet quarterly. Full application documentation should be submitted 1 month before the full RGF Panel meeting.
- 9.7 After the proposal has been reviewed, the applicant will be sent an e-mail (if internal) advising them that either:
- the proposal has been approved;
 - the proposal has been rejected outright;
 - the proposal should be re-submitted with major amendments; or
 - the proposal should be re-submitted with minor amendments.
- If amendments are required, recommendations on what is sought will be included.
- 9.8 If only minor amendments are required, approval will normally be granted on receipt of satisfactory amendments using the level 1 approval process. If major amendments are required, the re-submitted application may be put back through the same level of the approval process as when initially submitted.
- 9.9 Haringey Council may **share information** on research applications, and/or enter correspondence or dialogue regarding their merits, with other organisations such as local NHS trusts or other local authorities at any time. This decision would be based on the stated or implied scope of the research, in order to facilitate the best possible decision-making process and/or a reduced overall administrative burden.
- 9.10 There is no **automatic right of appeal** against decisions made through this procedure.

10. The Research Governance Panel

- 10.1 The Council has a Research Governance Panel to carry out both scientific and ethical review of research proposals. The membership of the panel shall be managed by the Head of Policy, Equalities and Partnership. Panel members may include representatives of partner organisations, and/or service users or carers, as well as Council staff. All panel members should have a commitment to mainstreaming equalities and diversity issues and should additionally:
- have experience of quality research involving potentially vulnerable populations; or
 - have experience of considering ethical questions; or
 - have experience of data protection issues; or
 - possess qualifications to at least first degree level which include a significant research element; or
 - be 'expert by experience' of potential issues through using the services themselves.
- The criteria are set out in the Research Governance Panel's terms of reference.
- 10.2 The Research Governance Panel may make its decisions on medium-risk and high-risk proposals by e-mail correspondence, or its members may decide to hold face-to-face panel meetings on a scheduled basis or as needed, at which decisions can be made.

11. Criteria for review and risk assessment

- 11.1 If a project has failed to meet any of the prerequisites for consideration to be given to approval (as set out in sections 7 and 8 above), it will be immediately rejected.
- 11.2 Otherwise, all projects will be assessed using the [risk assessment tool](#) which is available to download for information in the Research Governance section of the Council's website. In summary, the criteria that risk will be assessed against are:
- Risk to participants (informed consent and ability to withdraw)
 - Researcher competence (experience and knowledge of topic)
 - Nature of information being sought (how personal/sensitive etc)
 - Appropriateness of methodology
 - Methods of data collection (level of face-to-face contact etc)
 - Level of privacy to participant (anonymity and/or confidentiality)
 - Relationship between researcher and participants (potential conflicts of interest)
 - Personally identifiable research data (controls on access)
 - Storage (security of data)
 - External considerations (sensitivity of study)

- 11.3 Equalities and diversity is a key element of Haringey Council's response to the needs and requirements of all residents, employees and partners. This applies equally to all research and research-related activity within the services the Council provides and commissions. All would-be researchers should be familiar with the Council's Equal Opportunities Policy Statement¹⁶. In addition to the requirements of the RGF, Haringey Council therefore expects that equality of opportunity will be ensured amongst the group(s) being studied in all research projects, and believes that all good quality research projects will suitably reflect the diversity of the borough. This will be used as an additional criterion by Haringey Council in assessing whether to grant approval for research applications covered by this policy. Research projects which promote equalities or add to the knowledge base on under-researched areas of need from an equalities and diversity perspective are particularly welcome.
- 11.4 If a research proposal has already received an independent review by another appropriate organisation, the Research Governance Framework advises that a local authority should not normally withhold approval unless there are local factors that would lead to an unacceptable impact. In these cases therefore a project will normally receive an initial assessment of low risk, allowing approval forthwith, subject to a review of its possible impact on the service, service users or staff to be studied, although the provision in paragraph 6.3 above still applies.

12. Collation of information on research projects

- 12.1 Haringey Council has duties under the RGF to ensure that there is "free access to information both on research being conducted and on the findings of research"¹⁷, and "to be aware of all research undertaken in... [the] organisation or involving participants... obtained through the organisation."¹⁸ To ensure this can be achieved in an efficient and timely manner, all information is centrally co-ordinated by the Policy, Equalities and Partnership Team.
- 12.2 A key element of this is entry by the Policy Equalities & Partnership team of details of all research projects related to social care and approved through this policy onto the **Research Register for Social Care** (<http://www.researchregister.org.uk>). This is a nationwide resource developed by the Social Care Institute for Excellence (SCIE) and freely accessible. Copies of entries are retained locally, together

¹⁶ Haringey Council, 'Equal Opportunities Policy Statement', www.haringey.gov.uk/index/council/how_the_council_works/equalities/equaloppssstatement.htm

¹⁷ DH, Research Governance Framework, p.14

¹⁸ ¹⁷ DH, Research Governance Framework, p.38

with tracking details on the status of applications and any more detailed information on the progress of projects.

- 12.3 Staff or any other individuals who **require information** on social care research projects in Haringey started since April 2008 are encouraged in the first instance to refer directly to the Research Register for Social Care, running a search for 'Haringey'. If further help or information is required the Policy, Equalities and Partnership Team should be contacted.

13. Procedure for researchers, part 3: After approval

- 13.1 Approval that has been given to any research project only applies to the scope and methods for the research that were set out in the application when approved. Under the RGF, researchers have a responsibility to submit **substantive changes** for approval.¹⁹ Therefore, any proposed substantive changes to the research to be conducted must be notified to the Head of the Policy, Equalities and Partnership Team which shall have the discretion to refer these changes through the approval process if they deem it necessary. The researcher(s) may not put the proposed changes into effect until they have received written clearance to do so.
- 13.2 Haringey Council will expect all normal principles of good practice to be adhered to during the conduct of research studies. However, researchers should be particularly aware that the Mental Capacity Act 2005 lays down **statutory requirements regarding consultees on research with people who lack capacity to consent**. For each person who lacks capacity, a person must be identified who can act as a consultee. The consultee will be asked to advise the researcher(s) on whether the person who lacks capacity would want to take part in the research study. Full details are given in chapter 11 of the Mental Capacity Act Code of Practice 2007.²⁰ The outline process is as follows:
- If possible the researcher(s) must find a 'personal consultee' who is involved in the person's care, interested in their welfare and willing to help, but not someone who is paid to care or has a professional relationship. Typically this would be a family member, a friend or an unpaid non-professional who holds power of attorney. The selection of a consultee must be informed by any wishes or feelings the person lacking capacity has previously expressed about who they would or would not like to be involved in future decisions.

¹⁹ DH, Research Governance Framework, p.32

²⁰ DCA, [Mental Capacity Act Code of Practice](#), 2007 Chapter 11.

- If no personal consultee is available, a consultee must be nominated who has no connection with the study²¹ and is willing to be consulted about the participation in the study of the person lacking capacity. Head of the Policy, Equalities and Partnership Team or a nominated principal policy officer shall liaise with an appropriate manager (e.g. the manager of the service which is providing the care to the person lacking capacity) to nominate a consultee. A 'nominated consultee' may be a paid carer or someone with a professional relationship. The nominated consultee will perform the same role as a personal consultee. They may consult any family members, friends or carers who were unwilling or unable to act as the consultee themselves, or any professional colleagues with an interest in the person who lacks capacity. They should disregard their own views on the study and consider only the views and feelings of the person who lacks capacity.
- Each personal or nominated consultee should be provided with similar information to that which would ordinarily be given to a person with capacity who was being asked to consent to take part in a research study.

If the consultee advises that the person would not have wanted to take part if they had the capacity to consent, or could be unhappy about the study, the researcher(s) must abide by this.

- 13.3 In addition, a person who lacks capacity to consent must be immediately withdrawn from participation in a research study if they indicate in any way that they want to withdraw, e.g. if they become upset or distressed.
- 13.4 Any **adverse occurrence** in any research project must be reported immediately by the researcher(s) to the Head of Policy, Equalities and Partnership. The Policy, Equalities and Partnership Team shall ensure that it is recorded alongside other internally held information on the project concerned.²²
- 13.5 In keeping with the standard in the RGF on information, all researchers are expected to make **a copy of their findings** available to Haringey Council, once they have been through any internal review. Minor alterations may be made if necessary to protect the confidentiality of participants in the study, and Haringey Council accepts in advance that research findings may contain evaluation and/or criticism of its

²¹ If in any doubt, refer to the detailed definition in Department of Health (February 2008), '[Guidance on nominating a consultee for research involving adults who lack capacity to consent](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131)', at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131

²² Department of Health [Research governance framework for health and social care: implementation plan for social care](#) 14 May 2004

services. Research will be entered on the national **Research Register for Social Care** (<http://www.researchregister.org.uk>)

14. Review

- 14.1 This policy will be **reviewed annually**, or sooner if new legislation, codes of practice or national standards are introduced.
- 14.2 This review process will aim to meet the expectation contained in the RGF that the Council should be able to identify and learn from failures associated with any research undertaken through or within the organisation.²³

15. Further reading

- 15.1 Researchers without strong recent experience should read some of the following, to ensure they are freshly familiarised with the ethical implications of research activity in social care:
- Leathard A. & McLaren S. (eds.) (2007), *Ethics: Contemporary Challenges in Health and Social Care*, Bristol: Policy Press
 - McLaughlin H. (2006), *Understanding Social Work Research*, London: Sage
 - Adams R., Dominelli L. & Payne M. (eds.) (2005), *Social Work Futures: Crossing Boundaries, Transforming Practice*, Basingstoke: Palgrave Macmillan.
- 15.2 The websites of RIPFA and RIP contain an extensive set of links to online resources relating to research with vulnerable users of social care. Ripfa ([Research in Practice for Adults](#)) promotes the use of evidence-informed policy and practice in adult health and social care and RIP ([Research in Practice](#)) provides a similar service in relation to children. See <http://www.ripfa.org.uk/> or <http://www.rip.org.uk/>

²³ DH Research Governance Framework page 40

Appendices

Appendix A: Data Protection Act 1998, Freedom of Information Act 2000 and Caldicott guidance²⁴

Everyone involved in implementing research governance and carrying out research needs to be aware of their responsibilities under the following:

- Data Protection Act 1998
- Freedom of Information Act 2000
- Caldicott Principles

Data Protection Act 1998

The purpose of the Data Protection Act (DPA) is to protect the rights of individuals by ensuring the ways in which data is obtained, stored, processed, shared by others and so on is strictly governed. The DPA relates to personal data or information held by organisations about individuals. Failure to comply could result in prosecution.

Under the Act, individuals have a right:

- to see any information held about them;
- to challenge organisations if appropriate;
- to have inaccurate information changed or deleted; and
- to claim compensation if appropriate.

The 1998 Act includes 'all structured data in relevant filing systems'. This includes both electronic and manual files. A relevant filing system may be structured either by reference to individuals or by reference to criteria relating to individuals. It includes manual records e.g. structured files in filing cabinets containing personal data.

Personal data includes anything that can help identify a living individual, for example their name, address, car registration, National Insurance number, etc. Although the DPA doesn't apply to the records of deceased individuals, it should be noted that the Caldicott Guidelines suggest that the same level of respect for confidentiality should be afforded to the records of those who are deceased as is given to those who are living. Personal data will therefore be considered to apply to data or information from which any individual can be identified.

Sensitive personal data includes information concerning racial/ethnic origin, political or religious beliefs, trade union membership, physical or mental health, details of sexual orientation, criminal record etc. In this case, the data subject must give their explicit consent (informed and written consent) before data can be processed. If consent cannot be given, and no legal guardian or

²⁴ Based upon SSRG, 'Research Governance Framework Resource Pack', chapter 8

advocate is able to give written consent on behalf of the data subject, processing must only take place where necessary and justifiable.

What are the Data Protection Key Principles?

- 1) Personal data must be processed fairly and lawfully. Data can only be processed if one of the following conditions applies:
 - (i) The individual about whom the data has been collected has given informed consent i.e. they clearly understand the purpose for which the data is being collected and how it will be stored.
 - (ii) It is necessary for -
 - performance or contract;
 - compliance with legal obligation;
 - protection of a person's vital interests, i.e. their life;
 - administration of justice;
 - crown/public functions; or
 - legitimate interests of a data controller/third party.
- 2) Personal data must only be used for the stated purpose and should not be used in any other way without explicit consent from the data subject.
- 3) Personal data shall be adequate, relevant and not excessive.
- 4) Personal data shall be accurate and where necessary, kept up to date.
- 5) Personal data processed for any purpose or purposes shall not be kept for longer than is necessary.
- 6) Personal data shall be processed in accordance with the rights of data subjects (stated above).
- 7) Security measures shall be taken to prevent unauthorised or unlawful processing of personal data and to protect against accidental loss or destruction or damage to personal data.
- 8) Personal data shall not be transferred to a country or territory outside the European economic area, unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

The Act also covers any personal data that is obtained from, or used for the Internet/Intranet including digitised images on web pages, photographs, e-mail addresses, personal images recorded on CCTV, and so on.

Freedom of Information Act 2000

The Freedom of Information Act (FoIA) gives a general right of access to all types of recorded information held by public authorities, including the NHS and local authorities. Exemptions from that right are specified within the Act (for example, information relating to personal data, law enforcement, national security, etc). The Act is fully retrospective and came into effect on 1 January 2005.

Access to personal and patient information is still governed by the Data Protection Act 1998. The Freedom of Information Act gives right of access to non-personal information and amends the DPA to cover all personal information.

Part VII (Amendments of Data Protection Act 1998) covers amendments relating to personal information held by public authorities, including:

- Extension of meaning of 'data'.
- Right of access to unstructured personal data held by public authorities.
- Exemptions applicable to certain manual data held by public authorities.
- Particulars registrable under Part III of the Data Protection Act 1998.

Both the Freedom of Information Act and the Data Protection Act are administered by the Information Commissioner.

Caldicott Principles

The Caldicott Review of Patient-Identifiable Information (1997) developed six principles governing the uses made of confidential patient information within NHS settings.²⁵ The Caldicott principles were subsequently adopted by local authorities.

Principle 1 --- Justify the purpose(s)

Every proposed use or transfer of personally identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate Guardian.

Principle 2 --- Do not use personally identifiable information unless it is absolutely necessary

Personally identifiable information items should not be used unless there is no alternative.

Principle 3 --- Use the minimum necessary personally identifiable information

Where use of personal identifiable information is considered to be essential, each individual item of information should be justified with the aim of minimising the need to identify individuals.

Principle 4 --- Access to personally identifiable information should be on a strict need-to-know basis

Only those individuals who need access to personally identifiable information should have access to it, and they should only have access to the information items they need to see.

Principle 5 --- Everyone should be aware of their responsibilities

Actions should be taken to ensure that those handling personally identifiable information --- both practitioner and non-practitioner staff --- are aware of their responsibilities and obligations to respect an individual's confidentiality.

Principle 6 --- Understand and comply with the law

Every use of personally identifiable information must be lawful. Someone in each organisation should be responsible for ensuring that the organisation complies with legal requirements.

²⁵ Department of Health (December 1997), [The Caldicott Committee, 'Report on the Review of Patient-Identifiable Information'](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403), http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403

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