UK policy framework for health and social care research

Issued for comment

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Introduction and background

Principles

1. Purpose

1.1. The HRA and the UK Health Departments are committed to an environment where:

- care users and the public are given, and take, the opportunity to participate in health and social care research, and continue to feel safe when they do;
- applying to do research is simple and getting a decision is quick and predictable;
- researchers find it easy to do high-quality, ethical research;
- commissioners and providers of health and social care appreciate how health and social care research benefits care users and staff;
- industry sees the UK as a great place to do health research;
- money from charities and other research funders goes into carrying out research, not into getting through unnecessary hoops before it starts; and

- research projects get registered, the data and tissue they collect can be made available, where appropriate and with safeguards, for future analysis and research findings get published and also summarised for those who took part in them.

1.2. Research is a core function of health and social care. It is essential for our health and well-being and for the care we receive. Research improves the evidence base, removes uncertainties and can lead to improvements in future care, and the quality of current care provided by organisations that take part in research may be higher. Improved care can give people a better quality of life and the country benefits from more money and jobs if the UK environment for research attracts international research funders to invest in this country and carry out their research here. Research involves staff in our universities, hospitals and social services in something that develops their skills. It also involves care users and the public in something that may benefit them and people like them, not only by their participation in research but also through their involvement in the design and conduct of research, or as members of research approval bodies such as research ethics committees.

1.3. The UK policy framework for health and social care research sets out policy and standards for the ethical conduct and proportionate, assurance-based management of research in health and social care, so as to support and facilitate high-quality research in the UK that commands the confidence of care users[1] and the public.

1.4. With due regard to relevant UK and EU legislation, this policy framework sets out high-level principles, requirements and standards, which will be implemented through operational frameworks provided by the Health Research Authority (HRA) and the Devolved Administrations. This will achieve compatibility across the UK for the ethics, conduct and management of research in health and social care[2].

2. Scope

2.1. This policy framework applies to research projects involving providers of care that are within the legislative and policy responsibility of any of the four UK Health Departments (see appendix). This applies to research that care users take part in, either directly (e.g. research involving a treatment or an interview) or indirectly (e.g. research involving previously collected data or tissue that could identify the individual). It also includes research involving the providers' employees or partners, either as research participants or as researchers. Relevant providers include hospitals that are part of the NHS[3], independent contractors to the NHS (such as GPs), local authorities and private or voluntary organisations that provide health or social care under contract with the NHS or with local authorities.

[1] This document uses the term 'case user' to mean a recipient of health care, social care or other services provided by health or social care organisations.
[2] Although this document is relevant to all health and social care research, its legal remit does not generally encompass children's social care research in England or Scotland.
[3] References to the NHS include Health and Social Care (HSC) in Northern Ireland.

2.2. For the purpose of this policy framework, research is defined as the attempt to derive generalisable and/or transferrable[4] new knowledge by addressing clearly defined questions with systematic, rigorous and repeatable methods[5]. This excludes audits of practice, service evaluations[6] and market research. It includes activities that are carried out before and after any change to care that gets made for the purpose of the research (i.e. the interventional part of the research), such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes projects that aim to generate hypotheses (e.g. pilot studies)and projects whose primary purpose is educational to the researcher, either in acquiring research skills or in obtaining an educational qualification. Projects that are not research according to this definition should not be presented within health and social care providers as research and should not be conducted or managed in accordance with this framework.

2.3. The involvement of care users or the public in the design, management or conduct of research may be subject to local controls but does not require approval in accordance with this framework (e.g. from a research ethics committee), even if the research itself does.

2.4. This document is not intended exhaustively to compile or replace all the principles, requirements and standards published by individual bodies with an interest in research. It remains the responsibility of those to whom relevant legal requirements and professional standards apply to ensure that they also satisfy those requirements and standards.

3. Implementation

3.1. This high-level policy framework is implemented through national operational policies, standard operating procedures and operational platforms. Individuals and organisations with responsibilities under this policy framework should not design their own process for implementing the principles it sets out. The recognised operational provisions which implement this framework include:

- resources for researchers and sponsors – www.hra.nhs.uk/resources
- requirements for research ethics committee review and guidance and policy for research ethics committees – www.hra.nhs.uk/research-ethics-committee-members/guidance-on-ethical-review-for-members
- information for care users and the public – www.hra.nhs.uk/patients-and-the-public
- systems for applying for and managing research approvals – the Integrated Research Application System (IRAS) at www.myresearchproject.org.uk and the HRA Assessment and Review Portal (HARP)

[4] NB This definition involves an *attempt* at generalisability and/or transferability. The actual generalisability and/or transferability of some research findings may only be established once the project has been completed.
[5] Research which lacks these characteristics because of its poor quality is not excepted from this policy framework.
[6] Unless carrying out the same exercise elsewhere would predictably (rather than coincidentally) produce the same findings and those findings increase the evidence base.

3.2. These operational provisions support people with responsibilities for the ethics, conduct and management of research to comply with this policy framework. They also encourage the pursuit of high-quality research that:

- involves care users and the public appropriately;
- meets their needs;
- accesses participants and information quickly and efficiently;
- ensures safety and confidentiality; and
- produces findings that improve the evidence base and may lead to better health and well-being.

4. UK-wide responsibilities

4.1. The policy framework references and interprets, as required, the relevant legislation in the EU and UK and sets out the application of this legislation in each country. The policy framework is consistent with recognised ethical standards and with models of good practice as they apply to particular types of research involving human participants[7]. The policy framework takes care to interpret these, recognising the need for different, proportionate and appropriate application in particular study types.

4.2. In accordance with the Care Act 2014 and with the agreement of the Devolved Administrations[8], this policy framework replaces the Research Governance Frameworks previously issued in each of the four UK countries:

- England: www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf
- Wales: wales.gov.uk/docs/dhss/publications/governance/090929researchen.pdf
- Scotland: www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf
- Northern Ireland: www.dhsspsni.gov.uk/research_governance_framework.pdf

4.3. Although responsibilities for health and social care have been devolved to the administrations in Wales, Scotland and Northern Ireland, the four UK Health Departments[9] are committed to maintaining compatible standards for research ethics, conduct and management across the UK. Otherwise, cross-border research could be undermined by a need to comply with incompatible requirements between England, Wales, Scotland and

[7] References to participants include people who could be identified by the data or tissue involved in a research project.
[8] The Devolved Administrations are the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety in Northern Ireland.
[9] The four UK Health Departments are the Department of Health, the Department for Health and Social Services (Wales), the Scottish Government Health Directorates and the Department of Health, Social Service and Public Safety (Northern Ireland).

Northern Ireland. With the agreement of the Devolved Administrations and the UK Ethics Committee Authority[10], the HRA may publish policy and operational frameworks that are UK-wide. Except where otherwise stated, these UK-wide frameworks, including this document, apply to all research in health and social care[11]. While ensuring UK-wide compatibility, the frameworks take into account where legal and operational differences do exist (see appendix for details).

5. Development, status and maintenance

5.1. This policy framework has been developed with the full support of the four UK Health Departments, who were represented on the steering group chaired by the HRA that oversaw its development.

5.2. In accordance with Section 111(6) and (7) of the Care Act 2014, the status of this document is guidance with which NHS trusts and local authorities in England are legally expected to comply. Compliance with this guidance by them and other health and social care providers (such as independent contractors in primary care and private and voluntary organisations providing services under contract) also helps bodies that commission care to fulfil their legal duty under the Health and Social Care Act 2012 to promote the conduct of research. This guidance also applies to research involving relevant care providers in Wales, Scotland and Northern Ireland, by agreement with the Devolved Administrations. In addition, bodies that hold a contract with the National Institute for Health Research (NIHR) are required to comply with this guidance as a condition of contract.

5.3. By agreement with the Devolved Administrations and in accordance with the Care Act 2014, the HRA is responsible for maintaining this document.

6. Audience

6.1. This document is aimed primarily at those with responsibilities for the conduct and management of research, to help them fulfil their duties to care users and the public. Executive summaries for different audiences, including for care users and the public, will be available on the HRA website.

7. Principles that apply to all health and social care research

7.1. The rights, safety and well-being of the research participant prevail over the interests of science and society.

7.2. All the people involved in conducting a research project must be qualified by education, training and experience to perform their tasks.

7.3. Research projects must be scientifically sound and guided by ethical principles in all their aspects.

[10] Under the Medicines for Human Use (Clinical Trials) Regulations 2004, UKECA is the body that establishes, recognises and monitors research ethics committees and approves their operating procedures. UKECA's members are the HRA and the Devolved Administrations.

[11] Apart from research that is wholly in children's social care in England or Scotland, which are outside the remit of the HRA and the Scottish Government Health Directorates.

7.4. Care users and the public should be involved, where appropriate, in the design, management and conduct of research.

7.5. Research must be designed, reviewed, managed, undertaken and made public in a way that ensures integrity, quality and transparency.

7.6. The design and performance of the research project must be clearly described and justified in a research proposal or protocol[12], conforming to a standard template where applicable. The research proposal or protocol must include any specified information.

7.7. The researchers and sponsor should consider relevant guidance with respect to commencing and conducting the research project.

7.8. Before the research project is started, foreseeable risks and inconveniences must be weighed against the anticipated benefit for the individual research participant and other present and future recipients of the health or social care in question. A research project should be started and continued only if the anticipated benefits justify the risks.

7.9. A research project may be started only if a research ethics committee and any other relevant statutory approval body have favourably reviewed the research proposal or protocol, where their review is required.

7.10. Information about research projects must be made publicly available, normally before they start, and their findings must be made accessible after they have finished.

7.11. The arrangements for involving research participants either directly or indirectly must respect and, through provision of appropriate information, support their autonomy, choice, privacy and understanding of the distinction between the research and the standard practice which they could expect to experience if they did not take part in the research. Where research participants' explicit consent is required, it must be voluntary and appropriately informed.

7.12. The rights of all research participants to physical and mental integrity, to privacy and to the protection of the data concerning them in accordance with the law must be safeguarded.

7.13. Provision must be made for insurance or indemnity to cover any liability which may arise in relation to the design, management or conduct of the research project.

7.14. All information collected for or as part of the research project must be recorded, handled and, as appropriate, stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of individual care users remains appropriately protected.

7.15. Non-compliance with the principles or requirements set out in this policy framework may be subject to administrative measures available to research ethics committees or the HRA. These measures must be proportionate and effective in the circumstances and give appropriate consideration to actions that are also available to others such as the research

[12] The terms 'research proposal' and 'protocol' are meant interchangeably.

funder, the researchers' employers, the police and the relevant professional and statutory regulators.

Principles that apply to interventional health and social care research

7.16. The following principles apply in addition to the principles above:

a. The available information about the intended deviation from normal treatment or care must adequately support the proposed research.

b. The research proposal or protocol must explain any appropriate arrangements for ongoing provisions after the research intervention period.

c. All information about treatment or care provided as part of the research project and their outcomes must be recorded, handled and, as appropriate, stored in such a way that it can be understood by others involved in the research participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the research participants remains protected.

d. The duty of care owed to all care users continues to apply when they take part in research. An appropriately qualified health or social care professional[13] must retain responsibility for the treatment or care given to research participants and for decisions about treatment or care made on their behalf.

e. Information about the findings of the research should be provided to those who took part in it.

8. Principles that apply to individuals and organisations

8.1. There should be clear designation of responsibility and accountability with clear lines of communication between all those involved in research. Communication pathways should be clear in terms of what, how, who, when and why, with documented roles and responsibilities. Collaboration has a central role within a research project. Clear, upfront agreement of principles and procedures for each project are essential to the effective conduct and success of a study, as well as mitigating some risks.

Chief investigators

8.2. The chief investigator is the overall lead researcher for a research project. Chief investigators have overall responsibility for:

a. the design, registration and conduct of a research project;

b. developing proposals that are scientifically sound and ethical;

c. submitting the design for independent expert review;

[13] Who may or (particularly where the research team is not local to the research site) may not be a member of the research team.

d. submitting the proposal for review, if required, by a research ethics committee and any other relevant approval bodies;

e. ensuring that they and the research team they lead are qualified by education, training and experience to discharge their roles in the study;

f. preparing information for participants;

g. arranging to make information about the study available, normally before it starts, and to make findings, data and tissue accessible as appropriate after it has finished; and

h. providing information about the findings of the research to participants.

8.3. Students should not normally[14] take the role of chief investigator at any level of study.

8.4. Research has to be conducted in accordance with a research proposal or protocol – a document that describes clearly what will be done in the research. This is important so that the researchers can all understand consistently what they are supposed to do and so that the research can be properly analysed and, where appropriate, reproduced. Public involvement plays an important role in study design and planning and can help reduce delays in approvals. Well-planned and well-written research proposals, protocols and procedures are key to carrying out research successfully. They help avoid the need for subsequent amendments, which are time-consuming and costly for the funder, the researchers and the approval bodies. However, high-quality research proposals, protocols and procedures are only effective if they are followed. Not adhering to the research proposal or protocol has the potential for adverse impact in a number of ways and to all parties involved. For study participants, this compromises any informed consent given; for the researcher, it creates a scientific and reputational risk that the study data (or their credibility) may be compromised; and for sponsors, there is often a financial and resource implication, particularly where a suspension to recruitment or extensive investigation are required.

8.5. Research proposals, protocols and procedures should be clear, comprehensive and easily accessible by the relevant people. Good document management and version control are essential so that, for instance, the same single version of the research proposal or protocol is being followed in the same way by everyone involved. Otherwise, the data collected could not be reliably compared, undermining the findings of the research. There is often a requirement for documents to be revised and updated during the lifespan of studies and these requirements may come from various organisations. It is important to ensure that changes to the research proposal or protocol are submitted for review, if required, by a research ethics committee and any other relevant approval bodies and that they are introduced uniformly across all relevant research sites.

[14] Exception may be made for an experienced care practitioner or manager undertaking a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

Research teams

8.6. The research team is the group of people involved in the conduct of a research project. It may include care professionals, academics, care users, members of the public, research professionals, students and/or scientists. For multi-site research, a single research team led by the chief investigator may undertake the activity at all the sites, or there may be different research teams at different sites, led either by the chief investigator or by a 'principal' investigator who takes responsibility for the conduct of the research at the site. Research teams are responsible for:

a. conducting the research to the agreed research proposal or protocol, in accordance with legal requirements, guidance and accepted standards of good practice;

b. providing information for participants; and

c. ensuring participants' welfare while they are taking part in the research.

8.7. Where consent is required:

a. potential participants should normally be provided by the research team with the information they need to help them decide whether they wish to take part in research or not;

b. a permanent and portable copy of the information sheet should normally be made available to all potential research participants; and

c. consent should normally be documented and available for inspection, unless there are good reasons for not doing so and this has been agreed with the research ethics committee.

8.8. Proportionality should be applied to the provision of information to potential research participants. The more research deviates from established practice or otherwise detrimentally affects the balance between risks and benefits, the greater the amount of information that needs to be provided to potential participants. By the same token, the closer the research is to standard practice, the less need there is to provide care users with detailed and lengthy information. Simple and efficient trials looking at the effectiveness of routinely used standard treatments should be facilitated so that care users can be recruited in a way that complies with the law but does not unduly burden either the care user or the care professional seeking consent.

Funders

8.9. The funder is the organisation or group of organisations providing funding for the research project. The funder may be the sponsor. The funder is responsible for:

a. assessing the scientific quality of the research as proposed;

b. establishing the value for money of the research as proposed, ensuring costs to all parties are identified and described and championing the value of research to health and social care;

c. considering the suitability of the research environment in which the research will be undertaken, particularly the priorities and constraints in health and social care where research will have an impact on care provision; and

d. requiring that a sponsor is in place before the research begins.

Sponsors

8.10. The sponsor is the individual, organisation or group that takes responsibility for securing the arrangements to set up, start, manage and finance a study. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research[15]. The sponsor is responsible for:

a. confirming that everything is ready for the research to begin;

b. putting and keeping in place arrangements to set up, start, finance and manage the study, including its competent project management and risk management;

c. establishing mechanisms to identify and address poorly planned research and poor-quality research proposals or applications;

d. satisfying itself that the research proposal or protocol has satisfied independent expert review and that the investigators, research team and research sites are suitable;

e. satisfying itself that, where required, the study has a favourable research ethics committee opinion and any other statutory approvals before it begins;

f. satisfying itself that the chief investigator has made appropriate arrangements for making information about the study available, normally before it starts, and for making findings, data and tissue accessible as appropriate after it has finished;

g. ensuring that roles and responsibilities of the parties involved in the research are agreed and appropriately documented; and

h. ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for managing the study.

8.11. Sponsors of clinical trials of investigational medicinal products have particular legal duties. See www.hra.nhs.uk/resources for details.

8.12. Universities and colleges should accept the role of sponsor for all educational research conducted by their own students, unless the student's employment mean it is more

[15] The employer or funder is not automatically the sponsor; they have to actually take the responsibilities of being the sponsor.

appropriate for a health or social care provider to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role.

8.13. A research culture should be fostered amongst undergraduate students by encouraging an awareness of research and enabling them to develop skills in research methods. Supervisors (or course leaders, where different) should be encouraged to develop and lead research projects that individual students at Masters level and below can contribute to at different stages.

8.14. For projects with no material ethical issues (see www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service), academic staff are expected to make a single 'batch' application for ethical review on behalf of a number of different students.

8.15. Undergraduate students leading individual research projects in isolation which involve direct contact with care users should normally be discouraged unless supervisor to student ratios would safely permit this and the risk is judged to be low.

8.16. Students from non-health related courses such as business studies or IT wishing to undertake research which involves accessing care users or their data or tissue in a health or social care setting should be offered a co-supervisor with a relevant care-related background to help them understand the care context and negotiate their way through the research process.

Research sites

8.17. Research sites are the locations where a research project is carried out. In health and social care research, they are normally also providers of health or social care and may also be the employer of members of the research team. Research sites are responsible for:

a. being aware of all research activity being undertaken within or through the organisation and ensuring that the roles and responsibilities of individuals at the research site and any collaborating parties are agreed and appropriately documented for individual research projects;

b. ensuring any such research is conducted and managed in accordance with this policy framework, including relevant operational guidance (see 4.1), the approved research proposal or protocol and related documents for the individual study; and

c. being assured that, if required, the research has a favourable research ethics committee opinion and any other relevant statutory approvals before care users take part (including indirectly, through the involvement of data or tissue that could identify them).

8.18. Research sites can direct any comments or questions they have about research ethics committees' or other approval bodies' decisions to the relevant authority, but they must not duplicate or repeat checks undertaken by research ethics committees or other approval bodies such as the HRA, MHRA or HFEA. Because it is reasonable for research sites to rely on checks carried out by these bodies, liability for any harm to a research participant that arose

from failure to carry out those checks properly would shift from the site to the approval body. The decision about whether an individual site will, according to its capacity and capability, take part in a research project remains with that site. If a research participant suffers injury or damage as a result of the site's failure to carry out its capacity and capability checks properly then the site may still be liable in that respect.

8.19. Research funding should not be wasted and the production of evidence to inform future care should not be hampered or delayed by poor intelligence or processes at research sites:

a. Research sites are expected to make information available about their capacity and capability to carry out different types of research so that sponsors can tell quickly and easily where they should place their studies to best effect.

b. Research sites must keep themselves in a position to be able promptly, efficiently and proportionately to assess their ability to carry out an individual research project. Research sites must have good, up-to-date working knowledge of their research capacity and capability. If a site needs to undertake additional enquiries to assess its capacity and capability to carry out a specific research project, that assessment must be proportionate and timely.

c. If a site needs to put in place additional arrangements to carry out a specific research project, that process must take into account the sponsor's plan for starting the study at that site.

d. Research sites are expected to accept reliable assurances from recognised authorities and each other and must not repeat checks that have already been carried out. This includes assurances about the ethics and safety of the research project, the legal compliance of the proposed research project, the acceptability of contracts and costs and the competence, character and indemnification of members of the research team who are not substantively employed at the site. Decisions about researchers' suitability must not be based on inappropriate HR processes.

e. Research involving participants who get transferred to another site must be facilitated by the transferring site providing all relevant information to the receiving site to support its continuation of the research. The transfer of participants from another site must be well managed by the receiving site to safeguard continuity of care.

f. Where there is an urgent need or small window of opportunity for research, such as public health emergencies or in the wake of a terrorist attack, this must command quick co-operation among relevant parties to enable the research.

Professional bodies

8.20. Professional bodies such as the Health and Care Professions Council are responsible for professional standards and for ensuring compliance with these standards, e.g. by assessing fitness to practice. These standards normally apply to the professionals' research activity as well as to their provision of care, teaching etc. In cases where research misconduct also constitutes professional misconduct, the relevant professional body retains its responsibility

for taking action, alongside any action taken by other bodies such as other relevant regulators, the researcher's employer and the police.

Regulators

8.21. The HRA's purpose is to protect and promote the interests of care users and the public in health research. The HRA protects care users and the public from unethical research while enabling them to benefit from ethical research quickly and easily, by ensuring processes and safeguards are both effective and proportionate. Other regulators with a remit in research, such as the Medicines and Healthcare products Regulatory Agency (MHRA) for trials of medicines and medical devices and the Human Fertilisation and Embryology Authority (HFEA) for embryo research, co-operate with each other and with the HRA to co-ordinate and standardise regulatory practice. This co-operation is underpinned by 'memoranda of understanding' between these bodies, which set out how they work together to improve and simplify the regulatory environment. Memoranda of understanding are published at www.hra.nhs.uk/resources/hra-working-in-partnership.

Employers

8.22. Employers are the organisations employing the chief investigator and members of the research team, including research teams at individual sites. They may also be research sites, sponsors and/or funders. Employers are responsible for:

a. encouraging a high-quality research culture, including

- ensuring employees are supported in and held to account for the professional conduct of research
- ensuring effective financial management and calculation of costs, in support of financial probity and value for money as indicators of quality;

b. ensuring researchers understand and discharge their responsibilities;

c. providing written procedures, supervision and training that supports effective collaboration, encourages care with financial resources and raises awareness of the wider environment within which clinical research is conducted; and

d. taking action if misconduct or fraud is suspected.

8.23. Employers of research staff need to ensure appropriate individual learning and competence. This includes acknowledging existing experience, qualifications and skills, rather than just giving training. It is important to confirm that individual members of the research team have an appropriate level of awareness of the correct procedures, what those require and the importance of following them. It is also important to understand the wider context of any error or breach that does occur. Systems should be in place not only to enable the identification of failures or breaches but also to place responsibility with the relevant party. For instance, if an error or breach occurs owing to insufficient time to complete a number of tasks, providing training will not in itself solve the problem or reduce the risk of a repeat.

Lessons learnt from experience should be identified and implemented, including through incorporation into training and personal development.

8.24. It is important to encourage open and honest reporting. It is widely recognised in health and social care that a culture of openness and honesty encourages safety. Incident reporting is important in all research and is strongly encouraged so that lessons can be learnt and improvements made. Errors can only be rectified and improvements made to reduce adverse impacts and increase the quality of research outcomes if they are reported in a timely way. For this to be truly effective, a culture of openness and honesty is essential, with a focus on improvement rather than blame.

Health and social care providers

8.25. Providers are organisations that provide health or social care. Providers' involvement in research is generally as research sites, when they may also be the employer of members of the research team. The sponsor may also be a provider. Providers may also provide services to research sites or may identify potential participants for research sites. In addition to any responsibilities they may have in those capacities, organisations that are providers are responsible in their capacity as providers for:

a. complying with this policy framework, in accordance with their legal duty under Section 111 of the Care Act 2014 or as agreed by the relevant Devolved Administration;

b. retaining responsibility for the care of participants to whom they have a duty; and

c. in England, contributing to the fulfilment of legal duties to promote research under the Health and Social Care Act 2012.

Appendix

1. This policy framework applies to slightly different areas of health and social care in each UK country:

Country	UK Health Department	Remit
England	Department of Health	NHS and adult Social Care
Wales	Department for Health and Social Services	NHS and Social Care
Scotland	Scottish Government Health Directorates	NHS and adult Social Care
Northern Ireland	Department of Health, Social Services and Public Safety	Health and Social Care

2. Similarities and differences in application across the UK of the legal requirements reflected in this policy framework are as follows:

Legislation	Application			
	England	Wales	Scotland	Northern Ireland
Abortion Act 1967	✓	✓	✓	
Abortion Regulations 1991	✓	✓		
Abortion (Scotland) Regulations 1991			✓	
Access to Health Records Act 1990	✓	✓	✓	
Adults with Incapacity (Scotland) Act 2000 §51			✓	
Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002, as amended 2007			✓	
Care Act 2014 §109–119 and Schedule 7	✓	✓	✓	✓
Data Protection Act 1998	✓	✓	✓	✓
Health Act 2009	✓	✓		
Health and Social Care Act 2012	✓	✓		
Health and Social Care (Community Health and Standards) Act 2003	✓	✓		
Health Service (Control of Patient Information) Regulations 2002	✓	✓		
Health and Social Care Act 2008	✓	✓		

Legislation	Application			
	England	Wales	Scotland	Northern Ireland
Health (Wales) Act 2003		✓		
Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010	✓	✓	✓	✓
Human Tissue Act 2004 §1	✓	✓		✓
Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006	✓	✓		✓
Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006	✓	✓	✓	✓
Human Tissue (Scotland) Act 2006 §40, 48			✓	
Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006			✓	
Independent Health Care Regulations (Northern Ireland) 2005				✓
Ionising Radiation (Medical Exposure) Regulations 2000, as amended 2006	✓	✓	✓	
Ionising Radiation (Medical Exposure)Regulations (Northern Ireland) 2000				✓
Local Government and Public Involvement in Health Act 2007	✓	✓		
Medical Devices Regulations 2002	✓	✓	✓	✓
Medicines for Human Use (Clinical Trials) Regulations 2004, as amended 2006 (twice), 2008	✓	✓	✓	✓
Mental Capacity Act 2005 §30–34	✓	✓		
Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006	✓			
Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007		✓		
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007	✓			

Legislation	Application			
	England	Wales	Scotland	Northern Ireland
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007		✓		
Mental Health Act 1983; s.114A		✓		
Misuse of Drugs Act 1971	✓	✓	✓	✓
National Health Service Act 2006	✓	✓		
National Health Service (Wales) Act 2006		✓		
Nursing and Midwifery Council (Midwives) Rules Order of Council 2012/3025	✓	✓	✓	✓
Nursing Homes Regulations (Northern Ireland) 2005				✓
Poisons Act 1972	✓	✓	✓	
Private and Voluntary Health Care (Wales) Regulations 2002		✓		
Residential Care Homes Regulations (Northern Ireland) 2005				✓