



## UK policy framework for health and social care research

### Issued for public consultation

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### 1. Context

- 1.1. The Health Research Authority (HRA) and the UK Health Departments<sup>1</sup> are committed to an environment where:
- patients, service users<sup>2</sup> and the public<sup>3</sup> are given, and take, the opportunity to participate in health and social care research, and are confident about doing so;

<sup>1</sup> 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 Services and Public Safety (Northern Ireland).

- new treatments, care and other services are developed through ethical and scientifically sound research for the benefit of patients, service users and the public;
- applying to do research is simple and getting a decision is quick and predictable;
- researchers find it straightforward to do high-quality, ethical research;
- commissioners and providers of health and social care appreciate how health and social care research benefits patients, service users, staff and the public;
- industry sees the UK as a great place to do health and social care research;
- money from charities and other research funders goes into carrying out research, not into navigating needless bureaucracy or duplicating previous work; and
- research projects get registered, the data and tissue they collect can be made available for future analysis, where appropriate and with adequate consent and safeguards, and research findings get published and 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 should improve the evidence base, reduce uncertainties and lead to improvements in future care, while the quality of current care may be higher in organisations that take part in research and adopt research findings. 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 develops the skills of staff in our universities, businesses and health and social care. It also involves patients, service users and the public in the pursuit of knowledge that may benefit them and others, not only by their participation in research but also by their involvement in its design and conduct, in public engagement about research, as members of research approval bodies such as research ethics committees or in funding research through taxes and charitable donations.

## **2. Purpose**

2.1. The UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards. These principles protect and promote the interests of patients, services users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

2.2. With due regard to relevant legislation within the UK and European Union, this policy framework sets out principles and responsibilities at a high level. The implementation of these will be supported by operational arrangements and guidance provided by the HRA and

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<sup>2</sup> This document uses the term ‘patients and service users’ to mean recipients of health care, social care or other services and support provided by or on behalf of health or social care organisations.

<sup>3</sup> The public includes carers, relatives of patients and service users and healthy volunteers.

the Devolved Administrations, working in collaboration to ensure a consistent approach to co-ordinating and standardising regulatory practice. This will achieve compatibility across the UK for the ethics, conduct and management of health and social care research<sup>4</sup>.

### 3. Scope

3.1. This policy framework applies to health and social care research that is within the responsibility of any of the four UK Health Departments (see appendix). This includes:

- research concerned with the protection and promotion of public health;
- research undertaken in or by<sup>5</sup> a UK Health Department, its non-Departmental public bodies or the NHS<sup>6</sup> and social care providers; and
- clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.

3.2. For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable<sup>7</sup> new knowledge to answer or refine questions with scientifically sound methods<sup>8</sup>. This excludes audits of practice and service evaluations<sup>9</sup>. It includes activities that are carried out in preparation for, and following, any change to treatment, care or other services that gets made for the purpose of the research (i.e. the interventional part<sup>10</sup> of the research), such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services) and projects that aim to generate hypotheses. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework.

3.3. The involvement of patients, service users or the public in the design, management or conduct of research may be subject to local controls but is not subject to approval (e.g. from

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<sup>4</sup> 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 except where the project also involves health research, adult social care research or children's social care research in Wales or Northern Ireland.

<sup>5</sup> Including health or social care research funded by any of the UK Health Departments.

<sup>6</sup> References to the NHS include Health and Social Care (HSC) in Northern Ireland.

<sup>7</sup> NB This definition involves an *attempt* at generalisability or transferability. The *actual* generalisability or transferability of some research findings may only become apparent once the project has been completed.

<sup>8</sup> Research proposals which lack these characteristics because of their poor quality are not exempt from this policy framework.

<sup>9</sup> Except service evaluations that are designed to produce generalisable findings.

<sup>10</sup> This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey.

a research ethics committee) or management in accordance with this policy framework, even if the research itself is.

- 3.4. This document draws on relevant sources<sup>11</sup> but cannot exhaustively compile all the principles, requirements and standards that may be issued separately by individual bodies with an interest in research. In particular, it does not repeat requirements that apply generally and are not specific to health and social care research, such as legislation regarding age of legal capacity, equality, health and safety, Welsh language etc. It remains the responsibility of those to whom relevant legal requirements and professional standards apply to ensure that they also meet those requirements and standards, in line with the guiding principles set out in this policy framework.
- 3.5. This document is specific to *health and social care* research<sup>12</sup>. Other research is outside its scope. Also outside its scope are matters relating to activities that are not health and social care *research*<sup>13</sup>, e.g. audits of practice. Those activities may well present ethical or other issues, but if they are not issues of *research* ethics etc, it would be inappropriate for this policy framework to address them as though they were.
- 3.6. The principles and responsibilities set out in this policy framework are deliberately at a high level and, as such, apply to health research and social care research equally. However, health research and social care research are generally different in nature, scale, volume and funding, as well as in the mix of stakeholders, organisational context and range of academic disciplines. Individuals and organisations with responsibilities under this policy framework are therefore expected to take appropriate account of these differences when reflecting the principles and responsibilities set out in this document in their own policies, procedures and practice.

#### **4. Implementation**

- 4.1. Implementation of this high-level policy framework is supported by national operational policies and guidance, standard operating procedures (SOPs) and operational platforms. Individuals and organisations with responsibilities under this policy framework are expected to adopt these operational provisions wherever relevant, not design their own, and should reflect in their existing policies, procedures and practice the principles and responsibilities set out in this policy framework and in the relevant operational provisions. The operational provisions which support implementation of this policy framework include<sup>14</sup>:

- resources for researchers and sponsors – [www.hra.nhs.uk/resources](http://www.hra.nhs.uk/resources);

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<sup>11</sup> These sources include legislation (see appendix) and other publications about good research practice, such as the [ADASS/SSRG resource pack for social care](#), [ESRC Framework for Research Ethics](#), [ICH GCP](#), the previous Research Governance Frameworks, [RESPECT Code of Practice](#), [UUK research integrity concordat](#) and [WMA Declaration of Helsinki](#).

<sup>12</sup> See glossary for definitions.

<sup>13</sup> See paragraph 3.2 for definition.

<sup>14</sup> The HRA provides these by agreement with the Devolved Administrations for UK-wide use.

- expectations and requirements for research ethics committee review, and standards and guidance for research ethics committees – [www.hra.nhs.uk/research-ethics-committee-members/guidance-on-ethical-review-for-members](http://www.hra.nhs.uk/research-ethics-committee-members/guidance-on-ethical-review-for-members);
- information for patients, service users and the public – [www.hra.nhs.uk/patients-and-the-public](http://www.hra.nhs.uk/patients-and-the-public); and
- systems for applying for and managing research approvals – the Integrated Research Application System (IRAS) at [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk) and the HRA Assessment and Review Portal (HARP).

4.2. 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 patients, service users and the public appropriately;
- meets their needs;
- accesses participants and information quickly and efficiently;
- minimises the risk of harm to participants and protects their confidentiality in accordance with their consent and the law; and
- produces findings that improve the evidence base and may lead to better health and well-being.

## 5. UK-wide responsibilities

- 5.1. The policy framework reflects the relevant legislation in the EU and UK and takes account, where relevant, of the application of this legislation in each UK 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<sup>15</sup>. In reflecting these, the policy framework has taken care to recognise the value of proportionate and appropriate application in different types of research.
- 5.2. In accordance with the Care Act 2014 and with the agreement of the Devolved Administrations<sup>16</sup>, this policy framework replaces the Research Governance Frameworks previously issued in each of the four UK countries.
- 5.3. Although responsibilities for health and social care have been devolved to the administrations in Wales, Scotland and Northern Ireland, the four UK Health Departments are committed to maintaining compatible standards for research ethics, conduct and management across the UK. Otherwise, cross-border research could be undermined by incompatible expectations between England, Wales, Scotland and Northern Ireland. With

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<sup>15</sup> References to participants include people whose data or tissue are involved in a research project.

<sup>16</sup> The Devolved Administrations include the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety (Northern Ireland).

the agreement of the Devolved Administrations and the UK Ethics Committee Authority<sup>17</sup>, 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 health and social care research<sup>18</sup>. While ensuring UK-wide compatibility, these frameworks take into account where legal and operational differences do exist (see appendix for details).

## **6. Development, status and maintenance**

- 6.1. This policy framework has been developed in partnership between the four UK Health Departments and the Health Research Authority.
- 6.2. In accordance with Section 111(6) and (7) of the Care Act 2014, the status of this document is guidance to which NHS trusts and local authorities in England must have regard<sup>19</sup>. 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 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.
- 6.3. in accordance with the Care Act 2014, the HRA is responsible for maintaining this policy framework in England and does so on behalf of the UK by agreement with the Devolved Administrations.

## **7. Audience**

- 7.1. This document is aimed primarily at individuals and organisations with responsibilities for the conduct and management of research. Summaries for different audiences, such as patients, service users and the public, are available on the HRA website.

## **8. Principles that apply to all health and social care research**

- 8.1. The safety and well-being of the research participant prevail over the interests of science and society.
- 8.2. All the people involved in conducting a research project are qualified by education, training and experience, or otherwise competent, to perform their tasks.

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<sup>17</sup> UKECA is the body that establishes, recognises and monitors research ethics committees and approves their operating procedures. UKECA's members are the HRA, the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety (Northern Ireland).

<sup>18</sup> 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.

<sup>19</sup> This means they are expected to comply with it unless they can demonstrate an overriding legal justification, e.g. if it is established that complying with the policy framework would breach some other statutory requirement, then that incompatible statutory requirement will take precedence over the relevant aspects of the policy framework.

- 8.3. Research projects are scientifically sound and guided by ethical principles in all their aspects.
- 8.4. Patients, service users and the public are involved, where appropriate, in the design, management and conduct of research.
- 8.5. Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.
- 8.6. The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents.
- 8.7. The researchers and sponsor consider relevant legislation and guidance with respect to conducting and managing the research.
- 8.8. Before the research project is started, foreseeable risks and inconveniences are mitigated and weighed against any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question<sup>20</sup>. A research project is started and continued only if the mitigated foreseeable risks do not outweigh any anticipated benefit.
- 8.9. A research project is started only if a research ethics committee and any other relevant approval body have favourably reviewed the research proposal or protocol, where their review is expected or required.
- 8.10. Information about research projects is normally made publicly available<sup>21</sup> before they start and their findings are normally made accessible after they have finished, in compliance with any applicable regulatory standards.
- 8.11. Information about the findings of the research is normally available, in suitable form, to those who took part in it.
- 8.12. The arrangements for involving research participants either directly or indirectly (e.g. through the involvement of data or tissue that could identify them) respect and, through provision of appropriate information according to their capacity to understand, 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 participants' explicit consent is sought, it is voluntary and appropriately informed. Where consent is refused or withdrawn, this is done without reprisal.
- 8.13. The rights of all research participants to physical and mental integrity, to respect for privacy and to the protection of the data concerning them in accordance with the law are safeguarded.

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<sup>20</sup> A formal, structured risk assessment is only expected where identified as essential. The risk:benefit ratio will normally be sufficiently described and considered as part of review processes such as research ethics committee review.

<sup>21</sup> A number of registers exist for clinical trials; for other health and social care research, this principle may be satisfied by relying on the Health Research Authority's routinely published summaries of research ethics committee applications ([www.hra.nhs.uk/news/research-summaries](http://www.hra.nhs.uk/news/research-summaries)).

- 8.14. Appropriate provision is made for insurance or indemnity<sup>22</sup> to cover liabilities which may arise in relation to the design, management and conduct of the research project and any commercialisation of the findings.
- 8.15. All information collected for or as part of the research project is recorded, handled and, as appropriate, securely stored in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to appropriate use for research and protection of privacy.
- 8.16. Compliance with the principles set out in this policy framework should be demonstrable, transparent and accountable. Non-compliance may be subject to administrative measures available to research ethics committees and/or, in England, the HRA. These measures will be proportionate and effective in the circumstances and give appropriate consideration to actions that are also available to others such as the research funder<sup>23</sup>, the researchers' employers, the police, the relevant professional and statutory regulators and other bodies, such as health and social care commissioners, UK Health Departments and Parliament, to which organisations with responsibilities under this policy framework may be accountable<sup>24</sup>.

*Principles that apply to interventional health and social care research*

- 8.17. In addition to the principles above, the following principles apply to interventional research, i.e. where a change in treatment, care or other services is made for the purpose of research:
  - a. The available information (including evidence from previous research) about the intended deviation from normal treatment, care or other services adequately supports the proposed research.
  - b. The research proposal or protocol explains any special arrangements, if appropriate, after the research intervention period has ended (e.g. continuing or changing the treatment, care or other services that were introduced for the purposes of the research).
  - c. All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and, as appropriate, securely stored in such a way and for such time that it can be understood by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected.
  - d. The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care

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<sup>22</sup> Special provision is not expected unless existing arrangements (e.g. professional insurance, membership of NHS Litigation Authority schemes) provide inadequate cover.

<sup>23</sup> Non-compliance by NIHR contractors will normally be a breach of contract.

<sup>24</sup> Non-compliance by NHS trusts or local authorities in England will normally be a breach of the law (Section 111(7) of the Care Act 2014).



professional<sup>25</sup> retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services.

## **9. Principles that apply to individuals and organisations**

9.1. 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<sup>26</sup> roles and responsibilities. Dialogue and collaboration have a central role within a research project. Clear, upfront discussion of issues and agreement of principles and procedures for each project are essential to its effective conduct and success, as well as mitigating some risks. All individuals and organisations with responsibilities under this policy framework should understand the value of research to health and social care and recognise the importance of co-operation and shared endeavour as critical to its success.

### *Chief investigators*

- 9.2. The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team (see paragraphs 9.6–9.8), chief investigators are responsible for the design, overall conduct, analysis and reporting of a research project, including:
- a. developing research proposals and protocols that take into account systematic reviews of relevant existing research evidence and other relevant research in progress and that are scientifically sound, safe, ethical, legal and feasible, and ensuring that they remain so for the duration of the research, taking account of developments while the research is ongoing;
  - b. submitting the research proposal or protocol for independent expert review and revising it in light of that review;
  - c. submitting the proposal for review<sup>27</sup> and obtaining approval, if expected or required, by a research ethics committee and any other relevant approval bodies;
  - d. satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project;
  - e. preparing information for potential participants that is clear and relevant to their decision about taking part in the research;

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<sup>25</sup> Who may or (particularly where the research team is not local to the research site) may not be a member of the research team.

<sup>26</sup> Any documentation should be proportionate. Roles and responsibilities should be agreed and understood by all the relevant parties, but are not expected to be re-documented separately if their description for the purpose of review processes such as research ethics committee review is sufficient.

<sup>27</sup> Including appeals where relevant.

- f. arranging to make information about the research publicly available, normally before it starts, and to retain and make accurate findings, data and tissue accessible, as appropriate, after it has finished;
  - g. starting the research only once everything is ready for it to begin;
  - h. arranging to make information about the findings of the research available to participants, as appropriate.
- 9.3. Students should not normally<sup>28</sup> take the role of chief investigator at any level of study.
- a. Relevant 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. Undergraduate students conducting research projects in isolation which involve direct contact with patients, service users or the public in a health or social care setting should normally be discouraged unless supervisor-to-student ratios would safely permit this and the risk is judged to be low.
  - b. A research culture should be fostered amongst relevant undergraduate students by encouraging an awareness of health and social care research and research ethics and enabling them to develop skills in research methods. Students from courses that are not primarily related to health and social care, such as business studies or IT, who wish to undertake research involving patients or service users, their data or tissue, or the public in a health or social care setting should have a co-supervisor with a relevant care-related background to help them understand the care context and negotiate their way through the research process.
  - c. The contribution of students to the development, conduct and reporting of the research should be appropriately acknowledged, e.g. in accordance with journal editors' authorship criteria<sup>29</sup>.
- 9.4. Research should<sup>30</sup> 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 research 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 subsequent amendments<sup>31</sup>, which are time-consuming and costly for the funder, the researchers and the

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<sup>28</sup> Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or 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.

<sup>29</sup> Such as the [International Committee of Medical Journal Editors recommendations for the conduct, reporting, editing and publishing of scholarly work in medical journals](#).

<sup>30</sup> Or must, if there is a legal requirement, e.g. in the case of clinical trials of investigational medicinal products.

<sup>31</sup> Where research deliberately entails modifying parameters or procedures during its course (e.g. adaptive clinical trials, iterative approaches in qualitative research), amendments should be avoided by the proposal or protocol specifying the adaptation schedule and processes up front.

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 research participants, this compromises any informed consent given; for the researcher, it creates a scientific and reputational risk that the research 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 appropriate.

- 9.5. 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 an expectation or requirement for documents to be revised and updated during the lifespan of studies and these expectations and requirements may come from various organisations. It is important to ensure that changes to the research proposal or protocol are submitted for review, if expected or required, by a research ethics committee and any other relevant approval bodies and that they are introduced uniformly across all relevant research sites.

#### *Research teams*

- 9.6. The research team is the group of people involved in the conduct of a research project. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists. Research team members' accountability should be clearly agreed between them and their employer(s), especially where multiple disciplines, collaborating organisations or patients, service users and the public are involved in a single research team. 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. demonstrating their suitability to conduct the research;
  - b. acquiring any particular knowledge and skills in order to conduct the research;
  - c. conducting the research according to the approved research proposal or protocol and any complementary information (such as the research ethics committee application form), in line with legal requirements and other applicable principles and standards;
  - d. providing information for potential participants that is clear and relevant to their decision about taking part in the research; and
  - e. ensuring participants' safety and well-being in relation to their participation in the research and reporting adverse events, as appropriate.
- 9.7. Where consent is sought:

- a. potential research participants should be provided, normally by the research team, with the information they need to help them decide whether they wish to take part in research or not, including summaries of systematic reviews of relevant existing research evidence showing why the proposed research is justified and of any other relevant research in progress, and should be given reasonable time to reach their decision;
  - b. a permanent and portable copy of any information sheet should normally be made available to all participants; and
  - c. consent should be documented and available for inspection, unless there are good reasons for not doing so and this has been agreed with a research ethics committee.
- 9.8. 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 the anticipated 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 patients and service users with detailed and lengthy information. For instance, pragmatic trials looking at the effectiveness of routinely used standard treatments should be facilitated so that patients and service users can be recruited in a way that complies with the law but does not unduly burden either patients and service users or care professionals seeking consent.

#### *Funders*

- 9.9. The funder is the organisation or group of organisations providing funding for the research project. The funder may be the sponsor (see paragraphs 9.10–9.12). The funder is responsible for:
- a. assessing (or arranging for assessment of) the scientific quality and, where appropriate, value for money of the research as proposed, involving patients, service users and the public effectively in funding decisions;
  - b. reviewing information about attribution of costs to confirm that costs to all parties have been identified and described, in accordance with national guidance where applicable, and that costs to the health and social care system are not disproportionate compared to research costs;
  - c. considering whether the research is really achievable within the settings as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health and social care if the research will have an impact on care provision;
  - d. making funding conditional on a sponsor and on relevant approvals being in place before the research begins; and
  - e. using contracts and conditions of funding to promote compliance with this policy framework, in particular to encourage chief investigators to arrange to make

information about research publicly available, normally before it starts, and to make accurate findings, data and tissue accessible, as appropriate, after it has finished.

### *Sponsors*

- 9.10. The sponsor is the individual, organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project. All health and social care research will have a sponsor. The sponsor is normally expected to be the employer (see paragraphs 9.19–9.21) of the chief investigator in the case of non-commercial research or the funder in the case of commercial research<sup>32</sup>. The sponsor has overall responsibility for the design and management of the research, including:
- a. verifying that everything is ready for the research to begin in a safe and timely manner;
  - b. putting and keeping in place arrangements to finance and manage the research project, including its competent risk management;
  - c. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications;
  - d. ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable;
  - e. satisfying itself that, where expected or required, the research has a favourable research ethics committee opinion and all relevant approvals before it begins;
  - f. satisfying itself that the chief investigator has made appropriate arrangements for making information about the research publicly available, normally before it starts, and for retaining and making accurate 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;
  - h. ensuring appropriate<sup>33</sup> provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project and any commercialisation of the findings; and
  - i. ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments (see paragraph 9.2.a).
- 9.11. Sponsors of clinical trials of investigational medicinal products have particular legal duties. See [www.hra.nhs.uk/resources](http://www.hra.nhs.uk/resources) for details.

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<sup>32</sup> The employer or funder is not automatically the sponsor; they knowingly take the responsibilities of being the sponsor.

<sup>33</sup> See footnote 24.

- 9.12. Universities and colleges should accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role.

#### *Contract research organisations*

- 9.13. A contract research organisation (CRO) is a person or an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of the sponsor's activities. A sponsor may delegate any or all of these activities to a CRO, but the ultimate responsibility, e.g. for the quality and integrity of the research data, always resides with the sponsor. The CRO is responsible for implementing quality assurance and quality control in respect of the activities delegated to it. Any activity that is delegated to and assumed by a CRO should be specified in writing. Any activity not specifically delegated to and assumed by a CRO is retained by the sponsor.

#### *Research sites*

- 9.14. Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care (see paragraph 9.22) and/or the employer (see paragraphs 9.19–9.21) of members of the research team. Research sites are responsible<sup>34</sup> for:
- a. demonstrating that the location is suitable for the research;
  - b. being aware of all research activity being undertaken in or through the site;
  - c. ensuring that the roles and responsibilities of individuals at the site and any collaborating parties are agreed and appropriately documented for individual research projects; and
  - d. ensuring (including by taking assurances from others in a position to give them) that, if expected or required, the research has a favourable research ethics committee opinion and all relevant approvals before research participants take part (including indirectly, through the involvement of data or tissue that could identify them).
- 9.15. When deciding whether to take part in a research project, research sites<sup>35</sup> can direct any comments or questions they have about research ethics committees' or other approval bodies' decisions to the relevant authority, but they should not duplicate checks undertaken by research ethics committees or other approval bodies. 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 the approval body's failure to carry out those checks

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<sup>34</sup> Where the location of the research is wholly independent of any of the individuals and organisations with responsibilities under this policy framework (e.g. a public or private space that is not under contract for the research, such as a public library, a café or a research participant's home), these responsibilities fall instead to the principal investigator's employer, except 9.14.b, which is waived.

<sup>35</sup> Where the location is independent as above, 'principal investigator's employer' should be read for 'site' in paragraphs 9.15 and 9.16, except 9.16.f, where 'research team' should be substituted.

properly would be offset from the site to the approval body. If the site relied on its own checks, it would take on liabilities in respect of those checks that could otherwise have been offset to the approval body and would (where the site is an NHS trust or local authority in England and/or holds a contract with NIHR) normally be in breach of the Care Act 2014 requirement in England to have regard to HRA guidance and/or the NIHR contract condition of compliance with this document. The decision about whether an individual site will 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 make that decision properly then the site may still be liable in that respect.

- 9.16. Research funding should not be wasted, and the production of evidence to inform future care should not be hampered or delayed, by poor information or processes at research sites:
- a. Research sites are expected to make information available about their capacity and capability to support different types of research so that sponsors can tell quickly and easily where they should place their studies to best effect.
  - b. Research sites are expected to 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 should have good, up-to-date working knowledge of their research capacity and capability. When undertaking any additional enquiries in deciding whether to take part in a specific research project, those enquiries are expected to be proportionate and timely.
  - c. If a site needs to put in place additional arrangements to support a specific research project at the intended location, that process should take into account the views of the sponsor and research team about the timetable for starting the research at that location, particularly for multi-centre projects.
  - d. Research sites are expected to accept reliable assurances from others in a position to give them, not repeat checks that others carry out. This includes assurances about the ethics and safety of the research project, its legal compliance, the suitability of contracts and costings and the competence, character and indemnification of members of the research team who are not substantively employed at the site. Decisions about research team members' suitability should not be based on inappropriate HR processes, such as irrelevant occupational health checks or duplicative checks of character.
  - e. Research sites should take steps to avoid disproportionate 'one size fits all' processes and duplication of effort, especially in demanding and assessing information, e.g. when research sites are involved in multi-centre projects or when they do repeat business with chief investigators, sponsors etc already known from previous projects.
  - f. Research involving participants who get transferred to another research site is expected to 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 should be correspondingly well managed by the receiving site.

- g. Where there is an urgent need or small window of opportunity for research, such as public health emergencies, this is expected to command quick co-operation among relevant parties to enable the research.

### *Professional bodies*

- 9.17. Professional bodies such as the General Dental Council, General Medical Council, Health and Care Professions Council and Nursing and Midwifery 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, and should therefore treat, the professionals' research activity in the same way as 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*

- 9.18. Regulators are statutory bodies that oversee particular activities according to their functions, which are set out in legislation. There are a number of regulators in the UK with a remit for activities related to health and social care research (the HRA) or to health research only (the MHRA, the HFEA and the Human Tissue Authority). The HRA, MHRA and HFEA all have functions relating to the approval of research, as does the Administration of Radioactive Substances Advisory Committee. These organisations are responsible for co-operating with each other, and the HRA and the Devolved Administrations must do so too, in order to co-ordinate and standardise the regulation of health and social care research. In doing so, the HRA has a particular responsibility for ensuring that this regulation is proportionate. This co-operation is underpinned by 'memoranda of understanding'<sup>36</sup> between these bodies, which set out how they work together to improve and simplify the regulatory environment, and other agreements which arrange for one body to perform functions on behalf of others. For instance, research that is clearly lower-risk gets processed accordingly, e.g. through research ethics committees' proportionate review service; applications to all the key research approval bodies are made through a single UK-wide Integrated Research Application System provided by the HRA; and guidance for researchers is provided by the HRA on behalf of the Devolved Administrations for UK-wide use.

### *Employers*

- 9.19. 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, including research integrity, and

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<sup>36</sup> Memoranda of understanding are published at [www.hra.nhs.uk/resources/hra-working-in-partnership](http://www.hra.nhs.uk/resources/hra-working-in-partnership).



- ensuring effective management of employees and their work, including employees' safety and well-being, financial management and calculation of costs in support of financial probity, and agreement with their partners<sup>37</sup> (e.g. funders, sponsors, collaborators, commercial partners, network members, integrated board etc) and employees about accountability and division of responsibilities, including arrangements for any intellectual property arising from research;
- b. ensuring researchers understand and discharge their responsibilities;
  - c. following good HR practice and providing written procedures, supervision and training that support accountability and effective collaboration, encourage care with financial resources and raise awareness of the wider environment within which health and social care research is conducted; and
  - d. taking appropriate action in the event of errors and breaches or if misconduct or fraud are suspected.
- 9.20. Employers of research staff should ensure appropriate individual learning and competence. This includes acknowledging existing experience, qualifications and skills, rather than just giving training. All training given should have measurable learning outcomes that are competence-based and directly linked to the competencies demanded by the employee's role and the procedures (such as SOPs) relevant to that role. It is important to confirm that individual members of the research team have an appropriate level of awareness of the correct procedures, what those entail 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.
- 9.21. 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*

- 9.22. Providers are organisations that provide health or social care. Providers' involvement in research is generally as research sites, when they are often also the employer of members of the research team and responsible for research participants' care. A provider may also be

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<sup>37</sup> This is particularly important for jointly funded posts and other dual employment, e.g. care professionals who also have a university role.

the sponsor for non-commercial research if it is the chief investigator's employer. Health and social care providers may also provide services to research sites, such as identifying potential participants or making information available for research elsewhere. In addition to any responsibilities they may have in the aforementioned capacities, organisations that are providers are responsible in their capacity as providers for recognising the importance of research in improving treatments, care and other services and their outcomes, including by:

- a. having regard to this policy framework according to their legal duty under Section 111 of the Care Act 2014 in England or as agreed by the relevant Devolved Administration;
- b. promoting opportunities to take part in health and social care research and retaining responsibility for the care of their patients and service users as research participants, including any associated excess treatment costs; and
- c. in England, contributing to the fulfilment of their commissioners' legal duties to promote research under the Health and Social Care Act 2012.

## Glossary

<b>chief investigator</b>	The overall lead researcher for a research project. Has overall responsibility for its design, conduct and reporting.
<b>employer</b>	The body or bodies that employ the investigators and research teams for a research project.
<b>funder</b>	The body or bodies that fund a research project.
<b>health research</b>	Any research into matters relating to people's physical or mental health. Excludes anything authorised under the Animals (Scientific Procedures) Act 1986).
<b>interventional research</b>	Research involving a change in treatment, care or other services made for the purpose of the research. Does not refer to research involving other methodological 'interventions', e.g. issuing a postal survey.
<b>must</b>	Where we use 'must', we mean it is a specific legal or regulatory requirement affecting an individual or organisation with responsibilities under this policy framework. The individual or organisation concerned must comply with these requirements.
<b>patients and service users</b>	Recipients of health care, social care or other services or support provided by or on behalf of health or social care organisations. Includes people receiving integrated health and social care, e.g. Health and Social Care (HSC) users in Northern Ireland, and people receiving community care in Scotland. Excludes children's social care service users in England and Scotland.
<b>principal investigator</b>	The lead researcher for a research project at a particular site. Has responsibility for the conduct of the project at that site.
<b>research</b>	The attempt to derive generalisable or transferable new knowledge. See paragraph 3.2 for more details.
<b>research site</b>	The organisation with day-to-day responsibility for the location where a research project is carried out.
<b>research team</b>	The people involved in the conduct of a research project. There may be different research teams for the project at different sites.
<b>should</b>	We use 'should' for expectations we regard as minimum good practice, but for which there is no specific legal requirement.
<b>social care research</b>	Any research into matters relating to personal care or other practical assistance for individuals (in England and Scotland, specifically individuals aged 18 or over) who are in need of care or assistance because of age, physical or mental illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or other similar circumstances.
<b>sponsor</b>	The organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project.

## Appendix

1. This policy framework applies to particular areas of health and social care in each UK country, according to the remit of the relevant UK Health Department:

Country	UK Health Department	Remit
England	Department of Health	health and adult social care
Wales	Department for Health and Social Services	health and social care
Scotland	Scottish Government Health Directorates	health 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	✓	✓	✓	✓
Freedom of Information Act 2000, as amended 2014	✓	✓		✓
Health Act 2009	✓	✓		
Health and Social Care Act 2008	✓	✓		
Health and Social Care Act 2012	✓	✓		
Health and Social Care (Community Health and Standards) Act 2003	✓	✓		

Legislation	Application			
	England	Wales	Scotland	Northern Ireland
Health Service (Control of Patient Information) Regulations 2002	✓	✓		
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 (Administration of Radioactive Substances) Regulations 1978	✓	✓	✓	✓
Medicines (Advisory Bodies) (No. 2) Regulations 2005	✓	✓	✓	✓
Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010	✓	✓	✓	✓

Legislation	Application			
	England	Wales	Scotland	Northern Ireland
Medicines for Human Use (Clinical Trials) Regulations 2004, as amended 2006 (twice), 2008	✓	✓	✓	✓
Medicines for Human Use (Miscellaneous Amendments) Regulations 2009	✓	✓	✓	✓
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	✓			
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 Homes Regulations (Northern Ireland) 2005				✓
Poisons Act 1972	✓	✓	✓	
Private and Voluntary Health Care (Wales) Regulations 2002		✓		
Public Services Reform (Scotland) Act 2010			✓	
Residential Care Homes Regulations (Northern Ireland) 2005				✓

EQUALITY AND PRIVACY SCREENING QUESTIONS

FOR EVERY HRA POLICY (*defined by the Equality and Human Rights Commission (EHRC) as a function, strategy, procedure, practice, project, or decision*) PLEASE ANSWER THE QUESTIONS BELOW TO DETERMINE WHETHER FURTHER ANALYSIS IS REQUIRED.

**YES /  
NO**

If yes, please copy and complete as required either the HRA Initial Equality Analysis and / or Initial Privacy Impact Assessment Template below. This one document can be found on the Intranet.

**Equality**

With due regard to our Equality Duty, could this policy have the potential to have a detrimental impact on anyone with a protected characteristic?

NO

**Privacy**

With due regard to the Data Protection Act, does this policy involve the use of Personal Information?

NO