# UK policy framework for health and social care research

v3.3 07/11/17

# Contents

# Introduction and background

## 1. Context

1.1. The Health Research Authority (HRA) and the UK Health Departments (The four UK Health Departments are the Department of Health (England), the Department of Health (Northern Ireland), the Scottish Government Health and Social Care Directorates and the Department for Health and Social Services (Wales)) are committed to an environment where:

- patients, service users (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) and the public (including carers, relatives of patients and service users and healthy volunteers) are given, and take, the opportunity to participate in health and social care research and to get involved in its design, management, conduct and dissemination, and are confident about doing so;

- safer, more efficient or more effective treatments, care and other services are developed and tested 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, with predictable timelines;

- 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, and make their resources available for research;

- industry sees the UK as a great place to do health and social care research, and increases its investment for the benefit of patients and service users;

- 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, with adequate consent and privacy safeguards, and research findings (i.e. the findings that the research was designed to produce; for guidance on incidental and other health-related findings, (see Wellcome policy position) 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 care. Evidence; (BMJ Content), (BMJ Content), (Journals Content) suggests the quality of current care may be higher in organisations that take part in research, adopt a learning culture and implement 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 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 setting research priorities, in the design, management, conduct and dissemination of research, 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 account of legal requirements and other standards. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate (This means having an approach to mitigating risks that gives at least the same consideration to the risks that arise if the research does not take place as to those that arise if it does, and the same consideration to their likelihood as to their impact. The risk appetite should favour the research taking place. The prevailing focus should be on the risks to the potential participants and the target population, not on the reputational risks), 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. This policy framework sets out principles and responsibilities at a high level that take account of relevant legislation in the UK. It will be supported by operational arrangements and guidance provided by the HRA and 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 management and conduct of health and social care research (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 Northern Ireland or Wales.)

## 3. Scope

3.1. For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable (NB This definition involves an *attempt* at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The *actual* generalisability or transferability of some research findings may only become apparent once the project has been completed) new (Including new knowledge about existing treatments or care) knowledge to answer or refine relevant questions with scientifically sound methods (Projects that are not designed well enough to meet this definition are not exempt from this policy framework – paragraph 9.10.a.) This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part (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) 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), projects that aim to generate hypotheses, methodological research and descriptive research. 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. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at HRA Decisions Tool.

3.2. This policy framework applies to health and social care research that is within the responsibility of the HRA or the Devolved Administrations' Health Departments (appendix 1). This includes:

- research concerned with the protection and promotion of public health;
- research undertaken in or by (including health or social care research funded by any of the UK Health Departments) a UK health Department, its non-Departmental public bodies or the NHS (References to the NHS include Health and Social Care (HSC) in Northern Ireland) and social care providers (Reference to NHS and social care providers include contractors providing services under contract with care providers or commissioners (including services purchased by service users from their own resources or

their ‘personal budget’), e.g. general practitioners (GPs), privately run treatment centres, care homes, magnetic resonance imaging (MRI) services), 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 within the health and social care systems (Including research involving prison health services. that might have an impact on the quality of those services.

3.3. The activity of involving patients, service users or the public in the design, management, conduct or dissemination of research should not be managed as though it is research in its own right. Information on arrangements and controls relating to public involvement is available from INVOLVE.

3.4. This document draws on relevant sources (These sources include legislation (appendix 2) and other publications about good research practice, such as the ADASS/SSRG resource pack for social care, ESRC Framework for Research Ethics, the principles of ICH GCP, the previous Research Governance Frameworks, RESPECT Code of Practice, UUK Concordat to support research integrity and WMA Declaration of Helsinki) 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 and expectations that apply generally and are not specific to health and social care research, such as professional standards or legislation regarding age of legal capacity, equality, health and safety, Welsh language, whistleblowing 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. The principles and responsibilities set out in this policy framework are deliberately at a high level and apply to health research and social care research equally. However, health research and social care research can be different in nature, scale, setting, 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. This policy framework largely sets out what is (or should be) already happening. It is therefore not expected to add to the workload of researchers

or others with responsibilities under this framework. The intention is to remove unnecessary bureaucracy for researchers, both in what the framework expects of them directly and what it expects of others that then affects them. 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 (The HRA provides these by agreement with the Devolved Administrations for UK-wide use)

- resources for researchers and sponsors – HRA planning and improving research page;
- expectations and requirements for research ethics committee review, and standards and guidance for research ethics committees;
- information for patients, service users and the public; and
- systems for applying for and managing research approvals – the Integrated Research Application System (IRAS) at My Research Project and the HRA Assessment and Review Portal (HARP).

4.2 These operational provisions support people with responsibilities for the management and conduct 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 in its design, management, conduct and dissemination;
- meets the needs of patients, service users and the public;
- accesses participants and information quickly and efficiently;
- minimises the risk of harm to participants and protects their confidentiality in accordance with their consent, where required, 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 UK and takes account, where relevant, of the application of this legislation in each UK country while supporting UK-wide compatibility and consistency. 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 (References to participants include people whose data or tissues are involved in a research project.) In reflecting these, the policy framework has taken care to recognise the value of their proportionate application to different types of research.

5.2. In accordance with the Care Act 2014 and with the agreement of the Devolved Administrations (The Devolved Administrations include the Department of Health (Northern Ireland), the Scottish Ministers and the Welsh Ministers), 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 services have been devolved to the administrations in Northern Ireland, Scotland and Wales, the four UK Health Departments are committed to maintaining compatible standards for research ethics (Covered separately in *Governance arrangements for research ethics committees*, SOPs and guidance – see the HRA about us page), management and conduct across the UK. Otherwise, cross-border research could be undermined by incompatible expectations between England, Northern Ireland, Scotland and Wales. With the agreement of the Devolved Administrations and/or, where applicable, the UK Ethics Committee Authority (UKECA) (UKECA is the body that establishes, recognises, monitors and approves the standard operating procedures of research ethics committees that review clinical trials of investigational medicinal products. UKECA's members are the HRA, the Department of Health (Northern Ireland), the Scottish Ministers and the Welsh Ministers), the HRA may publish policy, guidance and procedures that are UK-wide. Except where otherwise stated, these UK-wide publications, including this document, apply to all health and social care research (Apart from research that is wholly in children's social care in England or Scotland, which is outside the remit of the HRA and the Scottish Government Health and Social Care Directorates). While ensuring UK-wide compatibility, these documents take into account where legal and operational differences do exist (appendix 2 for details) and proactively address them to minimise their potential impact on cross-border research.

## 6. Development, status and maintenance

6.1. This policy framework has been developed in partnership between the four UK Health Departments and the HRA. It applies in England, Northern Ireland, Scotland and Wales.

6.2. In accordance with Section 111(6) and (7) of the Care Act 2014, the status of this document is statutory guidance to which local authorities, NHS trusts and NHS foundation trusts in England must have regard (This means deviating only when there is a justified reason for doing so). 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.

6.3. Maintenance of the policy framework is undertaken by the HRA in conjunction with the Devolved Administrations. It will be updated on a regular basis to link to relevant references and will be revised in light of significant developments (e.g. changes in clinical trials regulation) or otherwise at intervals agreed between the HRA and Devolved Administrations.

## 7. Audience

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

# Principles

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

8.1. The following statement of principles serves as a benchmark for good practice that the management and conduct of all health and social care research in the UK are expected to meet.

### Principle 1: Safety

The safety and well-being of the individual prevail over the interests of science and society.

### Principle 2: Competence

All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

### Principle 3: Scientific and Ethical Conduct

Research projects are scientifically sound and guided by ethical principles in all their aspects.

### Principle 4: Patient, Service User and Public Involvement

Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.

### Principle 5: Integrity, Quality and Transparency

Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

### Principle 6: Protocol

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 - see the HRA Planning and Improving Research page.

### Principle 7: Legality

The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.

### Principle 8: Benefits and Risks

Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and

inconveniences once they have been mitigated (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.)

### Principle 9: Approval

A research project is started only if a research ethics committee and any other relevant approval body (i.e. the HRA, the Administration of Radioactive Substances Advisory Committee (ARSAC), the Human Fertilisation and Embryology Authority (HFEA) or the Medicines and Healthcare products Regulatory Agency (MHRA)) have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.

### Principle 10: Information about the Research

In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).

### Principle 11: Accessible Findings

Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

### Principle 12: Choice

Research participants (Either directly, or indirectly through the involvement of data or tissue that could identify them) are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

### Principle 13: Insurance and Indemnity

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

### Principle 14: Respect for Privacy

All information collected for or as part of the research project is recorded, handled and stored appropriately and 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 their appropriate use for research and appropriate protection of privacy.

### Principle 15: Compliance

Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

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

8.2. In addition to the principles above, the following principles apply to interventional research only, i.e. where a change in treatment, care or other services is made for the purpose of research:

### Principle 16: Justified Intervention

The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

### Principle 17: Ongoing Provision of Treatment

The research proposal or protocol and the participant information sheet explain the special arrangements, if any, 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).

### Principle 18: Integrity of the Care Record

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

### Principle 19: Duty of Care

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 professional (Who may or (particularly where the research team is not local to the research site) may not be a member of the research

team) 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. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

# Responsibilities

## 9. Responsibilities of 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 (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) 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. Those with experience of good practice in the management and conduct of research are encouraged to share their knowledge with novices.

### Chief investigators

9.2. The chief investigator is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project, including:

a. satisfying themselves that the research proposal or protocol takes into account any relevant systematic reviews, other research evidence and research in progress (Research studies may replicate previous research, but should acknowledge the reason for doing so), that it makes effective use of patient, service user and public involvement where appropriate and that it is scientifically sound, safe (i.e. that the risk of harm has been minimised as much as possible and is not expected to outweigh the benefits), ethical, legal and feasible and remains so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying themselves that the research proposal or protocol has been submitted for appropriate independent expert ('peer') review (For educational research, the chief investigator will be a supervisor who may provide an appropriate level of review) and revised in light of that review;

c. satisfying themselves that, if expected or required, the proposal has been submitted for review by and obtained approval from a research ethics committee and any other relevant approval bodies;

d. satisfying themselves (For multi-site projects, this may be delegated to the principal investigator at each research site) that everyone involved in the conduct of the research is qualified by education, training (Training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards – HRA Researcher Suitability and Training page) 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. satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research – Consent and Participant Information Guidance.

f. adhering to the agreed arrangements (paragraph 8.10) for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);

g. adhering to the agreed arrangements (paragraph 8.11) for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished (Funders or others may set expectations about making data and tissue available);

h. starting the research only once the sponsor has confirmed that everything is ready for it to begin;

i. adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments; and

j. adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate to participants.

9.3. Students should not normally (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) take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders.

a. Relevant supervisors (or course leaders, where different) should be encouraged to develop and lead research projects that individual students at master's level and below can contribute to at different stages. Undergraduate students should only conduct research projects in isolation that involve direct contact with patients, service users or the public in a health or social care setting if on-site supervision arrangements mitigate any risks.

b. A research culture should be fostered amongst relevant undergraduate students by encouraging an awareness of health and social care research, research ethics and public involvement, 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 relevant experience that will help them understand the care context and the associated research process.

c. The contribution of students to the development, conduct and reporting of the research should be appropriately acknowledged like that of other contributors, e.g. in accordance with journal editors' authorship criteria.

9.4. Research should (Or must, if there is a legal requirement, e.g. in the case of clinical trials of investigational medicinal products) 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, if necessary, reproduced. Public involvement (i.e. working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research) plays an important role in research design and planning. Well-planned and well-written research proposals, protocols and procedures are key to carrying out research successfully. They help avoid subsequent amendments (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), 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 and reputational risk to all parties involved. For research participants, this compromises any informed consent given; for the researcher, it creates a scientific 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 involved.

9.5. Research proposals, protocols and procedures should be clear, comprehensive and easily accessible to the research team. 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, if approved (Or if they give effect to urgent safety measures), 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) (Or directly with the sponsor, where this accountability does not arise in the context of their employment, e.g. in the case of research team members who are patients, service users or the public) and documented, 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 to chief investigators and sponsors 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 compliance with any applicable regulatory standards and guidance;

d. providing information in a suitable format for potential participants that is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research; and

e. ensuring participants' safety and well-being in relation to their participation in the research (e.g. by asking questions about the patient's experience with the research intervention) and reporting adverse events where expected or required.

9.7. Where consent is sought:

a. potential research participants should be provided, normally by the research team, with the information (Guidance on preparation of participant information, including proportionate arrangements, is available at HRA Decisions Tool) they need to help them decide whether they wish to take part in research or not, and should be given reasonable time to reach their decision. The information should be provided in a suitable format. Unless otherwise justified (e.g. by feedback from public involvement), the information should include a concise explanation of relevant research evidence and research in progress that shows why the proposed research is justified;

b. a permanent and accessible copy of any information sheet should normally be made available to all participants; and

c. consent should be documented and available for inspection by relevant regulators.

9.8. Proportionality should be applied to the provision of information to potential research participants (Guidance on applying a proportionate approach to the process of seeking consent is available at HRA Planning and Improving research page. 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 can be recruited in a way that complies with the law but does not unduly burden either patients or the care professionals seeking their consent.

### Funders

9.9. The funder is the organisation or group of organisations providing funding for the research project. The funder is normally the sponsor in the case of commercial research. The funder is responsible for:

a. assessing (or arranging for assessment of) the scientific quality, the relevance of the research to the target population and, if appropriate, the value for money of the research as proposed, involving patients, service users and the public where appropriate in funding decisions;

b. reviewing information about the attribution of costs to confirm that costs to all parties (including excess treatment costs) have been identified and described in accordance with national guidance – Government Publications Guidance where applicable, and that the costs are not disproportionate compared to the value of the output;

c. considering (with advice if necessary) 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 ongoing funding conditional on a sponsor and relevant approvals (paragraph 8.9) being in place before the research begins (but not before initial funding is released, as some funding may be needed in order to put these in place); and

e. using contracts (e.g. model agreements, where applicable – see the UKCRC Governance and conditions of funding to promote compliance with this policy framework, in particular to encourage arrangements (paragraphs 8.10 and 8.11) for making information about research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee) and for retaining and making accurate findings, data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished.

### Sponsors

9.10. The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. 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 (The employer or funder is not

automatically the sponsor; they explicitly accept the responsibilities of being the sponsor). The sponsor has overall responsibility for the research, including:

a. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:

   - take into account systematic reviews of relevant existing research evidence and other relevant research in progress,
   - make appropriate use of patient, service user and public involvement and
   - are scientifically sound (e.g. through independent expert review) (For educational research, the scientific validity and quality may be established by the chief investigator (i.e. the supervisor) at a level appropriate to the nature of the course), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying itself that the investigators, research team and research sites are suitable;

c. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;

d. ensuring adequate (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

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants (For educational research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements);

f. ensuring that, where expected or required, the research has approval from a research ethics committee (Whether outright or following a provisional opinion, resubmission or appeal) and any other relevant approval bodies before it begins;

g. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;

h. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;

i. ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and 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.

9.11. Sponsors of clinical trials of investigational medicinal products have particular legal duties – see the HRA Planning and Improving Research page for details.

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 take on this role. Sponsors of educational research should ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the sponsor's oversight responsibilities due to location or expertise, the sponsor should agree co-supervision arrangements with a local care practitioner.

### 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 (This does not prevent appropriate CROs from acting as the sponsor's legal representative – see the HRA Planning and Improving Research page. 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 and/or the employer of members of the research team. Research sites are responsible (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 or a café), these responsibilities fall instead to the principal investigator's employer, except 9.14.b, which is waived) for:

a. demonstrating to relevant approval bodies and sponsors 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 documented for individual research projects; and

d. satisfying themselves (e.g. by taking assurances from others in a position to give them) that, if expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before research participants take part (including indirectly, through the involvement of data or tissue that is likely to identify them).

9.15. Research sites (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) should have confidence in accepting assurances from other bodies about the compliance with relevant legislation and national standards of proposed research activities, without duplicating review of those proposals. Accepting assurances carried out to national standards reduces the organisation's risk of misunderstanding or misinterpreting its obligations. The HRA indemnifies NHS research sites that accept assurances from the HRA against any claim covered by the NHS Litigation Authority arising as a result of incorrect assurances. If an NHS organisation undertakes its own checks that duplicate the assessments made by the HRA, the organisation will be liable for its own decisions made on the results of those checks and any consequences of those decisions. Organisations remain responsible, including through monitoring and training, for ensuring that the research activities are conducted in accordance with their applicable legal obligations.

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 e.g. NIHR Policy and Standards page.

b. Research sites are expected to keep themselves in a position to be able promptly, efficiently and proportionately to assess their ability to take part in 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. This includes assurances about the ethics and safety of the research project, its compliance with the law and other standards (e.g. confidentiality), 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, including patients, service users and the public. Decisions about research team members' suitability should not be based on inappropriate HR processes, such as disproportionate training expectations (e.g. GCP or health and safety training for individuals, roles or projects that do not need it), irrelevant occupational health checks (e.g. vaccination history where there is no contact with patients or service users) 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 requesting 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 (A transferring site will have been a research site for the project. Where an organisation is simply identifying participants for research taking place elsewhere, it does not count as a transferring site) providing all relevant information to the receiving site to support the receiving site's continuation of the research. The transfer of participants from a transferring site should be correspondingly well managed by the receiving site.

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

h. Research sites may designate staff to facilitate these activities that fulfil their responsibilities under this policy framework. Such staff may act as a shared resource across more than one site.

### Regulators of professions

9.17. Regulators of professions such as the General Dental Council, General Medical Council, General Pharmaceutical 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 practise. 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 regulator of the relevant profession 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.

### Other 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 Human Fertilisation and Embryology Authority, the Human Tissue Authority and the Medicines and Healthcare products Regulatory Agency).

a. The HRA, HFEA, MHRA and the Administration of Radioactive Substances Advisory Committee all have a role in co-operating with each other to approve research, and with the HTA (which licenses storage of tissue for research, not the research itself). This co-operation is underpinned by agreements between these bodies which set out how they work together to improve and simplify the regulatory environment, or arrange for one body to perform functions on behalf of others.

b. The HRA and the Devolved Administrations work together to co-ordinate and standardise the regulation of health and social care research.

9.19. The HRA has a specific role to ensure the following:

a. The regulation of health and social care research is proportionate, so that research that is clearly lower-risk gets processed accordingly.

b. Guidance for researchers is provided by the HRA on behalf of the Devolved Administrations for UK-wide use.

c. Applications to all the key research approval bodies are made through a single UK-wide Integrated Research Application System provided by the HRA.

d. Guidance is provided in one, easily accessible location.

e. Responses to applicants are standardised and timelines are predictable.

f. That HRA takes responsibility and liability for approvals where checks have been carried out only by the HRA and not by other organisations.

## Employers

9.20. Employers are the organisations employing the chief investigator and members of the research team (Excluding employers of people whose role in the research is not part of their employment, e.g. research team members who are patients, service users or the public.) The chief investigator's employer is normally the sponsor in the case of non-commercial research. Employers may also be funders, research sites and/or care providers. Employers are expected to:

a. encourage a high-quality research culture, including

- ensuring employees are supported in and held to account for conducting research in a professional manner, including research integrity, and
- ensuring effective management of employees and their work, including employees' safety, well-being, work environment and facilities,
- ensuring financial management and calculation of costs in support of financial probity and
- ensuring agreement with their partners (This is particularly important for jointly funded posts and other dual employment, e.g. care professionals who also have a university role) (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. ensure researchers understand and discharge their responsibilities;

c. follow good HR practice, including in the provision of assurances about researchers' suitability (paragraph 9.16.d; also 9.2.d, 9.6.a and 9.10.b); provide written procedures, supervision and training that support accountability and effective collaboration; encourage care with financial resources; raise awareness of the wider environment within which health and social care research is conducted; and bridge any gap between

employees' current competence and the competence needed for their work; and

d. take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected.

9.21. Employers of research staff should ensure appropriate individual learning and competence. This includes acknowledging existing experience, qualifications and skills, rather than just giving training. Relevant 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 adequate 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.

9.22. 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

9.23. Providers are organisations that provide health or social care. This includes organisations providing services under contract with NHS or local authority providers or commissioners (Including purchasing of services undertaken directly by those receiving care or support, from their own resources or from their 'personal budgets', i.e. local authority funding managed by or on behalf of the service user), e.g. general practitioners (GPs), privately run treatment centres, care homes or magnetic resonance imaging (MRI) services. Providers' involvement in research is generally as research sites, when they may also be the employer of members of the research team and responsible for research participants' care. A provider is normally 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. Where research participants are recruited independently of providers (e.g. patients identified through a disease charity or staff identified through a professional society), those providers have no decision to make about taking part in the research unless they are also research sites. In addition to any responsibilities they may have in their capacities as sites, employers and/or sponsors, providers should recognise the importance of research in improving treatments, care and other services and their outcomes by:

a. promoting opportunities to take part in health and social care research - see the NIHR News and Support page for examples;

b. retaining responsibility for the care of their patients and service users as research participants, including agreeing any associated excess NHS tariff treatment costs - see the NHS England page for guidance; and

c. having regard to this policy framework according to their legal duty under Section 111(7) of the Care Act 2014 (Applies in England to local authorities, NHS trusts and NHS foundation trusts) and contributing to the fulfilment of their commissioners' legal duties to promote research under the Health and Social Care Act 2012.

## Glossary

| | |
|---|---|
| chief investigator | The overall lead researcher for a research project. Has responsibility for its overall conduct. |
| employer | The body or bodies that employ the investigators and research teams for a research project. |
| funder | The body or bodies that fund a research project. |
| health research | Any research into matters relating to people's physical or mental health. Excludes anything authorised under the Animals (Scientific Procedures) Act 1986). |
| interventional research | 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. |
| must | Where we use 'must', we mean there is a specific legal requirement affecting an individual or organisation with responsibilities under this policy framework. |
| patients and service users | Recipients of health care, social care or other services or support provided by or on behalf of health or social care organisations, such as NHS patients and social care service users. Includes people receiving integrated health and social care, e.g. Health and Social Care (HSC) users in Northern Ireland. Excludes children's social care service users in England and Scotland. |
| principal investigator | The lead researcher for a research project at a particular site. Has responsibility for the conduct of the project at that site. |
| the public | The general public. Includes carers, relatives of patients and service users and healthy volunteers. |
| public involvement | Working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research. |
| research | The attempt to derive generalisable or transferable new knowledge – paragraph 3.1 for more details. |
| research site | The organisation with day-to-day responsibility for the location where a research project is carried out. |

| | |
|---|---|
| research team | The people involved in the conduct of a research project. There may be different research teams for the project at different sites. |
| should | We use ‘should’ for expectations we regard as minimum good practice, but for which there is no specific legal requirement. |
| social care research | 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. |
| sponsor | The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. |

## Appendix 1: Remits

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

| Country | Body | Remit |
|---|---|---|
| England | Health Research Authority | health and adult social care research |
| Northern Ireland | Department of Health (Northern Ireland) | health and social care |
| Scotland | Scottish Government Health and Social Care Directorates | health and adult social care |
| Wales | Department for Health and Social Services | health and social care |

# Appendix 2: Laws

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

| Legislation | Application England | Application Northern Ireland | Application Scotland | Application Wales |
|---|---|---|---|---|
| Abortion Act 1967 | Yes | No | Yes | Yes |
| Abortion Regulations 1991 | Yes | No | No | Yes |
| Abortion (Scotland) Regulations 1991 | No | No | Yes | No |
| Access to Health Records Act 1990 | Yes | No | Yes | Yes |
| Adults with Incapacity (Scotland) Act 200 S51 | No | No | Yes | No |
| Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2020, as amended 2007 | No | No | Yes | No |
| Care Act 2014 S109-119 and Schedule 7 | Yes | Yes | Yes | Yes |
| Data Protection Act 1998 | Yes | Yes | Yes | Yes |
| Freedom of Information Act 2000, as amended 2014 | Yes | Yes | No | Yes |
| Health Act 2009 | Yes | No | No | Yes |
| Health and Social Care Act 2008 | Yes | No | No | Yes |
| Health and Social Care Act 2012 | Yes | No | No | Yes |
| Health and Social Care (Community Health and Standards) Act 2003 | Yes | No | No | Yes |
| Health Service (Control of Patient Information) Regulations 2002, ad amended 2016 | Yes | No | No | Yes |
| Health (Wales) Act 2003 | No | No | No | Yes |
| Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 | Yes | Yes | Yes | Yes |
| Human Tissue Act 2004 S1 | Yes | Yes | No | Yes |
| Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about | Yes | Yes | No | Yes |

| | | | | |
|---|---|---|---|---|
| Transplants) Regulations 2006 | | | | |
| Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 | Yes | Yes | Yes | Yes |
| Human Tissue (Scotland) Act 2006 S40, 48 | No | No | Yes | No |
| Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006 | No | No | Yes | No |
| Independent Health Care Regulations (Northern Ireland) 2005 | No | Yes | No | No |
| Independent Health Care Regulations (Wales) 2011 | No | No | No | Yes |
| Ionising Radiation (Medical Exposure) Regulations 2000, as amended 2006 | Yes | No | Yes | Yes |
| Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 | No | Yes | No | No |
| Local Government and Public Involvement in Health Act 2007 | Yes | No | No | Yes |
| Medical Device Regulation 2002 | Yes | Yes | Yes | Yes |
| Medicines (Administration of Radioactive Substances) Regulations 1978 | Yes | Yes | Yes | Yes |
| Medicines (Advisory Bodies) (No.2) Regulations 2005 | Yes | Yes | Yes | Yes |
| Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 | Yes | Yes | Yes | Yes |
| Medicines for Human Use (Clinical Trials) Regulations 2004, as amended 2006 (twice), 2008 | Yes | Yes | Yes | Yes |
| Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 | Yes | Yes | Yes | Yes |
| Mental Capacity Act 2005 S30-34 | Yes | No | No | Yes |

| | | | | |
|---|---|---|---|---|
| Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 | Yes | No | No | No |
| Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007 | No | No | No | Yes |
| Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007 | Yes | No | No | No |
| Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007 | No | No | No | Yes |
| Mental Capacity Act (Northern Ireland) 2016 S132 - 138 | No | Yes | No | No |
| Mental Health Act 1983 s.114A | No | No | No | Yes |
| Misuse of Drugs Act 1971 | Yes | Yes | Yes | Yes |
| National Health Service Act 2006 | Yes | No | No | Yes |
| National Health Service (Wales) Act 2006 | No | No | No | Yes |
| Nursing Homes Regulations (Northern Ireland) 2005 | No | Yes | No | No |
| Poisons Act 1972 | Yes | No | Yes | Yes |
| Psychoactive Substances Act 2016 | Yes | Yes | Yes | Yes |
| Public Services Reform (Scotland) Act 2010 | No | No | Yes | No |
| Residential Care Homes Regulations (Northern Ireland) 2005 | No | Yes | No | No |
| Social Services and Well-being (Wales) Act 2014 | No | No | No | Yes |

## Appendix 3: Relationship between principles and responsibilities

The relationship between the principles of good practice in the management and conduct of health and social care research and the responsibilities of individuals and organisations are set out below:

| Principle | | Responsibility |
|---|---|---|
| 1. | Safety | Chief investigator 9.2.a, i<br>Research team 9.6.e<br>Sponsor 9.10.a, g, i<br>Employer 9.20.a, 9.22 |
| 2. | Competence | Chief investigator 9.2.d<br>Research team 9.6.a, b<br>Sponsor 9.10.b, h<br>Research site 9.16.d<br>Employer 9.20.c, 9.21 |
| 3. | Scientific and Ethical Conduct | Chief investigator 9.2.a, b, c, 9.3, 9.4, 9.5<br>Funder 9.9.a<br>Sponsor 9.10.a, f<br>Research site 9.14.d, 9.16.d<br>Regulators 9.18<br>Employer 9.20.b |
| 4. | Patient, Service User and Public Involvement | Chief investigator 9.2.a, 9.3.b, 9.4<br>Funder 9.9.a<br>Sponsor 9.10.a |
| 5. | Integrity, Quality and Transparency | Chief investigator 9.4, 9.5<br>Research team 9.6, 9.6.c, 9.7.c<br>Funder 9.9.a<br>Sponsor 9.10.a, c, 9.13<br>Research site 9.14.b, c, 9.16.a, f<br>Employer 9.20.a, d, 9.22 |

| Principle | | Responsibility |
|---|---|---|
| 6. | Protocol | Chief investigator 9.2.a, b, i, 9.4, 9.5<br>Research team 9.6.c<br>Sponsor 9.10.a, i<br>Regulators 9.15 |
| 7. | Legality | Chief investigator 9.2.a<br>Research team 9.8<br>Sponsor 9.10.a, 9.11<br>Research site 9.15, 9.16.d<br>Regulators 9.15, 9.18<br>Provider 9.23.c |
| 8. | Benefits and Risks | Chief investigator 9.3.a, 9.4<br>Research team 9.8<br>Sponsor 9.10.h<br>Research site 9.15<br>Regulators 9.18<br>Employer 9.21 |
| 9. | Approval | Chief investigator 9.2.c, 9.5<br>Funder 9.9.d<br>Sponsor 9.10.f<br>Research site 9.14.d<br>Regulators 9.18 |
| 10. | Information about the Research | Chief investigator 9.2.f<br>Funder 9.9.e<br>Sponsor 9.10.e |
| 11. | Accessible Findings | Chief investigator 9.2.j<br>Funder 9.9.e<br>Sponsor 9.10.e |

| Principle | | Responsibility |
|---|---|---|
| 12. | Choice | Chief investigator 9.2.e<br>Research team 9.6.d, 9.7.a, 9.8 |
| 13. | Insurance and Indemnity | Sponsor 9.10.d, h |
| 14. | Respect for Privacy | Chief investigator 9.2.g<br>Funder 9.9.e<br>Sponsor 9.10.e<br>Research site 9.14.d<br>Regulators 9.16.d |
| 15. | Compliance | Chief investigator 9.2.a, i<br>Research team 9.6.c, 9.8<br>Funder 9.9.e<br>Sponsor 9.10.a, i, 9.11<br>Research site 9.15, 9.16.d<br>Regulators 9.15, 9.16.d, 9.17<br>Employer 9.20.a, b, d, 9.21, 9.22 |
| 16. | Justified Intervention | Chief investigator 9.2.a, b<br>Research team 9.7.a<br>Sponsor 9.10.a |
| 17. | Ongoing Provision of Treatment | Funder 9.9.b<br>Sponsor 9.10.h<br>Research site 9.16.c<br>Provider 9.23.b |
| 18. | Integrity of the Care Record | Chief investigator 9.2.i<br>Sponsor 9.10.i |
| 19. | Duty of Care | Research team 9.6.e<br>Provider 9.23.b |