Isle of Man Government
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Research Governance and Regulation
Public Health Directorate

Research Governance Framework for Health and Social Care Research

Information contained within this document is correct as at April 2023

Contents

Glossary

Chief Investigator (CI)	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 research project
Health Research	Any research into matters relating to people's physical or mental health.
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 & Service Users	Recipients of health care, social care or other services or support provided by or on behalf of the health or social care organisation, Manx Care.
Principle Investigator	The lead researcher for a research project at a particular site. Had the responsibility for the conduct of the project at the 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.
Research Site	The organisation with the 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 Isle of Man specifically for 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 circumstance.
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.

Introduction and background

1. Context

1.1 The Research Governance and Regulation (RGR) team is committed to an environment where: patients, service users, and the public are offered 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 and 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 streamlined and getting a decision is efficient, with well communicated timelines;
- researchers find it straightforward and attractive to do high-quality, ethical research;
- employees in Manx 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 Isle of Man 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 that is required, not into navigating bureaucracy or duplicating previous work; and
- research projects should be registered in a public database, the data and tissue they collect can be made available for future analysis (when appropriate with adequate consent and privacy safeguards), and research findings get published publically and summarised for those who took part in them.

2. Purpose

2.1 The Isle of Man Research Governance 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. They describe ethical conduct and proportionate management of health and social care research, so as to support and facilitate high-quality research in the Isle of Man that has the confidence of patients, service users, and the public and that demonstrates nationally and internationally that the Isle of Man is a good place to undertake research.

2.2 This policy framework sets out principles and responsibilities at a high level that take account of relevant legislation in the Isle of Man. It is based upon the Health Research Authority's (HRA) UK policy framework for health and social care research[1] and will be guided by procedures developed by the HRA, to ensure a consistent approach to co-ordinating and standardising regulatory practice. This will achieve compatibility between the UK and Isle of Man for the management and conduct of health and social care research.

3. Scope

3.1 This research governance framework adopts the HRA's definition of research, as set out in their online decision tool[2]. Studies considered to be research are those in which:

- participants are randomised to different groups and any treatment, care or services are allocated by randomisation;
- the study protocol demands changing treatment, care or services from accepted standards for any of the patients or service users involved; or
- the study is designed to produce generalisable or transferable findings.

[1] Health Research Authority (2017) UK policy framework for health and social care research. Available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf

[2] Health Research Authority (*n.d.*) Is my study research? Available at: http://www.hra-decisiontools.org.uk/research/

3.2 The specific types of research that fall within the remit of the RGR team have been determined based on the types of research that fall within the HRA's remit, which are set out in their second online decision tool[3]. This tool has been adapted for use within the Isle of Man context with permission from the HRA. Research studies within the RGR team's remit are those which:

- involve staff within Manx Care or linked providers;
- involve potential research participants identified in the context of, or in connection with, their past or present use of Manx Care or linked services, including participants recruited through these services as healthy controls;
- involve the collection, processing or use of information relating to any past or present users of Manx Care or linked services; involve potential research participants identified because of their status as relatives or carers of past or present users of Manx Care or linked services;
- are a clinical trial;
- involve a medical device;
- involve exposure to any ionising radiation;
- involve the processing of disclosable protected information on the UK Register of the Human Fertilisation and Embryology Authority (HFEA) by researchers, without consent;
- involve the collection, storage or use of human tissue;
- involve at any stage procedures involving adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity;
- relate to health and/or social care and involve offenders; or
- involve xenotransplantation.

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. For further information, please see the NIHR Centre for Engagement and Dissemination.

[3] Health Research Authority (*n.d.*) Do I need NHS REC review? Available at: http://www.hra-decisiontools.org.uk/ethics/

4. Implementation

4.1 This policy framework aims to detail what should happen with health and social care research within the RGR team's remit. It will not add to the workload of researchers or others with responsibilities under this framework. The intention is to provide clear information about what responsibilities stakeholders in research have, with details about research strategy to be available in the Research Strategic Plan. The document aims to streamline the process of research to make research easier, more attractive, and efficient to conduct.

5. Responsibilities and maintenance

5.1 The policy framework reflects the research legislation on the Isle of Man. The policy framework is consistent with recognised ethical standards and with models of good practice in the UK, and wider afield, as they apply to particular types of research involving human participants. In reflecting these, the policy framework has taken care to recognise the value of their proportionate application to different types of research.

5.2 This policy is applicable to health and social care research within the RGR team's remit, and although it follows the basic principles of the UK guidance, it must be followed for any research conducted on the Isle of Man whether or not it has already been approved in the UK.

5.3 Maintenance of the policy framework is undertaken by the RGR team in conjunction with the DHSC and Manx Care. It will be revised in light of significant developments or otherwise at intervals as determined by the RGR team.

6. Audience

6.1 This document is aimed primarily at individuals and organisations with responsibilities for the management and conduct of health and social care research. Summaries will be made available for patients, service users, or the public if requested.

Principles

7. Principles that apply to all health and social care research conducted on the Isle of Man

7.1 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 Isle of Man 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.

Principle 7: Legality

The researchers and sponsor familiarise themselves with and follow 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.

Principle 9: Approval

A research project is started only if the IOMREC, the RGR team, and any other relevant approval body 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 is made publicly available before they start (unless a deferral is agreed by the RGR team).

Principle 11: Accessible Findings

The findings for all research, 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 and the RGR team. In addition, where appropriate, information about the findings of the research is made available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

Principle 12: Choice

Research participants 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 the IOMREC 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 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. This insurance and indemnity must be in line with UK standards and agreed by the RGR team in advance of the conduct of research.

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. Any data processed for research should be done so in accordance with the General Data Protection Regulation (GDPR).

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 regulators, and other bodies, both on the Isle of Man and in the UK.

8. Principles that apply to interventional health and social care research

8.1 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 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 roles and responsibilities. Dialogue and collaboration have a central role within a research project. Clear, upfront discussion of issues and agreement of 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 and expertise with novices.

10. Chief investigators

10.1 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, 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, that it effectively incorporates Patient and Public Involvement and Engagement (PPIE), that it is scientifically sound, safe, 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 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 the RGR team, the IOMREC, 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. satisfying themselves (preferably through PPIE with a Research User Group) 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;

f. adhering to the agreed arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by the RGR team);

g. adhering to the agreed arrangements for making data and tissue accessible, with adequate approvals, consent and privacy safeguards, in a timely manner after the research has finished

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

i. adhering to the agreed requirements, 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.

10.2 Research should 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 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, helping to avoid subsequent amendments. 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.

10.3 Research proposals, protocols and procedures should be clear, comprehensive and easily accessible to the RGR team, the IOMREC and 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. As research can be dynamic and iterative in nature, there is often an expectation or requirement for documents to be revised and updated during the lifespan of studies. It is important to ensure that changes to the research proposal or protocol are submitted for review, if expected or required, by the RGR team, the IOMREC and any other relevant approval bodies and, if approved , that they are introduced uniformly across all relevant research sites. Approval for amendments from the RGR team and the IOMREC will be proportionate to the changes, and processed efficiently to minimise delays and disruption to the study.

11. Research teams

11.1 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 sponsor 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 conducted in both the UK and Isle of Man, if the chief investigator is not based on the Island, a principal investigator must be appointed who takes responsibility for the conduct of the research at the Isle of Man 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 IOMREC 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.

11.2 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, 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, including, but not limited to, the RGR team.

11.3 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. Overwhelming information does not make a potential participants choice more or less informed, however it could serve as a barrier to participation.

12. Funders

12.1 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) demonstrating to the RGR team 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 and providing information to the RGR team about the attribution of costs to confirm that costs to all parties (including excess treatment costs)

have been identified and described in accordance with the RGR team 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 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 and conditions of funding to promote compliance with this policy framework, in particular to encourage arrangements for making information about research publicly available before it starts (unless a deferral is agreed by the RGR team) 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.

13. Sponsors

13.1 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 the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research. 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), 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 the RGR team); 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 to participants;

f) ensuring that, where expected or required, the research has approval from the RGR team, the IOMREC 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.

13.2 Sponsors of clinical trials of investigational medicinal products have particular legal duties. An IOM Policy Framework for Clinical Trials into Investigational Medical Products will be developed.

14. Contract research organisations

14.1 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.

15. Research sites

15.1 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 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;

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 the RGR team, the IOMREC 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); and

e) ensuring that the research activities are conducted in accordance with their applicable legal obligations.

15.2 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 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.

b) 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, the RGR team, and research team about the timetable for starting the research at that location, particularly for multi-centre projects.

c) 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. Good Clinical Practice 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.

d) 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 multicentre projects or when they do repeat business with chief investigators, sponsors etc. already known from previous projects.

e) Research involving participants who are transferred to another research site is expected to be facilitated by the 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.

f) 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.

16. Regulators of professions

16.1 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.

17. Other regulators

17.1 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 Isle of Man and UK with a remit for activities related to health and social care research.

17.2 If approval is sought from a UK regulator for a study that is conducted in part in the UK, this will generally apply for research conducted in the Isle of Man (if the Isle of Man is used as a study site). This is the case for approval gained from HRA, HFEA, Medicines and Healthcare products Regulatory Agency (MHRA), the Administration of Radioactive Substances Advisory Committee (ARSAC) and the Human Tissues Authority (HTA) (which licenses storage of tissue for research, not the research itself).

17.3 Although regulators in the Isle of Man and UK aim for a consistent approach, approvals in the UK may not automatically apply to research conducted on the Isle of Man. UK HRA

and Research Ethics Committee (REC) approval are not applicable on the Isle of Man, therefore specific approval must be sought through the RGR team and the IOMREC.

17.4 If research has not been approved by any of the UK based authorities able to provide approval for studies on the Isle of Man (such as HRA, HFEA, MHRA, the ARSAC and the HTA), or the study is being conducted on the Isle of Man only, then regulatory approval must be sought from the RGR team who will consult UK regulatory bodies as necessary.

18. Employers

18.1 Employers are the organisations employing the chief investigator and members of the research team. 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 (e.g. funders, sponsors, collaborators, commercial partners) 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 (see paragraphs 10.1.d, 11.1.a, 13.1.b, 15.2.c); 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.

18.2 Employers of research staff should ensure appropriate individual learning and competence. This includes acknowledging existing experience, qualifications and skills. 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.

18.3 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.

19. Health and social care providers

19.1 Providers are organisations that provide health or social care. This includes organisations providing services under contract with Manx Care or privately run treatment centres, or care homes. 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

b) retaining responsibility for the care of their patients and service users as research participants; and

c) working in accordance with this policy framework.

Appendix

Appendix 1: 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:

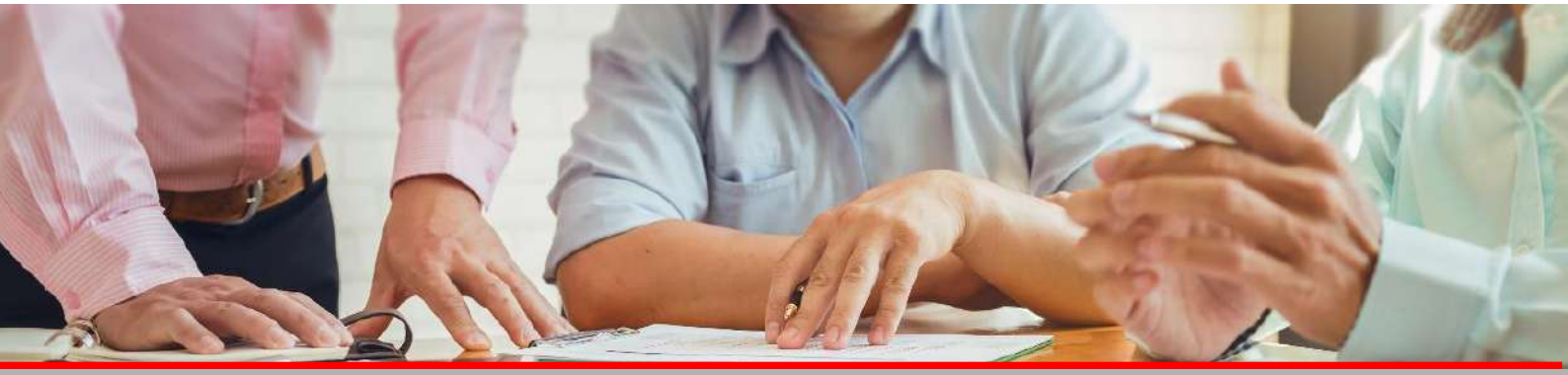
PRINCIPLE	RESPONSIBILITY
(1) Safety	Chief Investigator 10.2.a, i Research team 11.1.e Sponsor 13.1.a, g, i Employer 18.1.a, 18.2
(2) Competence	Chief Investigator 10.2.d Research Team 11.1.a, b Sponsor 13.1.b, h Research site 15.2.c Employer 18.1.c, 18.2
(3) Scientific and Ethical Conduct	Chief Investigator 10.1.a,b,c, 10.2, 10.3 Funder 12.1.a Sponsor13.1.a, f Research site 15.1.d, 15.2.c Regulators 17.1 Employer 18.1.b
(4) Patient, Service User and Public Involvement	Chief Investigator 10.1.a, 10.2 Funder 12.1.a Sponsor 13.1.a
(5) Integrity, Quality and Transparency	Chief Investigator 10.2, 10.3 Research team 11.1, 11.1.c, 11.2.c Funder 12.1.a Sponsor 13.1.a, c, 14.1 Research site 15.1.b, c, 15.2.e Employer 18.1.a, d, 18.3

PRINCIPLE	RESPONSIBILITY
(6) Protocol	Chief Investigator 10.1.a, b, i, 10.2, 10.3 Research team 11.1.c Sponsor 13.1.a, i
(7) Legality	Chief Investigator 10.1.a Research team 11.3 Sponsor 13.1.a, 13.2 Research site 15.2.c Regulators 17.1 Provider 19.1.c
(8) Benefits and Risks	Chief Investigator 10.2 Research team 11.3 Sponsor 13.1.h Regulators 17.1 Employer 18.2
(9) Approval	Chief Investigator 10.1.c, 10.3 Funder 12.1.d Sponsor 13.1.f Research site 15.1.d Regulators 17.1
(10) Information about the Research	Chief investigator 10.1.f Funder 12.1.e Sponsor 13.1.e
(11) Accessible Findings	Chief Investigator 10.1.j Funder 12.1.d Sponsor 13.1.e

PRINCIPLE	RESPONSIBILITY
(12) Choice	Chief Investigator 10.1.e Research team 11.1.d, 11.2.a, 11.3
(13) Insurance and Indemnity	Sponsor 13.1.d, h
(14) Respect for Privacy	Chief Investigator 10.1.g Funder 12.1.e Sponsor 13.1.e Research 15.1.d Regulators 15.2.c
(15) Compliance	Chief Investigator 10.1.a, i Research team 11.1.c Funder 12.1.e Sponsor 13.1.a, i, 13.2 Research site 15.2.c Regulators 15.2.c, 16.1 Employer 18.1.a, b, d, 18.2, 18.3
(16) Justified Intervention	Chief Investigator 10.1.a, b, Research team 11.2.a Sponsor 12.1.a
(17) Ongoing Provision of Treatment	Funder 12.1.b Sponsor 13.1.h Research site 15.2.b Provider 19.1.b
(18) Integrity of the Care Record	Chief investigator 10.1.i Sponsor 13.1.i
(19) Duty of Care	Research team 11.1.e Provider 19.1.b

Document Change Record

Version	Description
1.0 April 2023	First version created.



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