Isle of Man Government
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Research Governance and Regulation
Public Health Directorate

Governance for the Isle of Man Research Ethics Committee

The information contained within this document is correct as at December 2022

Contents

1. Introduction

1.1 What are research ethics committees and what do they do?

1.1.1 A Research Ethics Committee ("REC") is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.

1.1.2 Public Health within The Isle of Man Cabinet Office provides for a REC such that research proposals relating to health and social care can be reviewed in regard to ethical standards.

1.1.3 The REC is made up of members of the public, as well as people with specific knowledge that can help the Committee understand particular aspects of research proposals. All the Committee members are given training to understand research ethics.

1.1.4 When they review research proposals, RECs are independent of the researchers, the organisations funding the research and the organisations where the research will take place.

1.2 Why are RECs needed?

1.2.1 Research is a core part of the Health and Social Care. Research enables the services provided by the Isle of Man Government to improve the current and future health and well-being of the people of the Isle of Man. However, research sometimes involves a degree of risk because researchers cannot predict the outcome with certainty. It may also involve additional burdens or intrusions exceeding those involved in normal care.

1.2.2 Researchers must satisfy the REC that the research they propose will be ethical and worthwhile. Research Governance and Regulation (RGR) and the REC has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society.

1.2.3 In this way, a REC aims to protect people who take part in research. This helps promote public confidence about the conduct of researchers and the dignity, rights, safety

and well-being of research participants. As a result, more people will be encouraged to take part in research. This in turn leads potentially to more, better and quicker improvements in health and social care.

1.2.4 RGR enables ethical research in partnership with researchers and their sponsors. The REC review complements researchers' own consideration of the ethical issues raised by their research and their involvement of service users, care professionals, methodologists and statisticians, academic supervisors, data protection officers etc. at the design stage.

1.3 What is the purpose of this document?

1.3.1 Governance arrangements for the REC is a policy document of Public Health within the Cabinet Office. It describes what is expected from the REC that reviews research proposals relating to health and social care in the Isle of Man. It also explains when review by this Committee is required.

1.3.2 This policy covers the principles, requirements and standards for the Research Ethics Committee, including their remit, composition, functions, management and accountability.

1.3.3 Where a research study does not require review by the REC as determined in this document, review may be undertaken by research ethics committees established by universities or other institutions.

2. Purpose and scope

2.1 Summary

2.1.1 The principles, requirements and standards set out in this document apply to the Isle of Man Research Ethics Committee (IOMREC) reviewing research that relates to health and social care research carried out on the Isle of Man.

2.2 Purpose

2.2.1 Public Health are committed to enhancing the contribution research can make to the provision of health and social care on the Isle of Man. Research is essential for protecting and improving health and well-being, as well as for achieving modern, effective care services. At the same time, research can sometimes involve an element of risk, because research can involve trying something new. It is important that any risks are minimised and do not compromise the dignity, rights, safety and well-being of the people who take part. Proper governance arrangements are essential to ensure that service users and the public can have confidence in, and benefit from, high-quality, ethical research.

2.2.2 The public has a right to expect the highest scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements. The Isle of Man's Research Governance Framework sets out the responsibilities for the various elements of research governance. Governance arrangements for the IOMREC sets out principles, requirements and standards for IOMREC which reviews research proposals relating to health and social care research conducted on the Isle of Man.

2.3 Scope

Policy requirements for research ethics committee review

2.3.1 This document applies, and the requirement for IOMREC review must be considered where research is conducted on the Isle of Man and relates to any aspect of health and social care.

2.3.2 IOMREC review, as described in this document, is required if the researcher conducting the project answers yes to any of the following questions:

a) Will your research involve staff within Manx Care or linked providers?

b) Will your research 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?

c) Will your research involve the collection, processing or use of health or social care data relating to any past or present users of Manx Care or linked services?

d) Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of Manx Care or linked services?

e) Is your research a clinical trial?

f) Will your research involve a medical device?

g) Does your research involve exposure to any ionising radiation?

h) Does your research involve the processing of disclosable protected information on the UK Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

i) Will your research involve the collection, storage or use of human tissue (i.e. any material consisting of or including human cells)?

j) Will your research involve at any stage procedures (including use of tissue or information) involving adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?

k) Will your research relate to health and/or social care and involve offenders or those working within the Criminal justice system?

l) Does your research involve xenotransplantation?

2.3.3 Care providers owe a duty of care to users of their services. They are responsible for ensuring that ethical issues and risks in the course of the care they provide are considered. The IOMREC is not expected to consider applications in respect of activities that are not research, for example clinical audit, service evaluation and public health surveillance. Guidance on differentiating such activities from research is available from RGR. Any IOMREC member who gives advice on the ethics of such activities should make it clear that they are not doing so in their capacity as an IOMREC member and should be aware that they may not be indemnified by the Isle of Man Government for any such advice.

3. Role and remit

3.1 Summary

3.1.1 The IOMREC should act in an efficient, accountable and independent way to protect the dignity, rights, safety and well-being of people who take part in research.

3.2 Role of research ethics committees

Protection of research participants

3.2.1 Whatever the research context, the interests of participants come first. Their dignity, rights, safety and well-being must be the primary consideration in any research proposal, as well as in the IOMREC review. The IOMREC must be assured that there are proportionate safeguards to protect people taking part in research.

Science and society

3.2.2 The IOMREC act primarily in the interests of research participants. The interests of researchers and research are always secondary to the dignity, rights, safety and well-being of people taking part in research. The IOMREC also take into account the interests and safety of the researchers, as well as the public interest in reliable evidence affecting health and social care, and enables ethical and worthwhile research of benefit to participants or to science and society.

3.2.3 The benefits and risks of taking part in research, and the benefits of research evidence for improved health and social care, should be distributed fairly among all social groups and classes. Selection criteria in research protocols should not unjustifiably exclude potential participants, for instance on the basis of economic status, culture, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. IOMREC should take these considerations into account in reviewing the ethics of research proposals, particularly those involving under-researched groups.

Proportionate scrutiny

3.2.4 IOMREC review is proportionate to the scale and complexity of the research proposed. Research proposals that present no material issues of research ethics do not warrant consideration at a full meeting of the IOMREC. They should be identified on receipt in accordance with standard operating procedures so that the ethical review may be undertaken by a sub-committee of the IOMREC. The IOMREC's opinion on such proposals may be given by the sub-committee.

3.2.5 The IOMREC is independent and impartial. The IOMREC's opinion must be free, and must be seen to be free, from conflicts of interest. This includes freedom from pressures of:

a) political influence;

b) institutional affiliation;

c) trades union or profession-related interests;

d) direct or indirect financial inducement or any impression thereof;

e) coercion;

f) strategic concerns;

g) market forces; and

h) agency-, discipline- or topic-related bias.

3.2.6 Although the members of the IOMREC are appointed by the Isle of Man Director of Public Health, their decisions to advise are independent of Public Health, Department of Health and Social Care, Manx Care and the wider Isle of Man Government. Care providers, regulators, and the Government may not interfere in the deliberations or opinions of the IOMREC. The IOMREC plays no part in management decisions about the provision of care services or support for a research project.

3.2.7 The protection of research participants and the enabling of ethical research are best served by co-operation and communication between all those who share responsibility for the research. Except when it would compromise their independence, the IOMREC should collaborate appropriately with regulators, actual and potential research participants, researchers, funders, sponsors, employers, organisations providing care and care professionals. The IOMREC should also collaborate with RECs in the UK where appropriate, for example to share relevant information from previous applications or to share decisions around current research proposals taking place in both Isle of Man and UK sites.

Competence and efficiency

3.2.8 The IOMREC review must be competent, timely and authoritative. The membership, ongoing training and performance management of the IOMREC, as well as the operational and administrative support it receives, are arranged to maximise the quality, rigour and promptness of IOMREC review and the efficiency of their decision-making processes. The IOMREC should give its opinion within sixty calendar days of receipt of a valid application. The sixty-day period excludes the time an applicant may take to supply additional information requested by the IOMREC. The IOMREC may make a request for additional information once only, which must be in writing.

3.2.9 The IOMREC must operate according to the law in the conduct of their business, for example by following due process and complying with their own standard operating procedures. They must also have regard to all statutory provisions for ethical review of particular types of research, including research involving adults lacking capacity.

3.2.10 It is not the role of the IOMREC to offer a legal opinion on research proposals, but it may advise the researcher, sponsor or host organisation whenever it considers that legal advice might be helpful to them. Researchers, sponsors and organisations where the research is carried out remain responsible for making sure the research is conducted in accordance with the requirements of law, relevant regulators and guidance, including those relating to data protection, capacity, human tissue and Good Clinical Practice.

Compliance and enforcement

3.2.11 If an IOMREC review is required (see Section 2), organisations providing care must ensure that the research they host has a favourable IOMREC opinion. The research may not begin until a favourable IOMREC opinion has been given.

3.2.12 If an IOMREC review is required, sponsors may not allow any research they are sponsoring to begin without a favourable IOMREC opinion.

3.2.13 The chief investigator is the researcher who takes primary responsibility for the design, conduct and reporting of the research. The chief investigator is responsible for the content of the IOMREC application and for the scientific and ethical conduct of the research.

3.2.14 Although the IOMREC must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research, they are not responsible for enforcement if the research turns out to be unsafe or is not carried out as agreed. This responsibility rests with the relevant regulators or comparable bodies, as well as with the researchers' employer and sponsor and with the care organisations where the research takes place (or through which the researchers have access to participants, or their tissue or information) or where the researchers have contracts.

3.2.15 RGR should agree channels of communication on behalf of the IOMREC with the relevant bodies in order to exchange advice. The IOMREC should use these channels to alert

the bodies responsible for enforcement if they have grounds to suspect that enforcement action is warranted.

3.2.16 The IOMREC will receive annual reports about the progress of the research they have reviewed. These reports explain any developments affecting participants' dignity, rights, safety or well-being. The IOMREC should reconsider its favourable opinion in light of pertinent information that comes to its attention. If the IOMREC, given that information during its initial review, would not have reached a favourable opinion, it should notify any relevant statutory enforcement authority. Where the law does not specify the responsibility for enforcement, the IOMREC should notify the chief investigator and the sponsor that its opinion is no longer favourable.

3.3 Remit

3.3.1 The IOMREC has been established and will operate in accordance with the principles, requirements and standards set out in this document.

3.3.2 Public Health is the appointing authority that established the IOMREC. They will appoint and indemnify their members, seek their recognition if the law requires it and monitor their performance through annual reports. The appointing authority identifies a named officer who has responsibility for governance of the IOMREC on behalf of the Director of Public Health. The Director of Public Health has overall accountability. The responsibilities and functions of appointing authorities are listed in Annex D.

4. Composition and membership

4.1 Summary

4.1.1 The IOMREC harmonise public and professional opinion in reaching decisions about proposed research. The members reflect the diversity of society and do not represent vested interests.

4.2 Composition of research ethics committees

Nature of membership

4.2.1 The membership of the IOMREC should allow for a sufficiently broad range of experience and expertise so that the rationale, aims, objectives and design of the research proposals that it reviews can be effectively reconciled with the dignity, rights, safety and well-being of the people who are likely to take part.

4.2.2 The IOMREC is expected to reflect current ethical norms in society as well as their own ethical judgement. IOMREC members may come from groups associated with particular interests but they are not representatives of those groups. IOMREC members are appointed in their own right to participate in the work of IOMREC as equal individuals of sound judgement, relevant experience and adequate training in research ethics and IOMREC review.

4.2.3 The IOMREC should contain a mixture of people who reflect the currency of public opinion ('lay' members), as well as people who have relevant formal qualifications or professional experience that can help the IOMREC understand particular aspects of research proposals ('expert' members).

4.2.4 The IOMREC should reflect the diversity of the adult population of society, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. This applies to both the lay and expert membership. Public Health as the appointing authority should take steps to

publicise the work of the IOMREC and encourage applications for membership from groups who are underrepresented.

Appointment of members

4.2.5 Appointment of members should be by an open and fair process, compatible with the Nolan standards[1]. Vacancies should be filled following public advertisement in the press, and/or by advertisement via local professional and other networks as most appropriate to the vacancy to be filled. Potential candidates should be required to complete an application form and be interviewed. There should be standard written procedures for application and selection, which should comply fully with equality and human rights legislation.

Expert and lay members

4.2.6 The IOMREC should have expert members to ensure methodological and ethical expertise about research in care settings and in relevant fields of care, as well as professional expertise as care practitioners. This expertise should be appropriate to the types of research proposal the IOMREC reviews.

4.2.7 Lay members are people who are independent of care service delivery. Their primary professional interest is not care-related research. At least one half of the IOMREC's membership should be lay. At least half the lay membership should comprise people who have never been care professionals researchers in a care field, or chairs, members or directors of care service bodies or organisations providing care.

4.2.8 RGR should adopt and publish operational definitions of expert and lay members, taking into account other applicable requirements, and support the IOMREC to ensure an appropriate balance of members[2].

[1] The Nolan Standards are the basis of the ethical standards expected of Public Office holders in the UK. They detail the even principles of public life which are: selflessness, integrity, objectivity, accountability, openness, honesty, and leadership (UK Government website, 2018. Retrieved from: https://www.gov.uk/government/publications/the-7-principles-of-public-life)
[2] See Annex D: Definitions of Expert and Lay members of IOMREC

Affiliations

4.2.9 The IOMREC is constituted, and operates, independently of organisations that sponsor, conduct or host research. Members should absent themselves during consideration of research proposals that could be seen to create a potential or actual conflict of interest. IOMREC meetings should be attended so as to accommodate these absences while remaining quorate.

Quorum

4.2.10 For the purpose of effective debate, the IOMREC may have up to twelve members in total, including the Chair. A quorate meeting is one attended by no fewer than four members, including:

a) the Chair or, if unavailable, the vice-Chair or acting Chair;

b) one expert member; and

c) one lay member.

4.2.11 The IOMREC should be constituted so that it can function quorately for the duration of its scheduled meetings.

Officers

4.2.12 The IOMREC has a Chair and a Vice-Chair. If both are unavailable, another member will be acting Chair.

4.2.13 Appointees should receive any necessary supplementary training (e.g. in chairing skills) prior to taking office.

4.2.14 Officers are appointed for a specified period not exceeding five years. Appointments may be renewed. However, members should not normally serve more than two consecutive terms of five years. An acting Chair's appointment ceases when one of the other officers becomes available again or when his or her term as a member expires, whichever is sooner.

4.2.15 Officers may resign from office at any time by notification in writing to the Director of Public Health. They may continue as members of the IOMREC, subject to the disqualification and resignation procedures of its appointing authority.

Referees

4.2.16 The IOMREC may seek advice from specialist referees on any aspects of a research proposal that fall beyond the members' expertise. The IOMREC may seek referees' advice at their discretion or because the law requires them to do so. Referees' advice should only be sought on issues material to the IOMREC's review of the research proposal, i.e. issues of research ethics.

4.2.17 Terms of reference for referees should be established. Referees do not count towards the quorum or vote on decisions. They are not involved in any IOMREC business apart from advising on the issues put to them. Their advice is recorded in the minutes of the relevant IOMREC meeting.

Observers

4.2.18 IOMREC meetings are not public meetings. External observers may attend following a written invitation which states the terms and conditions of their attendance. Attendance will be agreed by the IOMREC and minuted accordingly.

4.2.19 Representatives of RGR may request to attend and observe any meeting with approval granted by the Chair. Approval for such requests will not be unreasonably withheld.

4.2.20 The Director of Public Health can attend and observe any meeting of the IOMREC with no prior notice.

4.2.21 Observers play no part in the deliberations of the IOMREC.

Advice to applicants

4.2.23 The IOMREC should take steps to facilitate communication with their potential or actual applicants through RGR. The IOMREC may designate a point of contact for more

detailed discussion. This includes advice about whether a proposed activity requires IOMREC review, or the content, submission or review of an application. The point of contact may be any of the IOMREC's members, officers of RGR or administrative staff supporting IOMREC.

Delegation

4.2.24 The IOMREC can appoint an executive sub-committee consisting of its members. The executive subcommittee can exercise any of the IOMREC's functions on its behalf, in accordance with standard operating procedures. In particular, the executive sub-committees can review and give an opinion of:

a) research proposals that present no material ethical issues;

b) information further to earlier review in full committee;

c) substantial amendments; and

d) annual progress reports.

4.2.25 If the IOMREC issues a provisional opinion reached in full committee, it may delegate the responsibility for determining its final opinion to the executive sub-committee of specified members.

4.2.26 Responsibilities of IOMREC officers may be delegated to RGR staff where the matters are administrative, in accordance with standard operating procedures. In particular, RGR officers may check evidence provided by applicants in response to requests for further information and issue letters confirming the IOMREC's opinion.

4.3 Conditions of membership

Terms of appointment

4.3.1 Written terms of appointment for IOMREC members should include the following:

a) duration of appointment;

b) renewal policy;

c) disqualification and resignation procedures;

d) policy concerning declaration of interests; and

e) details of allowable expenses.

4.3.2 IOMREC members are appointed for fixed terms not exceeding five years. Appointments may be renewed. However, members should not normally serve more than two consecutive terms of five years. Where a member is appointed as an officer during their second term, their membership may be extended until the completion of their term as an officer. Where the normal period of membership has expired, Public Health as the appointing authority may exceptionally extend a member's term while new members are appointed. Such extension should be for no longer than a year unless the member has rare expertise that is essential for the work of the IOMREC, in which case the appointment may continue to be renewed until a suitable replacement is found.

4.3.3 Former members may be reappointed to the IOMREC no sooner than two years after the end of their last term.

4.3.4 Attendance at meetings of other research ethics committees (such as an academic ethics committee) as a co-opted member, referee or observer is encouraged, in the interests of training and consistency.

Composition and membership

4.3.5 IOMREC members are normally required to attend in full at least two thirds of all scheduled IOMREC meetings in each year, barring exceptional circumstances. Attendance at scheduled sub-committee meetings should be taken into account.

4.3.6 IOMREC members may resign at any time in writing to the Chair or Director of Public Health.

4.3.7 IOMREC members should normally allow publication of their full name and, if applicable, their profession and institutional affiliation. In the interests of transparency and probity, any potential conflict of interest should be recorded and published with these personal details.

4.3.8 IOMREC members are unpaid volunteers. IOMREC may not charge an application fee or seek any other financial contribution or donation for or on considering a research proposal for which their review is required. Members receive no payment for contributing to the review of applications at scheduled meetings or for attending such meetings. The Chair is eligible to claim Attendance Allowance in line with Payment of Members' Expenses (Specified Bodies) (Amendment) Order 2018.

4.3.9 Travel expenses incurred during the course of an IOMREC member's duties are reimbursed in line with Payment of Members' Expenses (Specified Bodies) (Amendment) Order 2018.

Training

4.3.10 As a condition of appointment, IOMREC members must agree to take part in initial and continual training appropriate to their role.

Confidentiality

4.3.11 IOMREC members must maintain confidentiality regarding applications, meeting deliberations, information about research participants and related matters.

Indemnity

4.3.12 Each IOMREC member must be supplied with a personal statement regarding the indemnity provided by the appointing authority and its conditions.

Conduct

4.3.13 The meetings and proceedings of the IOMREC and their sub-committees are conducted in accordance with standard operating procedures.

5. Requirements of research ethics review

5.1 Summary

5.1.1 There is a standard process for applying to the IOMREC. RGR also review applications in accordance with standards.

5.2 Applying for research ethics committee review

5.2.1 Applications to the IOMREC should be made in accordance with a process set out in standard operating procedures for the IOMREC and in written guidance for applicants. This process covers the application from submission to opinion and on to subsequent notification of substantial amendments, annual progress reporting etc.

5.2.2 RGR should be prepared to offer accurate advice and guidance to potential and actual applicants. This includes being able to answer queries about whether IOMREC review is required, the application process (including the requirements for a valid application) and the review process (including the issues the IOMREC considers before reaching an opinion).

5.3 Requirements for a favourable opinion

5.3.1 The IOMREC gives a favourable opinion if it is assured about the ethical issues presented by the proposed research. These issues may vary, depending on the research in question. IOMREC members receive training and guidance about the issues they should consider, both in general and in particular cases. The training and guidance reflect recognised standards for ethical research, such as the Declaration of Helsinki, and take account of applicable statutory requirements for ethical review.

5.4 Principles of research ethics committee review

5.4.1 The IOMREC will receive training, guidance, standard operating procedures and quality assurance in order to support them to identify the relevant issues and consider them appropriately.

5.4.2 The IOMREC will receive guidance on the wider regulatory and governance environment for research and its reliability so that they can assess the assurances they receive. The IOMREC will accept credible assurances that others will do what is expected of them.

(a) The IOMREC need not reconsider the quality of the science, as this is the responsibility of the sponsor. It is expected that research will have been subject to review by one or more experts in the field (known as 'peer review'). The IOMREC will be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.

(b) The IOMREC can expect to rely on established mechanisms for ensuring the proper conduct of the research at individual sites. Organisations providing care that are subject to the Isle of Man's Research Governance Framework are responsible for the management, governance and monitoring of the research they host. Other standards assurance processes, such as inspection or accreditation of sites by regulators, may also be adequate for the IOMREC to be assured about the suitability of those sites.

(c) Where others have a regulatory responsibility, the IOMREC can expect to rely on them to fulfil it. If the law gives another body duties that are normally responsibilities of the IOMREC according to this document, the IOMREC will not duplicate them.

5.5 Expedited review

5.5.1 Some research requiring IOMREC review in accordance may be suitable for expedited review, e.g. because of a public health emergency or because the proposal presents no material issues of research ethics.

5.5.2 Standard operating procedures for expedited review of research proposals should specify:

a) the nature of the applications, amendments or other considerations that are eligible for expedited review;

b) the application and review process;

c) the quorum requirements; and

d) the status of decisions (e.g. whether they require ratification in full committee).

5.6 Transparency

5.6.1 The IOMREC should publish an annual summary of their opinions, whether favourable or otherwise.

6. Standard Operating Procedures

6.1 Summary

Common working practices promote efficiency and enable the IOMREC to work together as part of a consistent Research Ethics Service. Published standards allow researchers and the public to expect transparent accountability.

6.2 Purpose

Standard operating procedures for the IOMREC are essential to an efficient, consistent and accountable Research Ethics Service.

6.3 Content

6.3.1 Standard operating procedures take account of applicable laws and national guidance, advice and exemplars. They also reflect relevant internationally recognised principles and standards.

6.3.2 Standard operating procedures provide the operational detail for meeting the principles, requirements and standards set out in this document.

6.4 Compliance and accountability

6.4.1 The IOMREC adopts standard operating procedures and common working practices approved by Public Health, Cabinet Office.

6.4.2 IOMREC acts in accordance with their standard operating procedures and are ultimately accountable to their appointing body Public Health, for their governance in this respect.

6.4.3 IOMREC standard operating procedures are publicly available from the RGR website.

Annex A: Research Governance and Regulation

Research Governance and Regulation (RGR)

a) makes arrangements for the appointment of such administrative and other staff for the IOMREC as it considers necessary to enable them to perform their functions;

b) makes arrangements to provide the IOMREC with such accommodation and facilities as it considers necessary to enable them to perform their functions (including arrangements for such administration, maintenance, cleaning and other services as it considers necessary);

c) will ensure that they hold adequate finance to reimburse expenditure incurred by members in line with Payment of Members' Expenses (Specified Bodies) (Amendment) Order 2018;

d) collaborates with the IOMREC to establish sufficient provision for IOMREC review, according to a common administrative structure, so that applications are received and processed in a timely and efficient manner;

e) ensures that a rotation system (e.g. staggered tenure) is in place for IOMREC members so as to achieve business continuity, the development and maintenance of expertise within each IOMREC and the regular refreshment of debate;

f) handles appeals against the unfavourable opinions of the IOMREC;

g) develops and manages an annual training programme for IOMREC members and administrative staff and provides resources to support this training for the IOMREC;

h) develops, implements and maintains standard operating procedures for the IOMREC and provides advice and support to the IOMREC on procedural issues;

i) develops a quality assurance programme to encourage a consistently high level of service to applicants, including accreditation of the IOMREC, based on regular monitoring and audit of their operation and performance, and an appraisal scheme to support committee officers in performing their duties;

j) provides guidance and advice to assist the IOMREC in their work and encourage consistency of approach to common issues in research ethics;

k) provides advice to Public Health, and the Cabinet Office where appropriate, on the practical implications of implementing legislation, policy and guidance.

Annex B: Functions of Public Health as the appointing authority

Public Health

a) establishes the IOMREC to act for the whole of the Isle of Man, ensuring there is sufficient provision to meet the demand for IOMREC review;

b) establishes the IOMREC to act in relation to such descriptions or classes of research as are appropriate;

c) varies the extent to which the IOMREC may act under (a) and (b);

d) seeks recognition of its IOMREC if the law requires it;

e) nominates, if required, a successor Research Ethics Committee when the IOMREC cease to operate or are abolished or varied under (c) or have their recognition revoked;

f) appoints, with support from RGR, the members of the IOMREC in accordance with Governance arrangements for research ethics committees and the law to ensure that the IOMREC has the required composition;

g) through the Isle of Man Government, ensures members of the IOMREC are indemnified to relieve them of personal liability in respect of their opinions of the ethics of research given during their role as a member of the IOMREC;

h) facilitates the provision of funds to RGR for the operation of its IOMREC;

i) may enter into legal agreements to secure the accommodation and facilities required to support the operation of the IOMREC;

j) in collaboration with RGR, appoints the officers of the IOMREC, extends their tenure of appointment and terminates their appointment in accordance with its disqualification and resignation procedures, the requirements of Governance arrangements for research ethics committees and the IOMREC's standard operating procedures;

k) approves standard operating procedures for the regulation of the proceedings and business of the IOMRECs;

l) in collaboration with RGR, approves variations to, or revocation or suspension of, the standard operating procedures of the IOMREC; and

m) monitors the extent to which the IOMREC adequately perform their functions, through annual reports from the IOMREC, notification of their accreditation status and other mechanisms for quality assurance.

Annex C: Annual reports of the IOMREC

The IOMREC annual report to the RGR Unit shall include at least the following:

a) details of the officers and staff of the IOMREC;

b) details of the membership of the IOMREC, including for each member and their occupation, expert/lay status, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned;

c) the current register of members' interests;

d) the attendance record of each member during the year;

e) a list of full meetings held during the year, including their dates and the number of members attending;

f) the training record of each member;

g) a list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review); and

h) a report by the Chair on the IOMREC's work during the year.

Annex D: Definitions of Expert and Lay members of IOMREC

Expert members

1. An expert member means a member who:

a) is currently a registered "health care professional" (see paragraphs 2 and 3 below);

b) has professional qualifications or experience relating to the conduct of, or use of statistics in, research relating to health and social care (including the conduct of clinical trials), unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment (see paragraph 4 below);

c) is not a health care professional, but has previously been a registered medical practitioner or a registered dentist. (Note: No time limit is specified, so this applies where a person has been registered at any time in the past).

2. "Health care professional" includes the following:

- a doctor
- a dentist
- a nurse or midwife
- a pharmacist
- an ophthalmic optician
- a registered osteopath
- a registered chiropractor
- a person registered by the Health Professions Council which provides for registration of the following:
    - arts therapists
    - biomedical scientists
    - chiropodists / podiatrists
    - clinical scientists

- dietitians
- hearing aid dispensers
- occupational therapists
- operating department practitioners
- orthoptists
- paramedics
- physiotherapists
- practitioner psychologists
- prosthetists / orthotists
- radiographers
- speech and language therapists.

3. A person who has professional qualifications or expertise of the "conduct" of health and social care research can be defined as those who have had substantial involvement in the conduct of research in health and social care according to the following definition of research (taken from the Research Governance Framework):

Research can be defined based on three main principles:

- Intent: The aim of research is to derive generalisable or transferable knowledge, as opposed to measuring standards of care as with audit or service evaluation. Research seeks to find out what you should be doing, whereas audit examines whether planned activity is being carried out and its effectiveness.
- Treatment/service: Research often examines the effectiveness of new interventions, whereas neither audit nor service evaluation uses an intervention without a firm clinical basis.
- Allocation: Neither audit nor service evaluations allocate treatment or service by protocol.

4. This definition of conducting health and social care research means that, in addition to health care professionals with clinical experience, some non-health care professionals may also qualify as expert members where they are involved in laboratory tests and data analyses, in particular:

- Clinical trial data managers

- Academic researchers in the field of health and social care
- Hospital-based laboratory officers who are not registered health care professionals.

5. However, people whose qualifications and experience relate only to the management or monitoring of health and social care research would not qualify as expert members.

Lay members

6. Any member who is not an expert member is by definition a lay member.

7. A Lay member is a person who:

(i) has previously been a registered health care professional (see paragraph 2)

- except for previously registered doctors or dentists who still qualify as expert members (see paragraph 1(c));

(ii) has previously been a person involved in the conduct of health and social care research other than as a research subject (see paragraphs 3 & 4)

(iii) is or has been a chairman, member or director of a health service body or any other body providing health care

8. A Lay+ member is therefore a person who is not and never has been any of the following:

(i) a health care professional;

(ii) a person involved in the conduct of health and social care research other than as a research subject;

(iii) a chairman, member or director of a health service body or any other body providing health care.

Annex E: Glossary of Terms

Chair The member of IOMREC appointed to be Chair by the Cabinet Office, or its predecessor, in this capacity. Where the Chair is unavailable for any reason, his/her duties may be performed by the Vice-Chair.

CI Chief Investigator **-** The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

Ethics Moral principles that govern a person's behavior or the conducting of an activity.

GCP Good Clinical Practice.

Governance the action or manner of governing a state, organization, etc.

IEP Integrated Ethics portal – the Isle of Man online application system used to apply for health and social research approvals. See http://integratedethicsportal.gov.im/

IOMREC Isle of Man Research Ethics Committee.

Methodologist An expert in the methods used in a particular area of study or activity.

Nolan Principles The basis of the ethical standards expected of public office holders.

Protocol A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study.

Quorum The minimum number of members necessary to conduct the business of the group.

REC A Research Ethics Committee ("REC") is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.

Referee A person or body who gives expert advice to a REC on an application or any related matter.

Research site The organisation or unit responsible for conducting any of the research procedures in a study at a particular locality.

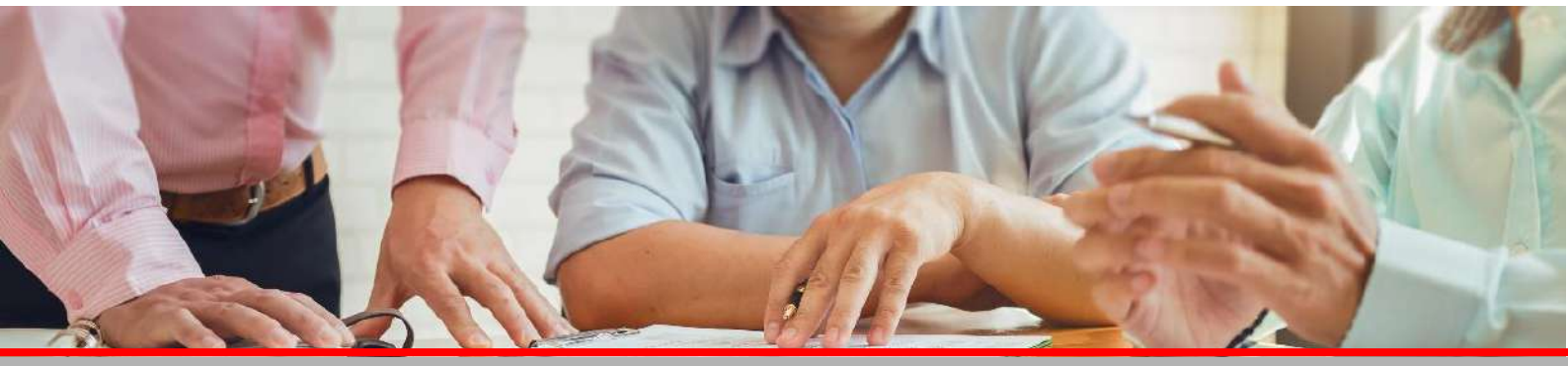
RGR Research Governance and Regulation – the Department of Public Health responsible for supporting the IOMREC

SOPs The Standard Operating Procedures.

Sponsor The person (or organisation) who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of the research.

Statistician An expert in the preparation and analysis of statistics.

The Declaration of Helsinki - The Declaration of Helsinki (DoH) is a set of ethical procedures regarding human experimentation developed for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics.



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