



# Isle of Man Government

*Reiltys Ellan Vannin*

Purpose	Report of IOMREC activity between 1 <sup>st</sup> January 2021 and 31 <sup>st</sup> December 2021
Committee Name	Isle of Man Research Ethics Committee
Committee Chair Committee Vice Chair	Ms. Lillian Boyle Ms. Nicci Igeoa
Author	Research Governance and Regulation, Public Health Directorate, Cabinet Office
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# Isle of Man Research Ethics Committee Annual Report 2021

## Introduction

The Isle of Man Research Ethics Committee (IOMREC) reviews health and social care research projects that meet the criteria for review<sup>1</sup>. This report provides a breakdown of activities undertaken by the IOMREC during meetings held in 2021.

## IOMREC Report Chair's Statement

*Welcome once again to the annual report of the Isle of Man Research Ethics Committee. We all embraced 2021 hoping that it would be different from 2020, unfortunately we almost immediately found ourselves once more dealing with the continuing impact of Covid and the ramifications for the level of research being undertaken on the Island. This was obviously reflected both in the volume of work for the Committee and indeed the way in which the Committee was able to carry on its role. We again reverted to online meetings and utilised opportunities to consider the way in which we approach research applications, how to more effectively utilise the online review system and of course to develop our training.*

*We have again seen fewer applications in 2021 but we are pleased to report that the substance and breadth of those which we have received have continued to develop and this can be seen later in the report in regard to the topics submitted for research during this year. In addition, the Committee itself and the supporting Department of Research and Development (RDR) have gone through a number of changes. RDR is now of Research Governance and Regulation (RGR) and is now under the auspices of the Isle of Man Public Health Directorate within the Cabinet Office. During 2021 we received support from Dr Paul Macadam and Dr Helen Baldwin and we appreciate their input to ensuring the smooth running of our processes. The Committee has also reshaped over the past 12 months and due to members stepping down we engaged in a more comprehensive recruitment exercise to widen the skills and experience of the Committee and again full details are provided within the body of the report.*

*My thanks go to all of what was the RDR team and previous, continuing and new members of the Committee for their services over the past 12 months. The existence of the Committee is key to ensuring that the Isle of Man continues to have a vibrant facility to offer credible research and development opportunities in all of its various formats. This remains a valuable attribute in the composition of the Island's offering and we are pleased to be support the research community and encourage applications for 2022.*

*Lillian Boyle*

*Chair*

*December 2021*

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<sup>1</sup> The criteria used for review can be found at: <https://www.gov.im/about-the-government/departments/cabinet-office/public-health/research-governance-and-regulation/research-application-submissions/>

## Members

### List of members

There are twelve IOMREC members, eight lay<sup>2</sup> (which includes both lay + and lay) and four expert. Table 1 provides a list of the members, their position and category within the IOMREC, and their date of appointment. One member left the Committee in early 2021 and further members were recruited in late 2021.

**Table 1.** Isle of Man Research Ethics Committee member details.

Officer type	Name	Category	Appointment / Resignation date
Chair	Lillian Boyle	Lay +	April 2018
Vice-Chair	Nicci Igoea	Lay	July 2018
Member	David Neilan	Expert	July 2018
Member	Alison Gomme	Lay +	July 2018
Member	Dr. Ameeta Patel	Expert	July 2018
Member	Isobel Hasnan	Expert	July 2018
Member	Lee Cowap	Lay +	October 2020
Member	Dr. Philip Harrison	Expert	November 2020 / April 2021
Member	Rich Sille	Expert	October 2021
Member	Marie Weale	Lay+	October 2021
Member	Adam Dempsey	Lay	October 2021
Member	Karen Duffy	Lay+	October 2021
Member	Shelley Flowers	Lay+	October 2021

### Training

Members are required to attend regular training, with a minimum of one day per year expected. In accordance with the Health Research Authority, five hours of self-directed learning equates to one

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<sup>2</sup> A Lay member is a person who:

- (i) has previously been a registered health care professional- except for previously registered doctors or dentists who still qualify as expert members;
- (ii) has previously been a person involved in the conduct of health and social care research other than as a research subject;
- (iii) is or has been a chairman, member or director of a health service body or any other body providing health care.

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.

full day's training. Online courses and interactive webinars are available through the Health Research Authority. Table 2 lists all training courses attended by each member and the month of attendance.

**Table 2.** Training courses attended during 2021.

Name	Training courses	Date	Hours	Total Hours
Lillian Boyle	'Ethical Principles in Clinical Research', National Institutes of Health (online)	February	1.0	8.25
	'The Only Way is Ethics', Health Research Authority (online)	February	0.5	
	Training on IOMREC process and appeals, RGR	March	0.5	
	Self-directed reading	May	0.5	
	Online reading of qualitative research articles	July	1.0	
	HRA Governance Arrangement for Research Ethics Committee and follow up articles	September	2.0	
	Sustainable integrity: How integrity and ethics can be maintained in terms of ethical values. Online course.	October	1.75	
	Ethics: The Devil is in the Detail. Online lecture.	November	1.0	
David Neilan	'Ethical Principles in Clinical Research', National Institutes of Health (online)	February	1.0	16.0
	'The Only Way is Ethics', Health Research Authority (online)	February	0.5	
	Training on IOMREC process and appeals, RGR	March	0.5	
	Research design & methodology – taught MSc module	April	7.0	
	Critical review & appraisal of research papers – taught MSc module	May	7.0	
Alison Gomme <sup>3</sup>	'Ethical Principles in Clinical Research', National Institutes of Health (online)	February	1.0	2.5
	'The Only Way is Ethics', Health Research Authority (online)	February	0.5	
	Training on IOMREC process and appeals, RGR	March	0.5	
	'Qualitative research' with reading, R&D	June	0.5	
Dr. Ameeta Patel	'Research Ethics in a Pandemic', Pager Podcast with Prof Alex London, Pennsylvania	January	1.5	4
	'Ethical Principles in Clinical Research', National Institutes of Health (online)	February	1.0	
	'The Only Way is Ethics', Health Research Authority (online)	February	0.5	
	'Qualitative research' with reading, R&D	June	0.5	
	'Research, Audit and Quality Improvement' – Research Governance and Ethics module, eLfH	November	0.5	
Isobel Hasnan	'Ethical Principles in Clinical Research', National Institutes of Health (online)	February	1.0	7.5
	'The Only Way is Ethics', Health Research Authority (online)	February	0.5	
	Training on IOMREC process and appeals, RGR	March	0.5	
	'Qualitative research' with reading, R&D	June	0.5	

<sup>3</sup> Member had pre-agreed leave of absence during the course of the year and therefore self-directed learning is pro rata.

	HRA covid-19 research guidance Clinical Trials of Medicinal Products – HRA Podcast	September December	2.0 3.0	
Nicci Igoea	'Ethical Principles in Clinical Research', National Institutes of Health (online) 'The Only Way is Ethics', Health Research Authority (online) Training on IOMREC process and appeals, RGR 'Qualitative research' with reading, R&D 'Do better research' podcast - S1 E2: 'Conducting ethical research' 'Navigating research ethics in dementia' podcast 'REC members help develop new tool to benefit people who participate in research' - HRA website Governance arrangements for research ethics committees: 2020 – HRA website	February February March June September October November November	1.0 0.5 0.5 0.5 0.75 0.5 0.25 0.75	4.75
Lee Cowap	'Ethical Principles in Clinical Research', National Institutes of Health (online) 'The Only Way is Ethics', Health Research Authority (online) 'Qualitative research' with reading, R&D	February February June	1.0 0.5 0.5	2.0

## Meetings

### Date of meetings

There can be up to ten IOMREC meetings scheduled within a year. A list of meetings for 2021 can be found in Table 3. The meetings scheduled for January, February, were cancelled due to no applications being submitted for those meeting dates. Though no applications were received for the March meeting, a meeting was held to review SOPs. Meeting held in June was to provide training. No applications were received for the September, November or December meetings, however these meetings were used to review governance documents, legislation, agree draft annual report and introduce new IOMREC members.

**Table 3.** Dates of 2021 meetings and members attendances.

Date	Attendees								RS	MW	AD	KD	SF
	LB	NI	DN	AG	AP	IH	LC	PH					
January	-	-	-	-	-	-	-	-	V	V	V	V	V
February	-	-	-	-	-	-	-	-	V	V	V	V	V
March	✓	✓	✓	✓	A	✓	A	A	V	V	V	V	V
May	✓	✓	✓	A	A	✓	A	V	V	V	V	V	V
June	A	✓	A	✓	✓	✓	✓	V	V	V	V	V	V
July	✓	A	✓	A	✓	✓	A	V	V	V	V	V	V
September	✓	✓	✓	A	✓	✓	A	V	V	V	V	V	V
October	✓	✓	✓	✓	A	A	A	V	V	V	V	V	V
November	✓	✓	A	✓	✓	A	A	V	A	✓	✓	✓	✓

December	✓	A	✓	A	✓	✓	A	V	✓	✓	A	✓	A
<b>Total attended</b>	<b>7</b>	<b>6</b>	<b>6</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>1</b>

- No meeting. A – Apologies. V – Position vacant.

### Meeting applications reviewed

During 2021 a total of three new applications were reviewed by the IOMREC (Table 4). In all cases, the Committee decided that a final opinion could not be issued until further information had been received from the application. In two of these cases, the Committee gave a favourable opinion with additional conditions following the submission of further information by the applicant. In one case the Committee gave a favourable opinion with standard conditions following the submission of further information by the applicant.

**Table 4.** Details of the applications processed at each meeting in 2021.

Date	New applications	Re-submitted applications	Applicant attended meeting for questions	Outcome of meeting	Final opinion
January	-	-			
February	-	-			
March	-	-			
April	-	-			
May	1	0	0	Provisional opinion with request for further information	Favourable with additional conditions
June	-	-			
July	1	0	0	Provisional opinion with request for further information	Favourable with additional conditions
September	-	-			
October	1	0	0	Provisional opinion with request for further information	Favourable with standard conditions
November	-	-			
December	-	-			
<b>Total</b>	<b>3</b>	<b>0</b>	<b>0</b>		

- No applications received for the meeting.

### Application details

Details for applications reviewed in 2021 are provided in Table 5. Two of these applications were educational projects.

**Table 5.** Research applications received and processed in 2021.

Application Title	Origin of research	Date of first meeting review	Date of second meeting review	Date of approval
An exploration of the support needs of young people with Dual Diagnosis within a small island population, identifying recommendations to inform the development of best practice	Educational	18/05/2021	N/A	01/07/2021
Is there a difference in the prescribing of antibiotics for common infections in GP practices since the implementation of telephone consultations during the Covid 19 pandemic?	Educational	27/07/2021	N/A	09/08/2021
Improving Quality of Life for people over 65 living with dementia-Pilot study	Third sector	05/10/2021	N/A	03/11/2021

### Annual and final reports

One annual report was received during 2021 in relation to proposals approved in previous years (See Table 6).

**Table 6.** Reports received in 2021.

Application Title	Origin of research	Date of approval	Final or annual report	Date received
Assessing the effectiveness of the Leeds Risk Index (LRI) patient profiling tool for the Community Wellbeing Service, an Island based healthcare system	DHSC	January 2020	Annual	March 2021

### Application management

Table 7 reports the management and processing of the applications reviewed.

**Table 7.** Application management information.

Average number of applications received per meeting	<1
Total number of applications to receive final opinion within 30 working days (excluding time taken by applicant following request for further information). taken over 30 working days for a response to applicant	3
Total number of applications given a favourable opinion with standard conditions	1
Total number of applications given a favourable opinion with additional conditions	2

Total number of applications given an unfavourable opinion	0
Total number of new applications awaiting applicant's response	0
Total number of annual progress reports received	1
Total number of final reports received	0