

Royal College of Physicians of Ireland
Faculties of Public Health Medicine & Occupational Medicine
Research Ethics Committee

Background

In 1995 the Research Committee of the faculty of Public Health Medicine produced a position paper entitled “Ethics in Public Health Medicine Research”. A set of procedures to ensure that public health research would be carried out in an ethical fashion was recommended. One of the recommendations was that the Faculty of Public Health Medicine under the auspices of the Royal College of Physicians of Ireland should set up a public health research ethics committee. The Research Ethics Committee was formed in 2001 (Appendix 1-Members)

Introduction

The research protocol is the cornerstone of an epidemiological research project where the purpose of the study, the design, the source population and the planned analyses are described and administrative issues and possible problems and limitations are considered. Protocols should reflect the four basic principles of autonomy, beneficence, non-maleficence and justice as outlined below. To design and conduct studies with inadequate resources and scientific skills may be construed as unethical.

Principles of the Research Ethics Committee

The principles underlying Public Health Research Ethics Committees have been enunciated by the International Epidemiology Association document “*Good Epidemiological practice: Proper Conduct in Epidemiological Research*”. The four principles are:

- Autonomy
- Beneficence
- Non-maleficence
- Justice

Terms of Reference

- To consider research protocols submitted for part 2 MFPHMI exam which have been submitted in adherence to Faculty guidelines
- To consider other research proposals emanating from Faculty Members, Faculty Fellows, public health training locations and other public health bodies within Ireland.

Part 2 MFPHMI Protocols

- Part 2 submissions should be submitted to the Research Ethics Committee as soon as possible **after** a supervisor has been appointed and discussed the application with the researcher
- Part 2 submissions received from UK applicants will also be considered

Submission procedure

Please complete the proposal form and return to the Faculty Administrator.

Applicants are responsible for ensuring the completeness of their application.

For your application to be considered it must be received by the Faculty **at least 4 weeks** prior to the next meeting of the Research Ethics Committee Meeting. Please ensure that you have included all relevant documents as per checklist.

Please note that further submissions to the Research Ethics Committee should be made in the following cases:

- Amendment to the submitted study
- Annual Progress Report and
- Study Termination Form.

Appropriate forms are available on the website or from the Faculty Administrator and further details are given below.

1. Amendment Notification Form

When any revision to an approved research protocol, patient information leaflet/consent form and/or advertisement for subject recruitment is desired, an amendment must be filed with the Research Ethics Committee. The amendment notification form must be completed indicating the changes; revisions may be within the protocol itself, the patient information leaflet/consent form or the advertisement.

2. Annual Progress Report

Every 12 months for the duration of the research project and until a study termination form is filed a brief summary of the progress to date should be submitted to the Research Ethics Committee.

3. Study Termination Form

When the study is terminated a form is required stating that participants are no longer studied or followed and therefore the Research Ethics Committee should officially terminate the study.

Research Ethics Committee Meetings 2011

Thursday, Thursday, 24th March

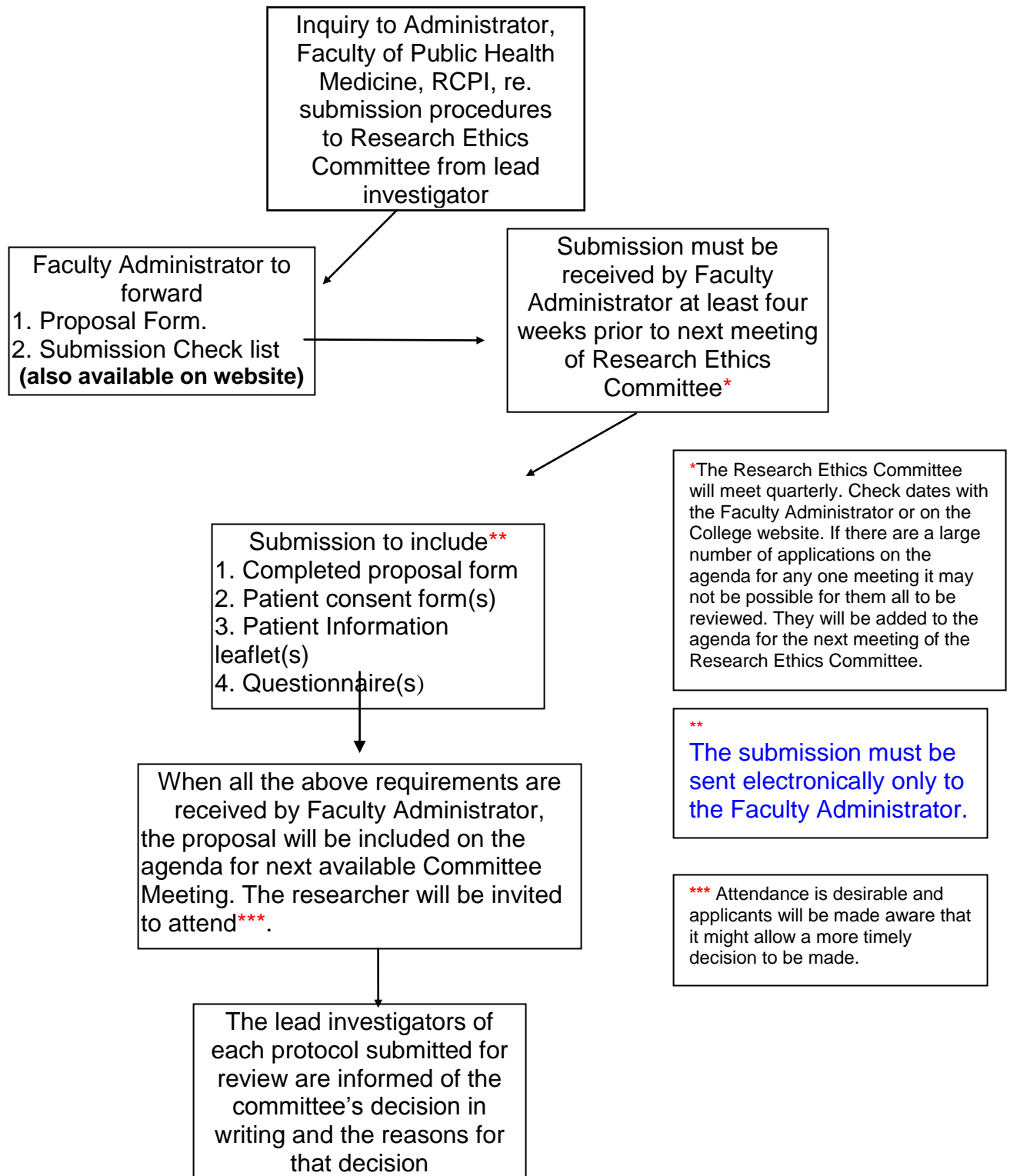
Thursday, 23rd June

Thursday, 22nd September

Thursday, 15th December

(at 11am in RCPI Frederick House)

Application Process



Decisions

There are 4 possible decisions of the Research Ethics Committee

1. Approved

2. Conditional Approval

Conditional approval of a protocol may be granted requiring minor modifications in the protocol and/or patient information sheet and/or patient consent form or responses to specific inquiries by the committee. In such an instance the investigator should submit a cover letter along with the appropriately modified submission form, protocol, consent form or supplemental information as requested with the changes highlighted.

3. Not Yet Approved

Not Yet Approved may be the decision of the Research Ethics Committee whereby it is of the opinion that there are modifications and clarification required to the extent that a resubmission should be made.

4. Rejection

Occasionally the Research Ethics Committee may reject protocols. This may occur if a protocol is not in keeping with the four basic ethical principles outlined above, e.g. research is unclear in its objectives or methodology, if the proposed research is not justified and/or poses severe or unnecessary risk to the study population.

5. Inappropriate to comment

The Committee may find it inappropriate to comment if a piece of research has been completed and it is not possible to amend or change it.

Lead Investigators Responsibilities

Initial Submission

- It is the responsibility of the Lead Investigator to provide the Research Ethics Committee with the appropriate information on the research protocol including initial submission, notification of subsequent modifications, terminations and outcome
- It is the responsibility of the Lead Investigator to have the appropriate medical indemnity in place

Notification of amendments, yearly updates and study termination

- The committee must be notified when studies are completed or terminated. A brief summary of progress to date should be submitted to the committee on a yearly basis.
- When any revision to an approved research protocol or written consent form is proposed the amendment must be brought to the attention of the Research Ethics Committee for approval.

Notification of Publications

- The committee should be notified of any scientific publications emanating from the research undertaken.

For your information some guidelines on documents are given below.

Patient information leaflet(s)

Patient information leaflet must include the following elements:

- A statement that the protocol involves research, an explanation of the purposes of the research and the expected duration of the subject's

- participation, and a description of the procedures to be followed
- Description of any reasonably foreseeable risks or discomforts to the subject
 - Description of any benefits to the subject or to others that may reasonably be expected from the research
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

Patient Consent Form(s)

Patient consent form should include the following elements:

- The title of the project/research and the name of the lead investigator clearly printed on the top of the form
- Space for signature/name/date of both the patient and witness/guardian and the investigator (or investigators nominee)
- Include the statement (or variant of)
“I’ve read and understand the attached patient information leaflet”
- Include the statement (or variant of)
“I understand that information will be kept on computer and/or paper and that these will be kept confidential

Research Ethics Committee Members

Name	Year	
Dr. Davida De La Harpe (Chair)	2007	Assistant National Director of Population Health – Health Intelligence
Ms. Ailbhe O’Neill	2006	University of Dublin, School of Law, Trinity College
Prof. Joe Barry	2002	Adelaide & Meath Hospital, Tallaght, Dublin 24
Mr. Shane Hill	2002	Director of Nursing, Cluain Mhuire Family Centre, Blackrock
Dr. Máirín Boland	2002	Department of Public Health, HSE Eastern Region
Prof. Ruairi Brugha	2006	Head, Dept of Epidemiology and Public Health, RCSI
Ms. Margaret Dawson	2009	Lay Person Representative
Paediatrics Rep	2010	tba
Dr. Emer Shelley	2002	Population Health Directorate, HSE
Dr. Mary Scully	2004	Department of Public Health, HSE Eastern Region
Dr Sean O’Brian	2009	Pathologist, St James’s Hospital, Dublin 8
Dr. Sharon Lim (Sec)	2011	SpR in Occupational Medicine, Civil Service Occupational Health Department
Prof. Anthony Staines	2002	Professor of Health Systems Research, School of Nursing, DCU
Dr John McDermott	2010	Occupational Health Physician, Healthwell Clinic, Dublin 15
Dr. TMR Jackson	2007	Department of Public Health Medicine, HSE South
Dr. Miriam Owens	2007	Health Protection Surveillance Centre
Dr. Una Fallon	2007	Department of Public Health, HSE Dublin Mid-Leinster
Dr. Alex Reid	2007	Occupational Health Physician, AMNCH, Tallaght, Dublin 24

Contacts

1. Administrator, Faculty of Public Health Medicine

Anne McMonagle
 Royal College of Physicians of Ireland,
 Frederick House
 19 South Frederick Street
 Dublin 2.
 Ph: 01-863 9700 Fax: 01-672 4707 e-mail: fphm@rcpi.ie

2. Secretary, Research Ethics Committee, Faculty of Public Health Medicine

Dr. Sharon Lim
 c/o Faculty of Public Health Medicine
 Royal College of Physicians of Ireland
 Frederick House
 19 South Frederick Street
 Dublin 2.
 Ph: (071) 9174750 e-mail: sharonlim@physicians.ie