

**Intermediate Cycle III Students
- Student Selected Component 2012 -**

Research & Audit Placements:

Placement One: 23 Jan - 1 Mar

Placement Two: 5 Mar - 13 Apr

Placement Three: 23 Apr - 8 Jun

Each placement will start with an orientation session.

Attendance at research orientation is compulsory.

- Research Ethics Committee Approval-

The first issue students will face is whether research ethics committee (REC) approval applies or not: another way to phrase this is, is the project you are involved in a research study or an audit?

The following guidelines for research ethics committees indicate that REC approval is required for research, but not for audit.

Irish Council for Bioethics (2004) Operational Procedures for Research Ethics Committees

All Research involving or impacting upon human participants requires ethics review by a research ethics committee before the research has started, except as stipulated below.

For the purposes of this Guidance, Research is defined as a systematic investigation to establish facts, principles or knowledge and a study of some matter with the objective of obtaining or confirming knowledge.

2.1 Specific Activities that may require REC review

Specific activities that may require REC Review include, but are not necessarily limited to the following:

- (a) Clinical Trials involving human participants
- (b) New treatments or interventions
- (c) Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), biological fluids
- (d) Physiological studies

- (e) Comparing an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognised as established by virtue of their recent development, discovery or use in a new or unfamiliar way
- (f) Innovative practices in health and disability service
- (g) Research conducted by students, which included all activities that meet the definition of research with human participants
- (h) Observational clinical research
- (i) Access to personal information by means of questionnaires, interviews or other techniques of information gathering
- (j) Research involving secondary use of data (use of data not collected for that research purpose) if any form of identifier is involved and/or if health information pertaining to individuals is involved
- (k) Case studies, when a series of subject observations allow possible extrapolation or generalisation of the results from the reported cases and when there is an intent to publish or disseminate the data.

Note to item 2.1 (g) above: As supervised student research is conducted primarily for the purpose of educating students on research techniques and methodologies, REC should review research protocols with a view to contributing to the students' education concerning scientific and ethical principles governing research.

2.2 Activities that may not require REC review

Review by a REC may not be required for:

- (a) Research utilising existing publicly available documents or data
- (b) Observational studies in public places in which the identity of the participants remains anonymous
- (c) Case study of one patient with the proviso that written informed consent has been obtained from the relevant subject
- (d) Quality assurance studies
- (e) Audits

The opinion of the REC should be sought whenever there is any doubt about the applicability of this guidance to a particular research project.

Assessing whether a given project is a research study or an audit can be quite difficult, and an easier place to start is figure out if the project is a research study as opposed to a clinical audit. (A clinical audit is one particular type of audit.)

The following guidelines for hospital staff outline the difference between research & clinical audit: -

Beaumont Hospital Clinical Governance Department Guidelines

Clinical Audit or Research

Background:

The aim of this short document is to assist healthcare professionals in ascertaining if the project they propose to conduct is a clinical audit or a research study.

Clinical Audit

Clinical audit is described as 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'.

Principles for Best Practice in Clinical Audit - NICE 2002

Clinical audit is about reviewing existing practice against evidence based clinical standards and ongoing results against those standards with resultant changes in practice to improve quality of care where gaps are identified.

The components of clinical audit are:-

- Selecting a topic
- Agreeing standards of best practice
- Measuring current practice against the standards
- Analysing data and comparing with standards
- Implement change if required
- Re-auditing to make sure practice has improved

To ascertain if a project is a clinical audit, concentrate on 3 key questions:-

Q1. Is the purpose of your project to try and improve the quality of patient care?

Q2. Will the project involve measuring current practice against standards?

Q3. Does the project involve anything being done to patients beyond their routine clinical management?

If the answer is yes to the first 2 questions and no to third, the project is likely to fall within the remit of clinical audit.

Clinical Governance Department Guidelines – continued –

	<i>Research</i>	<i>Clinical Audit</i>
Purpose	To provide new knowledge e.g. to set or change clinical standards.	Measures practice against evidence-based standards.
Methodology	Pre-specified research designs with hypotheses.	No allocation to treatment groups. Audit cycle: identify areas of non-conformity with evidence-base standards, implement practice change strategy and re audit.
Data analysis	Requires data analysis (quantitative or qualitative) to make inferences.	Simple statistics (e.g. means, frequencies) to compare audit cycles.
Ethical approval	Required.	Not required.
New treatments	May involve a completely new treatment or practice	Will never involve a completely new treatment or practice
Randomisation	May involve allocating patients randomly to different treatment groups.	Will never involve allocating patients randomly to different treatment groups.
Sample size	Statistically powered calculation.	Sufficient number of cases to influence practice based on findings.
Outcome	Improved knowledge.	Strategies in place to improve clinical practice.

The RCSI Research Ethics Committee has provided the following quick reference guide:

RCSI REC QUICK REFERENCE GUIDE

<i>Research</i>	<i>Clinical Audit</i>
Designed and conducted to generate new knowledge	Designed and conducted to provide new knowledge to provide best care
Quantitative research – Designed to test an hypothesis Qualitative research – Explores themes following established methodology	Designed to answer the question: “Does this service reach a predetermined standard?”
May involve a new treatment	Doesn’t involve a new treatment
May involve additional therapies, samples or investigations	Involves no more than the administration of a questionnaire or record analysis
May involve randomisation	Does NOT involve randomisation

If the study you are conducting is a research study, your supervisor will have applied for research ethics approval.

It is important to understand for you to understand what this process entailed, as all research you will conduct during your medical career will require research ethics committee approval.

Secondly, if your supervisor has not applied for research ethics approval on your behalf, your first task will be to **APPLY** for research ethics approval **AS SOON AS POSSIBLE**.



No research study is permitted to take place without Research Ethics Committee Approval.

No research study can start until Research Ethics Committee Approval has been received.

The research ethics committees at Beaumont Hospital and the Royal College of Surgeons are on standby to receive applications from SSC students and their supervisors during Research Orientation Week.

Their contact details and website addresses are as follows:



	
Ms. Stephanie O'Connor	Ms. Gillian Vale
Convenor Research Ethics Committee RCSI Research Office 121, St. Stephen's Green Dublin 2	Administrator Ethics (Medical Research) Committee Beaumont Hospital Dublin 9
01 402 23 73	01 809 2680
sloconnor@rcsi.ie	gvale@rcsi.ie
http://www.rcsiethics.info	http://www.beaumontethics.ie/index.htm
Apply to this Committee if your Participants are RCSI Students or Staff Members or Other Persons Recruited in the Community (e.g. supermarket shoppers)	Apply to this Committee if your Participants are Beaumont Hospital Patients or Staff Members or Other Persons Recruited in Beaumont Hospital (e.g. relatives & visitors)

Your application must be of A HIGH STANDARD.

Your application must be proofread and signed by your
PROJECT SUPERVISOR.

You will be required to submit to the appropriate Research Ethics Committee:

- a) An Application Form (including signatures)
- b) An Information Leaflet for your Study Participants
- c) A Consent Form (if applicable)
- d) Questionnaire (if applicable)
- e) Poster (if applicable)
- f) Interview Questions (if applicable)
- g) Focus Group Questions (if applicable)
- h) Data Collection Sheet (if applicable)

Please note that Beaumont Hospital and RCSI Research Ethics Committee both use different research ethics committee application forms.

The RCSI Ethics Committee uses an on-line ethics application form, and you must contact the REC Convenor to obtain a login & password to the on-line application system.

Beaumont REC uses a Microsoft Word ethics application form (available on the committee website) and you must contact the REC Administrator to inform her that you are preparing a submission.

Both committees however typically make the same comments during ethics committee review.

See 5 most common themes during REC Review (**Appendix One**)

There are template Information Leaflets and Consent Forms available on the Beaumont Hospital Committee website, which you can use as a starting point to designing your study Information Leaflet and Consent Form.

Both Beaumont Hospital and RCSI Research Ethics Committees expect you to use these templates and to adapt them to your study: <http://www.beaumontethics.ie/application/templates.htm>

Both committees typically make the same comments in relation to patient documentation.

See 5 most common themes during REC Review of Patient Documentation (**Appendix Two**)

Both committees have agreed to review 'SSC' applications which are low risk (i.e. typically involving data analysis, a questionnaire, survey, interview or focus group and -at most- a basic physical examination / medical history) in an expedited fashion.

This means that 'SSC students and their supervisors' will not need to wait for the next meeting to submit their ethics application for review.

Provided that the application is of A HIGH STANDARD, the application will be reviewed between meetings.

However, poorly drafted and sloppy applications will not be ACCEPTED FOR REVIEW.

Research Ethics Committees are tasked with protecting the safety and welfare of research participants, and this responsibility does not diminish, due to the time constraints a given researcher (including SSC students) may be working under.

A well-written submission reflecting a well-designed study is a MINIMUM REQUIREMENT from all applicants to both Research Ethics Committees.

APPENDIX ONE:

5 MOST COMMON THEMES ARISING DURING RESEARCH ETHICS COMMITTEE REVIEWⁱ

1. GENERAL STUDY DETAILS

Queries about investigators

e.g. includes the need for a Beaumont Hospital Consultant if Beaumont patients are involved

e.g. ensure the Principal Investigator (PI) is consistent throughout the application, and enclosures

e.g. include an expert co-investigator if necessary

Queries about Irish Medicines Board (IMB) issues

e.g. queries as to whether the application is for a clinical trial (if so, it must use a different application form)

Request for more information

- includes diverse requests such as the data from previous studies, PI's CV, Certs of Insurance, Funding etc.

2. STUDY DESCRIPTORS

Statistical analysis

- includes requesting details of the sample size, requesting a correct power calculation and recommending liaising with a biostatistician

Justify elements of the study

- includes justifying outcome measures, and commenting on the practicality of the timeframe

Provide more details on the study

- includes clarifying use of an endpoint, or particular outcome measure

3. STUDY PARTICIPANTS (RECRUITMENT & SELECTION)

Queries regarding inclusion/exclusion criteria

- includes requests to add exclusion criteria, requests that the criteria are consistent across the application form and patient documentation, and justification for certain criteria

Queries regarding recruitment

- includes comments regarding the feasibility of recruiting adequate numbers, confirming how participants will be recruited etc.

Clarify answers on the application form

- includes explaining terms in the application form that are not very clear

4. RESEARCH PROCEDURES

More detail on research procedures

- includes diverse requests such as clarifying what procedures controls will undergo, commenting on the use of a particular procedure etc.

Clarify what is part of routine care, and what is not

- includes laying out exactly what the study involves, and how this is separate from the treatment they (patients) already receive

Queries regarding aspects of treatment

- includes queries about the procedures if the procedures are treatments – e.g. how much time is spent with a physio etc.

5. DATA PROTECTION

Confidentiality

e.g. whether the data is anonymised or coded

e.g. whether identifiable data will be collected

Data Access

e.g. clarifying if medical records will be accessed

e.g. clarifying who will be accessing data

Data location

e.g. where data will be stored

e.g. whether data will leave the hospital (in particular)

e.g. if data will be sent abroad

APPENDIX TWO:

5 MOST COMMON THEMES ARISING DURING RESEARCH ETHICS COMMITTEE REVIEW OF PATIENT DOCUMENTATIONⁱⁱ

Patient Documentation includes patient information leaflets, consent forms, questionnaires, and any other documentation provided to the patient themselves.

1. Simplify material

e.g. use the [template Patient Information Leaflet and Consent Forms](#)

e.g. explain abbreviations

e.g. ensure all documentation is comprehensible to patients

2. Grammar/Formatting

e.g. typos

e.g. inappropriate use of headings

e.g. font-size

e.g. layout

3. Additional information required

e.g. ensure that all information necessary for the participant is included in their documentation – such as contact details, the risk of participating, and what will happen to any data collected etc.

4. Clarify Information in Patient Documentation

e.g. clarify whether a research procedure is part of the participants standard care

e.g. clarify who has access to the data collected etc.

5. Documents missing

e.g. not all relevant patient documentation has been included with the application – such as information leaflets specific to next-of-kin, parents etc.

ⁱ Kelleher, E., Stanton, A. (2011) An audit of applications reviewed by Beaumont Hospital Ethics (Medical Research) Committee before and after the adoption of a new application form

ⁱⁱ *ibid*