



GUIDE TO GOOD RESEARCH PRACTICE



UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Contents

SECTION 1: INTRODUCTION 01

- Purpose of the Guide 01
 - Research versus Audit 01
-

SECTION 2: RESEARCH CONCEPT AND HYPOTHESIS 03

SECTION 3: STUDY DESIGN AND PROTOCOL DEVELOPMENT 05

- 3.1 Categories of Research 05
 - 3.2 Randomisation 06
 - 3.3 Blinding 06
 - 3.4 Methodology 07
 - 3.4.1 Information Source 07
 - 3.4.2 Data Collection 08
 - 3.4.3 Sampling 09
 - 3.4.3(a) Power 09
 - 3.4.3(b) Sample Size Calculation 09
 - 3.4.4 Data Management 10
 - 3.4.5 Data Analysis 11
 - 3.4.6 Data Presentation 13
 - 3.5 Assessment of Subject Compliance and Withdrawal 14
 - 3.6 Ethical Considerations 14
 - 3.7 Interim Reports 14
-

SECTION 4: ETHICS AND HEALTH RESEARCH 16

- 4.1 When to Seek Ethical Approval (Guideline) 16
- 4.2 Ethics Committees Authorised to Provide Approval for Clinical Trials on Medicinal Products for Human Use. 18
- 4.3 Additional Legal Issues to Consider 19

Contents

SECTION 5: PROPOSAL DEVELOPMENT 20

■	5.1	Title Page	20
■	5.2	Introduction	20
■	5.3	Background and Rationale	20
■	5.4	Methodology	21
■	5.5	Budgetary Requirements	21
■	5.6	Linkages	21
■	5.7	Dissemination	22
■	5.8	Literature Review/Bibliography	22

SECTION 6: PUBLISHING 24

■	6.1	Abstract	24
■	6.2	Introduction	24
■	6.3	Materials/Subjects and Methods	24
■	6.4	Results	25
■	6.5	Discussion	25
■	6.6	Bibliography	26

SECTION 7: RESEARCH AND INTEGRITY 27

■	7.1	Plagiarism	27
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SECTION 8: REFERENCES 28

■		Appendix 1	31
■		Appendix 2	35
■		Appendix 3	37

1.1 PURPOSE OF THE GUIDE

The goal in creating this document is to supply healthcare workers with guidance on how to plan and execute their research projects in order to produce good quality data for analysis. The information supplied is intended to act as a guide through the key stages in conducting research and to provide some assistance to both the novice and more experienced researcher alike.

1.2 RESEARCH VERSUS AUDIT ²⁶

It is important to ensure that your investigation is actual research and not an audit. An audit “determines whether existing clinical knowledge skills and resources are being properly used...and the primary aim of audit is to improve the delivery of healthcare”. In contrast “research is concerned with generating new knowledge which will have a general application” and “seeks to influence clinical practice as a whole”.



Before undertaking a research project it is essential to develop a clear concept and define the hypothesis you want to test. **There are several sources of information available to achieve this:**

- Your own or supervisor's knowledge and expertise
- Review current literature published on the topic. This information can be accessed via library or internet: ¹⁴
 - Useful internet sites include:
 - Irish Medical Organisation (www.imo.ie)
 - Health Discovery (www.healthdiscovery.com)
 - National Library of Medicine (www.nlm.nih.gov)
 - PubMed (www.PubMed.gov)
 - Health on the Net (www.hon.ch/)
 - Medline Plus (www.medlineplus.gov/)
 - Sciseek (www.sciseek.com/)
 - Biocrawler (www.biocrawler.com/)
 - HSE Libraries Online (www.hselibrary.ie)
- Consult Cochrane reviews on the topic www.thecochranelibrary.com

Although the internet can be a very useful resource, it is important to critically evaluate the quality of the information you retrieve. Keep in mind the accuracy, reliability, relevance, objectivity and authority of the information you are sourcing.

Once you have analysed the information relevant to your topic of research it is important to refine your research idea and clarify the specific goal(s) and objective(s) of the study.

Consider whether you research is: ⁹

- Descriptive – what is happening?
- Explanatory – how and why it happens?
- Predictive – what or how it will happen?

Also consider if the research is applied or basic and make sure to avoid large scope that is vague and not clearly spelled out. Keep in mind; Who? What? Where? When? Why? and How?

Once you have clarified your ideas, determine from whom/what you will get your information, and if your sources of data will be from subjects directly or from the records of subjects. It is important at this stage to consider the research techniques and methodologies you will use and your general experimental design.

Also consider the following:

- Where will the research be conducted?
- What resources are available in terms of equipment, people, funding and facilities?

Your research project should be conceived, designed and implemented according to the highest possible standards.^{13, 18, 19} Development of your research protocol is a key step and normally a pre-requisite for ethical approval and funding applications. It forms the blueprint for how the study will be conducted. It should describe the design, methodology, statistical considerations and organisation of the study.

3.1 CATEGORIES OF RESEARCH:

Choose the type of research you will be conducting. **The options include but are not limited to:** ^{1, 2}

■ OBSERVATIONAL: ANALYTIC AND DESCRIPTIVE

Examples include:

- **CASE-CONTROL STUDIES**
 - Investigational samples are chosen on the basis of their disease or outcome of interest
 - Controls should be sourced from a similar population but not have the outcome of interest

- **COHORT-STUDIES**
 - The exposure of interest should be clearly described and used to classify the exposed group
 - Internal comparison group without exposure of interest will be used

- **CROSS-SECTIONAL STUDIES**
 - Exposure status and disease status are assessed at a single point in time
 - Provides useful data on the health status of the population at a given time

- **CASE REPORTS**

■ EXPERIMENTAL (see Appendix 2)

Examples include:

- Clinical Trials
- Non-interventional trials (including randomised controlled trials) as defined by EU directive May 2004 ⁷
- Non-clinical trials (may involve physiological studies, development of health and disability services and use of secondary data for epidemiology studies)
- Experimental studies can be designed in parallel, crossover and factorial fashion

3.2 RANDOMISATION ²⁴

In order to minimize bias subjects are generally randomised to the various treatment or test groups. **The randomisation can be:**

- Stratified
- Blocked
- Systematic
- Clustered

3.3 BLINDING ^{20, 21}

Blinding can also be introduced to reduce bias. The blinding approach used will need Ethics Committee (EC) approval. **There are two types of blinding;**

- **Single blind:** Either the patient/subject or investigator is not aware of the treatment been administered.
- **Double Blind:** Both the patient/subject and investigator are not aware of the treatment being administered.

Double blind design may not always be possible e.g. in surgical treatments

It is advisable to involve a qualified Biostatistician in order to ensure that the appropriate study design approach is used. **The expertise of a biostatistician will facilitate the following:**

- Selecting a suitable sample from your population of interest
- Ensuring that the sample size will give you enough power
- Choosing the correct statistical approach to data analysis

Statistical support is freely available to HSE employees in the Mid-West Region through the Statistical Consulting Unit at the University of Limerick.

- **Statistical Consulting Unit**
University of Limerick
Tel: +353 61 213471
Mob: +353 86 3866353
Fax: +353 61 334927
Email jean.saunders@ul.ie

3.4 METHODOLOGY

3.4.1 Information Source ²⁰

The protocol must detail the source of your data/information. **In the case of healthy volunteers or patients, provide specific details on:**

- How individuals are sourced
 - The public domain
 - A clinic
 - A register
- What inclusion/exclusion criteria were applied
- The recruitment/enrolment process
- If there was payment/compensation involved
- How patient consent was obtained and details of information sheets supplied

3.4.2 Data Collection

Data collection methods include: ⁹

- Surveys and questionnaires (using scales, measures and indices)
- Experimental tests, procedures and screens
- Interviews and focus groups

Ensure that you have considered what your reference point or control will be, i.e. that with which you can compare your data. The data you need to collect to test your hypothesis may be quantitative, qualitative or both. Qualitative data can be obtained from structured or semi-structured interviews, focus groups, surveys, questionnaires, photographs, videos and sound recordings. **This type of data is useful for:** ^{6, 15}

- Describing complex situations
- Providing an insight into how people make sense of experiences
- In the initial exploratory phase of a theme of investigation
- To further enhance or explain quantitative data

Quantitative data is typically numerical and can be sourced from surveys, questionnaires, and a range of laboratory and clinical procedures.²

Group	Sub-group	Examples
Categorical (Qualitative)	Nominal	Gender, blood group
	Ordinal	Indices associated with disease grades e.g. cancer tumours
Numerical (Quantitative)	Continuous	Results from measuring things e.g. weight, time spent waiting
	Discrete	Whole numbers and arise from counting things

3.4.3 Sampling ^{9, 21, 24}

Appropriate sampling is a critical part in the data collection process. **Representative samples can be obtained from a target population in several ways:**

- Systematic sampling - *may be atypical*
- Random sampling - *best option when trying to avoid bias*
- Convenience sampling - *bias may be hidden*

It is critical to the outcome of the research that a sufficient sample size is analysed to detect a difference between control and test groups. If a study is too small it may lack power to pick up differences. The sample must be large enough to avoid producing a false negative result.

3.4.3(a) Power

The probability of detecting a true difference is called power ($1 - \beta$).

The power of a study is low when:

- Large variability exists between the data and the standard deviation is large
- Small sample size
- Trying to detect subtle differences

The majority of studies seek to have a power of 80-90%. This can then be used to calculate the number of subjects that are required to detect a minimum clinically relevant difference

3.4.3(b) Sample size calculation (when you have continuous data – parameters known)

Quantify the following:

- Power: ($1 - \beta$); $\beta = 0.2$ to 0.3
- Significance Level (α): The level below which the null hypothesis is rejected (see page 12)
- Standard Deviation (σ)

- Smallest effect of interest/clinically relevant (δ)
- Standardised difference = $(\delta/\sigma) = D_s$

Refer to the Altman Power Plot for $f(\alpha, \beta)$

$$n^* \text{ in each group} = f(\alpha, \beta) \times 2 \sigma^2 / (\mu_1 - \mu_2)^2 = f(\alpha, \beta) \times 2/D_s^2$$

Assumes equal numbers in each group

For sampling and sample size calculations (including power calculations) a Biostatistician should be consulted unless you have experience in this area. Sample sizing methodology depends on the primary outcome variable type and is not always as straightforward as example given above.

3.4.4 Data Management ²⁰

Information must be provided on the approach used to obtain research data in terms of experiments, tests and procedures. **Efficient and accurate data management in research is key, and the following information should be stated:**

- The source of data
- Who will collect the data?
- Is the data accurate complete and unbiased?
- The time points for collections
- Why the data is being collected (e.g. baseline comparison, primary outcome etc)?
- Mention use of standardised tools
- The form in which the data will be presented.
- Method of data handling, recoding (paper/electronic and back-ups) security and retention
- Methods used for data transfer, protection and storage– must adhere to the Data Protection Act ⁵
- Patient/healthy volunteer confidentiality must be maintained at all stages of the research

3.4.5 Data Analysis

Analysis of Qualitative Data ^{6, 9, 15}

- Collect
- Reduce
 - Using numbers such as percentages
 - Identify recurring concepts, themes and groupings
- Draw conclusions and verify

There are a number of computer programmes available for qualitative analysis of data including NUD*IST, ATLAS, QUALRUS and NVIVO.

Analysis of Quantitative Data ^{2, 12, 21, 23}

Basic Characteristics of Quantitative Data

As previously stated a Biostatistician should be consulted during the study design and methodology stage. At this point suitable approaches to statistical analysis can be identified to suit the type of data collected.

Summaries include:

- Measures of Central Tendency
 - Mean; average
 - Median; middle value
 - Mode; most common value
- Measures of Variability
 - Standard Deviation; variation about the mean
 - Inter-quartile range
 - Range

Inferences can be made about data through construction of Confidence intervals and/or Hypothesis testing. The protocol should provide a summary on the statistical analysis that will be performed and the format in which the data will be presented.

Statistical Inference:

Confidence Interval Estimation (CI)

- Involves using an interval to estimate the population parameter. Usually set at 95% and indicates that a researcher is 95% confident that the data represents a plausible range of values for the true population value. The narrower the CI the better.

Hypothesis Testing

- The research objective is often expressed in the form of a null hypothesis. The null hypothesis states that no difference exists between control and test groups. The P value is the probability of a result occurring by chance.

If the p value < 0.05 – the null hypothesis is rejected, this implies significance
If the p value > 0.05 - do not reject the null hypothesis

Sufficient power is required to avoid errors.

Errors in Hypothesis Testing:

Type I Error

A difference is detected yet no difference exists - **false positive**. This probability is denoted α is equal to the significance level (usually 5%). This type of error can occur if the sample is biased and /or too small.

Type II Error

No difference is detected but a difference exists - false negative. This probability is denoted β and 20% is usually an acceptable level.

The types of hypothesis tests used to calculate the p-value include the chi-squared test of association and the t-test depending on the type of variable to be tested and the null hypothesis stated.

3.4.6 Data Presentation

Data can be presented as fractions, proportions, rates and whole numbers. The data can be formatted in several ways. **Examples include:**

- Tables – synopsis of raw data, usually in the form of means and standard deviations
- Graphs – x-axis independent variable (treatment), y-axis dependent variable (totals or means)
 - Histograms
 - Boxplots
 - Line graphs
 - Useful in showing data points over time

The juxtaposition of two different sets of data can create good visual effect.

In addition error bars can be used to show the level of variability about the mean.

- Pie Charts – can be used to display the contribution of each treatment to the whole

For further information on graphing data visit:

www.bettycjung.net/Graphing.htm

www.scene.asu.edu/habitat/data_present.html

3.5 ASSESSMENT OF SUBJECT COMPLIANCE AND WITHDRAWAL ²⁰

- What systems will be used to monitor patient/volunteer compliance?
 - How will a lapse in compliance be recorded/and followed-up?

- A subject can withdraw from a study at any time and for any reason
 - How will a withdrawal be documented?
 - Will the subject be followed-up?

3.6 ETHICAL CONSIDERATIONS

The researcher needs to determine if approval from an EC is necessary to conduct the research (see Section 4). If EC approval is deemed necessary then patient consent forms and information sheets must be prepared and then supplied to the appropriate EC.

3.7 INTERIM REPORTS

Where appropriate the Principal Researcher should coordinate the generation of interim reports summarising the progress of the research.

The production of interim reports would generally be necessary when conducting:

- Clinical trials (including trials on medicinal products as defined by EU Directive, May 2004) ⁷
- Non-interventional and non-clinical trials
- Longitudinal investigations

Interim reports are generally not necessary for:

- Short-term investigations using small sample sizes
- Cross-sectional studies

Interim reports may be requested by the EC that provided approval for the study, the institute or hospital hosting the research or the funding body that provided the financial support to conduct the investigation. The format of the report will vary depending on the body that has requested the information. **It may be in the form of:**

- An abstract or summary
- Scientific/Medical Paper

Details may be required on resource personnel, expenditure as well as significant scientific and medical output. In general, dissemination in science, health and public domains is also recommended where appropriate.

4 Ethics and Health Research

section four

Health researchers need to consider if ethical approval is a requirement to conduct their specific investigation. The declaration of Helsinki from the World Medical Association in June 1963 outlined the guidelines that medical practitioners and researchers must follow when engaging in trials that involve human subjects. This declaration also provides ethics committees with guidance and direction when reviewing research or clinical trial applications involving human subjects.

Principles of Ethical Review (As outlined by the Irish Council for Bioethics, website www.bioethics.ie):¹⁷

- Respect for persons
- Privacy and confidentiality
- Validity of research proposals
- Minimal risk to participants
- To neither discriminate or neglect individuals

Research involving human participants includes but is not limited to clinical trials. EC's are located throughout Ireland in hospitals, universities and research institutions to review applications to conduct research involving human participation.

4.1 WHEN TO SEEK ETHICAL APPROVAL (GUIDELINE)

Research proposals that involve human participation or the collection and use of primary and secondary data may require review by an EC. **The text below summarises when a researcher may require ethical approval from an EC:**

May Require EC Approval:¹⁷

- Clinical trials on medicinal products/medical devices involving humans
- New treatment or interventions
- Research involving human remains, cadavers, tissues, discarded tissues and biological fluids
- Physiological Studies

- Comparing an established procedure (therapeutic or diagnostic) with procedures not established
- Innovative practices in health and disability services
- Observational clinical research
- Research conducted by students that involves human participants
- Surveys or questionnaires used to collect personal information on individuals
- Use of data derived from individual records where people may be identified
- Case studies with a series of subject observations to extrapolate generalisations with the intent to publish/disseminate data

May Not Require EC Approval:

- Research using existing publicly available data or documents
- Quality Assurance Studies *
- Audit *
- Case study of 1 patient when informed consent has been obtained
- Observational studies in public places when the identity of the persons remains anonymous

** This statement does NOT imply that all quality assurance studies and audits are exempt from ethical approval. That will depend on the source on the information and whether confidentiality of patients or participants may be compromised.*

When in doubt as to whether your research proposal or project requires ethical approval then an EC should be consulted for their opinion.

The documentation required by the EC to consider an application for ethics approval generally includes but is not limited to:

- Signed and dated application form
- Protocol
- If a product (e.g. Pharmaceutical) is being assessed then a summary of all pharmacological, toxicological and clinical experience data on a product or device under investigation.
- Case report forms, patient information sheet, diary cards, questionnaires and consent forms.

- Curriculum Vitae of all investigators
- Process used to obtain consent
- Arrangements made to indemnify volunteers and investigators
- All other EC decisions made in relation to the proposal and any subsequent amendments that were made
- Description of the ethical considerations involved in the proposal

4.2 ETHICS COMMITTEES AUTHORISED TO PROVIDE APPROVAL FOR CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE

There are currently 13 ECs in Ireland that have been authorised to provide approval for of clinical trials on medicinal products as defined in the European Directive on Clinical trials on Medicinal Products for Human Use (May 2004). ⁷ When conducting clinical trials on medicinal products for human use guidance on applications for recognised EC opinion may be found at: www.dohc.ie/issues/clinical_trials_2004/

The ECs also function to provide approval for the many other forms of health research including non-clinical trials and observational studies.

See Appendix 1 for details on each committee.

See Appendix 3 for additional information on ECs operating in the Mid-West Region.

4.3 ADDITIONAL LEGAL ISSUES TO CONSIDER

- All Clinical Trials on Medicinal Products must be approved by the Irish Medicines Board ⁷
- When conducting Clinical Trials on Medicinal Products the recommendations detailed in the EU Directive, May 2004 must be adhered to.⁷ In addition investigators must follow the recommendations outlined in the EU Directive on Good Clinical Practice (GCP Directive 2005/28/EC) ⁸
- In cases where use and storage of biological tissue is necessary as part of a research protocol the principle investigator should insure that the recommendations outlined by The Irish Council for Bioethics are followed (Human Biological Material: Recommendations for Collection Use and Storage in Research 2005). ¹⁶
- Awareness of Data Protection Laws (see Data Protection Act 1988) ⁵
- That appropriate insurance is in place at the study site and that individuals conducting the study are indemnified
- The Control of Clinical Trials Acts 1987 and 1990 shall apply to clinical trials not subject to the Regulations outlined in the EU Directive, May 2004 (www.dohc.ie)
- In the case of research and trials involving the development of medical devices researchers should adhere to Good Manufacturing Practice (GMP), and comply with the EU Medical Device Directives (see www.ec.europa.eu/enterprise/medical_devices/index_enhtml). If the device will be tested and developed with a view to marketing in the United States the Food and Drug Administration (FDA) has set out a range of guidelines that must be followed (see www.fda.gov/cdrh/devadvice/)

5 Proposal Development

section five

5.1 TITLE PAGE ²⁰

Both a full title and short title are required:

- The full title should detail a summary of study design, exposure and outcomes of interest, patient population and setting.
- The short title is summary of the above.

Also include details of:

- Authors, investigators experts and advisors in the study (including Curriculum Vitae)
- Study site: Clinical laboratory, technical departments, clinics and institutions involved in the study
- A contents page
- List and definition of abbreviations

5.2 INTRODUCTION

State clearly the aim of the proposed research. This is generally a broad statement of intent. Subsequently elaborate on how the goal(s) will be achieved. The introduction should also contain details on the strategy (ies) you will employ to achieve your goals and objectives.

5.3 BACKGROUND AND RATIONALE

Summarises why you are conducting the research, referencing what has been published thus far in the area, how you plan to add to the knowledge base, who will benefit from potential outcomes, will benefits include potential discovery of new procedures, treatments or have a positive financial outcome?

5.4 METHODOLOGY

Include details of the following:

- Study design chosen and why
 - Randomised Controlled Trials, observational study etc.
- Data source, collection, storage and processing
- Subjects and sample size (a statement showing how sample size was calculated when appropriate)
- Patient information sheets and consent forms
- Ethical approval (if necessary for the study)
- Method of statistical analysis

5.5 BUDGETARY REQUIREMENTS

Supply concise details of predicted ongoing running costs including staff and non-staff costs (equipment, transport etc). If relevant to the funding call capital costs should also be addressed.

5.6 LINKAGES

Describe Linkages to other national and international research cohorts:

- Highlight any relevant collaborators you propose to engage with for the duration of the study
- Highlight their specific area of expertise and successful outcomes from any previous work that you have conducted with this group
- Mention the resources, techniques and equipment they will bring to the study

5.7 DISSEMINATION

Describe your plans to disseminate information/results during and at the conclusion of your research including milestones and deliverables. **Consider the following:**

- How often and through what medium do you plan to publicise your research data?
- Consider using seminars, conferences, research publications
- What is your expected publishing output?
 - Will you target local, regional national and international peer review journals?
- How will you monitor the scientific and clinical value of your research?

5.8 LITERATURE REVIEW/BIBLIOGRAPHY

It is usual practice to use the Vancouver method when referencing journals and texts. (International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals: www.nlm.nih.gov/bsd/uniform_requirements.html)

- **Standard Journal Article:** e.g.
Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. *N Engl J Med.* 2002 Jul 25;347(4):284-7.
- **Book or monograph:** e.g.
Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. *Medical microbiology.* 4th ed. St. Louis: Mosby; 2002.
- **Newspaper Article:** e.g.
Tynan T. Medical improvements lower homicide rate: study sees drop in assault rate. *The Washington Post.* 2002 Aug 12;Sect. A:2 (col. 4).

■ **World Wide Web Page (no author):** e.g.

Cancer-Pain.org [homepage on the Internet]. New York: Association of Cancer Online Resources, Inc.; c2000-01 [updated 2002 May 16; cited 2002 Jul 9]. Available from: www.cancer-pain.org

Please note that each funding institute or body will usually have its own specific template in terms of document layout and information requested. In general, the details required will cover the topics outlined above.

National and international research funding bodies include:

Health Research Board; www.hrb.ie

Science Foundation Ireland; www.sfi.ie

Enterprise Ireland; www.enterprise-ireland.com

Irish Research Council for Science, Engineering & Technology; www.ircset.ie

Irish Cancer Society; www.cancer.ie

Irish Heart Foundation; www.irisheart.ie

European Union; www.welcomeeurope.com

Wellcome Trust Foundation; www.wellcome.ac.uk

The editorial committee of each journal has its own standards and guidelines that must be adhered to for publication:

- Check each journal specific requirements before submission
- Refer to the Guidelines on Good Publication Practice ³

In general the basic sections of any journal will include most if not all of the following topics;

6.1 ABSTRACT

This is a very short summary of what was investigated by the researcher and why. It should summarise key results. In addition the key-words in the paper should be highlighted under the abstract text.

6.2 INTRODUCTION ⁴

This section should define the condition or problem being investigated and provide background information and concept. These should then be linked to the hypothesis being tested. The aims and objectives of the research must be clearly stated at this point. In addition, summarise what you have found and how, describe the limitations of the study and the importance of your findings.

6.3 MATERIALS/SUBJECTS AND METHODS

Provide details on the source of you data, ie patients, healthy volunteers, bio-banks, records etc and detail your inclusion/exclusion criteria. State the study design, is it experimental or observational? Supply information on what will be measured and how. Will you be using gold standard approaches, if so, what are they? Also discuss the

statistical methods used to analyse your data, i.e. confidence intervals or hypothesis tests.

6.4 RESULTS

Data may be presented in the form, of tables, charts histograms, images etc. Each figure detailing results must have a legend underneath summarising the content. The body of text in the results section should describe in a matter of fact way the data and not explain or account for the findings. The text should deal with the each figure of data in chronological order.

Figures, Tables and Legends – Critical for the paper’s success ⁴

- Most important part of paper
- Most neglected part of the paper
- Should be the first part to be designed and written
- Part of the paper that determines success or failure

6.5 DISCUSSION ⁴

This section of the paper allows the author to present his/her interpretation of the data and discuss the likely impact of the findings on current best practice in the specific field. It also provides the author with the opportunity to note the limitations of the study and describe future research that may be conducted in the area.

6.6 BIBLIOGRAPHY

Each journal will specify the format in which to present the bibliography this will usually be the Vancouver method (see section 5.8).

Note:

In cases where the author plans to release the findings to the mass media all participants in the study should be made aware of the findings in advance.

A researcher must conduct scientific/medical research and publish the findings in an ethical manner. The following actions are considered unethical practices in the scientific and medical communities: ^{3,10,11}

- Piracy - exploitation of ideas from others without acknowledgement
- Plagiarism - copying of ideas, data and text without acknowledgement
- Fraud - fabrication, falsification/invention of data

Be aware that multiple authorship disputes are also very common. The practice of gift or guest authorship should be avoided. Although there is no universally agreed definition of authorship it is essential that roles in matter of authorship and publication be agreed when the study is being designed. At this point the level of contribution and input to the study design and execution that is required to warrant authorship should be stated.

7.1 PLAGIARISM ²⁵

A recent article in the Irish Examiner highlights the problem of plagiarism and that this issue is not confined to those trying to establish themselves early on in their careers. The author correctly describes plagiarism as the blatant “disregard for the reputation and hard work of others”

Common unacceptable excuses include:

- Cut and paste error on ones personal computer resulting in references being “inadvertently omitted”.
- To plead ignorance as it is the first substantial work one has written.

In order to avoid the inadvertent plagiarism pitfall and general misconduct in scientific and medical research, the Committee of Publication Ethics (COPE) has produced a set of guidelines providing advice and direction. ³

1. Bland JM, Butland BK, Peacock JL, Poloniecki J, Reid F, Sedgewick P. Statistics Guide for Research Grant Applicants [monograph on the Internet]. No date [cited 2005 Dec12]. Available from: www.sgul.ac.uk/depts/chs/chs_research/stat_guide/guide.cfm#top
2. Bowers D, House A, Owens D. Understanding Clinical Papers. John Wiley & Sons; 2003.
3. Committee on Publication Ethics (COPE). Guidelines on Good Publication Practice [monograph on the Internet]. No date [cited 2005 Dec 21]. Available from: www.publicationethics.org.uk/guidelines/reports/2003/2003pdf15.pdf
4. Costello R. Getting on: As seen by someone who is getting on [homepage on the Internet]. c2000 [cited 2006 Jan 16]. Available from: www.nihs.ie
5. Data Protection Commissioner. Data Protection (Amendment) Act 2003 [statute on the Internet]. c2003 [cited 2006 Oct 17]. Available from: www.dataprotection.ie/documents/guidance/New_Act_Summary_website_version.pdf
6. Denzin, Lincoln. Handbook of Qualitative Research. 3rd ed. Sage; 2005
7. Department of Health & Children. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 [statute on the Internet]. c2004 [cited 2005 Nov 25]. Available from: www.dohc.ie/legislation/statutory_instruments/pdf/si20040190.pdf?direct=1
8. Department of Health & Children. European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment no. 2) Regulations 2006 [statute on the Internet]. c2006 [cited 2006 Sept 3]. Available from: www.dohc.ie/issues/consultation_good_clinical_practice_2006/Draft_Regulations.pdf?direct=1

9. Kane E. De- Bruin-O' Reilly M. Doing Your Own Research. London: Marion Boyars; 2001
10. Fenton J. Integrity in Medical Research & Publication [homepage on the Internet]. c2005 [cited 2005 Dec 21]. Available from: www.nihs.ie
11. Fenton JE, Jones AS. Integrity in Medical Research and Publication. Clinical Otolaryngology. 2002; 27, 436-439.
12. Gardner MJ, Altman Douglas G. Statistics with Confidence – Confidence intervals and statistical guidelines. London: British Medical Journal, 1994.
13. Wellcome Trust. Guidelines on Good Research Practice [monograph on the Internet]. c2002. [updated 2005 Nov; cited 2005 Dec 6] Available from: www.wellcome.ac.uk/doc%5Fwtd002753.html
14. Gupta R. Concept and Idea [homepage on the Internet]. c2005 [cited 2005 Dec 21]. Available from: www.nihs.ie
15. Houghton F. Qualitative Methodologies [homepage on the internet]. c2005 [cited 2005 Dec 21]. Available from www.nihs.ie
16. Irish Council for Bioethics. Human Biological Material: Recommendations for Collection, Use and Storage in Research. Dublin: Irish Council for Bioethics, 2005.
17. Irish Council for Bioethics. Operational Procedures for Research Ethics Committees: Guidance 2004. Dublin: Irish Council for Bioethics, 2004.
18. Medical Research Council; Ethics Series. Good Research Practice [monograph on the Internet]. c2000. [updated 2005 Sept; cited 2006 Nov 20]. Available from: www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415

19. International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use (ICH). ICH Harmonised Tripartite Guidelines; Guideline for Good Clinical Practice (GCP(E6.R1)) [monograph on the Internet] c 2002 [cited 2006 Nov 20] Available from www.emea.eu.int/pdfs/human/ich/013595.en.pdf
20. Medical Statistics Unit, UCLH R&D Directorate. Guidelines for Completing a Research Protocol for Observational Studies [monograph on the Internet]. c2006 [cited 2006 Sept 6]: Available from: www.uclh.nhs.uk/NR/rdonlyres/066EBB58-BB0F-462A-908A-86DB5FB9216A/0/obs_protocol_guidelines_2006.pdf
21. Petrie A, Sabin C. Medical Statistics at a Glance. Blackwell Publishing; 2003.
22. Browner W. Publishing and Presenting Clinical Research. 2nd ed. Lippincott Williams & Wilkins; 2006.
23. Saunders J, SCU, University of Limerick. Medical Statistics [homepage on the internet]. 2005 [cited 21 December 2005]. Available from: www.nihs.ie.
24. Saunders J, SCU, University of Limerick. Study Design & Methodology [homepage on the internet]. 2005 [cited 18 December 2005]. Available from: www.nihs.ie
25. Prone T. Copyright and Copy Wrongs. Irish Examiner. 2005 Nov 11.
26. Cooper M, Turpin G, Bucks R, Kent G. Good Research Practice Guidelines for the Conduct of Psychological Research within the NHS. [monograph on the Internet]. c2005 [cited 2006 Jan 17] Available from: www.bps.org.uk/downloadfile.cfm?file_uuid=E615A15A-1143-DFD0-7E9F-60808ED2875D&ext=pdf

Name of Ethics Committee	Address for correspondence	Date of recognition	Area for which committee may act	Description or class of clinical trials for which committee may act
SJH/AMNCH Research Ethics Committee	Tallaght Hospital, Dublin 24	13 July 2004	The whole State	Clinical trials of all descriptions and classes.
St Vincent's Healthcare Group Ethics and Medical Research Committee	Administrator, St Vincent's Healthcare Group Ethics and Medical Research Committee, Education and Research Centre, Elm Park, Dublin 4.	13 Sep 2004	The whole State	Clinical trials of all descriptions and classes.
Clinical Research Ethics Committee of the Cork Teaching Hospitals	Secretariat, Clinical Research Ethics Committee of The Cork Teaching Hospitals, 2200 Cork Airport Business Park, Kinsale Road, Cork	27 Sep 2004	The whole State	Clinical trials of all descriptions and classes.
HSE North East Area Research Ethics Committee	Secretary, HSE North East Area Research Ethics Committee, Dublin Rd, Kells, Co. Meath	26 Jan 2005	The whole State	Clinical trials of all descriptions and classes.

Name of Ethics Committee	Address for correspondence	Date of recognition	Area for which committee may act	Description or class of clinical trials for which committee may act
Research Ethics Committee, Mater Misericordiae University Hospital and Mater Private Hospital	Administrator, Research Ethics Committee, Mater Misericordiae University Hospital, Eccles Street, Dublin 7	22 Feb 2005	The whole State	Clinical trials of all descriptions and classes.
Beaumont Hospital Ethics Committee	Gillian Vale, Administrator, Ethics Committee, Beaumont Hospital, Beaumont Road, Dublin 9	9 March 2005	The whole State	Clinical trials of all descriptions and classes.
Galway Regional Hospitals Research Ethics Committee	Secretary Research Ethics Committee, Services Department, Block 2C, Main Hospital, University College Hospital, Newcastle Road, Galway	21 April 2005	The whole State	Clinical trials of all descriptions and classes.

Name of Ethics Committee	Address for correspondence	Date of recognition	Area for which committee may act	Description or class of clinical trials for which committee may act
Research Ethics Committee, Our Lady's Hospital for Sick Children	Secretary, Research Ethics Committee, Our Lady's Hospital for Sick Children, Crumlin, Dublin 12	17 May 2005	The whole State	Clinical trials of all descriptions and classes.
Irish College of General Practitioners Research Ethics Committee	Administrator, ICGP Research Committee, 4/5 Lincoln Place, Dublin 2	17 May 2005	The whole State	Clinical trials of all descriptions and classes.
Ethics Research Committee, National Maternity Hospital	Ms Denise O'Brien, Secretary, Ethics Research Committee, Masters /CEO Office, National Maternity Hospital, Holles Street, Dublin 2	20 July 2005	The whole State	Clinical trials of all descriptions and classes.

Name of Ethics Committee	Address for correspondence	Date of recognition	Area for which committee may act	Description or class of clinical trials for which committee may act
HSE South-Eastern Area Research Ethics Committee	Secretary, Research Ethics Committee Office, Old School Of Nursing, Waterford Regional Hospital, Dunmore Road, Waterford	30 Aug 2005	The whole State	Clinical trials of all descriptions and classes.
Research Ethics Committee Sligo General Hospital	Administrator, Research Ethics Committee, Sligo General Hospital, The Mall, Sligo	20 Sep 2005	The whole State	The Committee shall act in relation to clinical trials of all descriptions and classes other than those to which Regulation 13 (4) refers (i.e. gene therapy, somatic cell therapy etc.).
Ethics Research Committee HSE Mid-Western Area	Secretary, Ethics Committee, Mid-Western Regional Hospital, Dooradoyle, Limerick	22 March 2006	The whole State	Clinical trials of all descriptions and classes.

A CLINICAL TRIAL

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational products(s) and/or to identify any adverse reactions to an investigational product and/or to study absorption, distribution, metabolism and excretion of an investigational product (s) with the object of ascertaining safety and or efficacy. (ICH Harmonised Tripartite Guidelines for Good Clinical Practice.¹⁹

Also see: Pocock S J. Clinical Trials: A Practical Approach. John Wiley & Sons; 1990.

A CLINICAL TRIAL (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE REGULATIONS, MAY 2004)⁷

Any investigation in human subjects, other than a non-interventional trial intended:

- A. To discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal products, or
- B. To identify any adverse reactions to one or more such investigational **medicinal products**, or
- C. To study absorption, distribution, metabolism and excretion of one or more such investigational medicinal products, or
- D. To discover, verify, identify or study any combination or the matters referred to in A, B, or C with the object of ascertaining safety or efficacy of such products or both.

NON-INTERVENTIONAL TRIAL: (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE REGULATIONS, MAY 2004)⁷

Is a trial involving the study of one or more medicinal products which have a marketing authorisation where the following conditions are met:

- A. The products are prescribed in the usual manner in accordance with the terms of that authorisation.
- B. The assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a clinical trial protocol but falls within current practice.
- C. The decision to prescribe a particular medicinal product is clearly separated from the decision to include the patient in the study.
- D. No diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question
- E. Epidemiological methods are to be used for the analysis of the data arising from the study.

NON-CLINICAL TRIAL

Can be defined as an investigation to obtain information, advance knowledge and improve human well-being. Such studies may involve but not be limited to physiological studies, development of health and disability services and use of secondary data for epidemiology studies.

ETHICS COMMITTEES IN THE MID-WEST REGION

University of Limerick Research Ethics Committee

Applications to conduct research must be sought from the University REC by UL staff and students in the following circumstances:

- Direct experimentation on individuals
- Surveys or questionnaires posed to individuals
- Use of data derived from individual records where people may be identified

Please note that the EC at the University deals with investigations involving public and community participants only and not patients that are receiving treatment or therapy for an illness. If patients are involved approval must be sought from the Ethics Research Committee HSE Mid-Western Area

The operational procedures of this EC are as follows:

- Formal meetings are held monthly during the Academic Year (one per month except August), and the deadline for receipt of protocols is the last working day of the preceding month (allowance must be made for bank holidays etc.)
- There are 15 members on the committee
- Guidelines and application forms for research based in Science & Technologies or Business Humanities and Education can be downloaded from the ULREC website www.ul.ie/researchethics. Receipt of the application form will be acknowledged and allocated a ULREC Number.
- The main REC approves doctorate and staff directed proposals that involve members of the community as participants. Approval may be given immediately or pending minor changes. Approval can be given for up to 3 years and if the project has not started within a year approval may be rescinded.

University of Limerick Research Ethics Committee

The Secretary,
University of Limerick Research Ethics Committee
C/o Vice President Academic and Registrar's Office,
University of Limerick.

Ethics Research Committee HSE Mid-Western Area

Application for ethics approval must be sent to this EC when the research involves access to patients or clients and data/records within the health service. This ethics committee can provide approval for Clinical Trials on Medicinal Products for Human Use as defined by the EU Directive.⁷ Applications may be sent to this or one of the other twelve Ethics Committees which have been recognised under Regulation 7 of the EU Directive on Clinical Trials on Medicinal Products for Human Use.

http://www.dohc.ie/issues/clinical_trials/ethics_committees.html

(see Appendix 1)

The operational procedures of this EC are as follows:

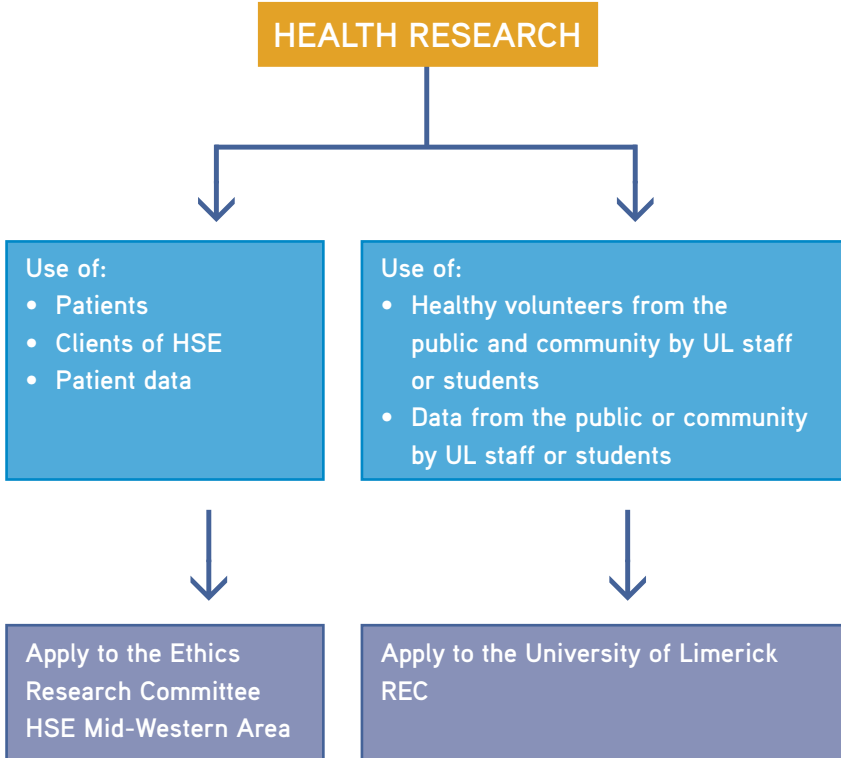
- Meetings take place once a month except in July, August and December.
- Applications and submissions to the ethics committee shall be received no less than three weeks in advance of the meeting at which the application is to be considered.
- Ms Bernadette Ryan can be contacted for information on meeting schedules Ph: 061-482482 or e-mail bernadettef.ryan@mailh.hse.ie
- One of the researchers involved in the proposed research must attend the EC meeting to present the research and explain any ethical issues.
- The application form to apply for ethical approval can be obtained from Ms Bernadette Ryan (Ph: 061-482482 or e-mail bernadettef.ryan@mailh.hse.ie)

- The committee members receive proposals in advance of each meeting. At this meeting the research proposal will then be; a) accepted, b) rejected outright, or c) accepted pending amendments. Following the meeting a letter will be sent to the applicant stating what changes must be made before approval can be given. Initial approval is granted for a 12 month period. If the study/project continues after 12 months then the primary investigator must reapply in writing (letter).
- All applications submitted must have the proposed research project supervised by a medical consultant from the HSE in the Mid-West Region.

Ethics Research Committee HSE Mid-Western Area

Secretary,
Ethics Committee
Mid-Western Regional Hospital,
Dooradoyle,
Limerick

ETHICS APPROVAL IN THE MID-WEST REGION

COMPLETE THE APPLICATION FORM
AND SUPPLY ALL RELEVANT DOCUMENTATION

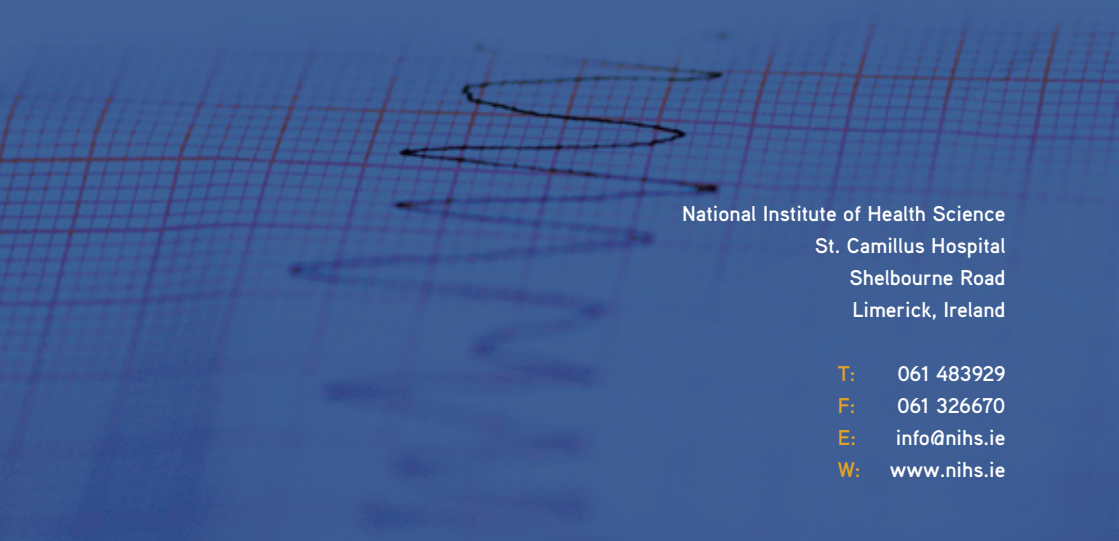
- Approval
- Approval pending protocol amendments
- Rejection

IF THE RESEARCH COMES UNDER:

Clinical Trials on Medicinal Products for Human Use

(As defined by EU Directive, May 2004 and authorised by the Irish Medicines Board)

Then the principal researcher must apply to the Ethics Research Committee HSE Mid-Western Area or one of the other 12 approved Ethics Committees that have been recognised by the Ethics Supervisory Body under regulation 7 of the EU Directive to approve such studies (See Appendix 1)

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