

## SCHOOL OF PHYSIOTHERAPY RESEARCH PROPOSAL FORM

LA TROBE UNIVERSITY  
FACULTY OF HEALTH SCIENCES  
SCHOOL OF PHYSIOTHERAPY

### *RESEARCH PROPOSAL*

Higher degree students are required to submit a written Research Proposal to their supervisors who will give feedback. The final written version is then submitted to the Chair of the School Research Committee and is evaluated by members of this Committee. Feedback is given to the supervisor, who will provide feedback to the student. When this process is finalised the student can proceed to give a verbal presentation. The written and verbal research proposals must be completed **BEFORE** any application is submitted for ethics. A copy of the final version of the research proposal must be submitted to the Postgraduate Coordinator for filing as evidence of progress.

**Name of Student :**

**Student Number :**

**Course of Enrolment :**

**Level of Study (Full-Time or Part-Time) :**

**Name of Principal Supervisor :**

**Name(s) of Co-Supervisor(s) :**

**Please complete all sections of this form. Adhere to the word limits for your subject. If you have no specified word requirement, do not exceed 12 pages.**

Project Title

*Provide a title that is clear, brief, precise and informative to workers outside your field.*

*The title should be no more than 15 words.*

Seven-line summary (12 point font) outlining why this project needs to be conducted.

*This summary should briefly state :*

- *the aims of the research.*
- *the reasons why this project should be conducted.*
- *expected outcomes (hypotheses).*
- *the relevance of the research.*

<b>TIMETABLE FOR THE PROJECT</b>		
<i>Year</i>	<i>Months</i>	<i>Tasks to be Completed</i>

*List the timetable for research tasks. Provide a brief title for each stage of the project. Examples of tasks to be included in this table include the following: literature review, research proposal, ethics application, verbal presentation of research proposal, preparing test protocols, data collection, data analysis, data interpretation, writing up of results, etc.*

## *Guidelines for the RESEARCH PROPOSAL*

Before you start, you may wish to consider the following :

- What aspects of the articles that I have read can be used to assist in the development of my research proposal?
- What are the limitations of the previous research that I need to consider in designing my project?
- What are the strengths of the previous research that I need to consider in designing my project?
- What can be learnt about the manner in which the data from previous research has been collected and analysed?
- Are there common mistakes across a number of the reviewed articles?
- What is the general consensus in the literature and do I have sufficient evidence to support/refute/ignore this consensus?
- What are the theoretical issues learnt from these articles that can guide the development of my expected outcomes and hypotheses (where applicable)?

Using the headings supplied, write your research proposal using the following format: 12 point font, Times New Roman, double-line spacing.

### **Overview of Thesis Plan**

Provide an overview of the study/studies to be conducted for your degree. Where applicable, describe how the specific project described below fits into the overall plan.

### **Background to the Project** (approximately 25% of word limit)

In this section you should :

- Identify the problem and briefly **summarise past research** that has contributed to the formulation of your project. Wherever possible, use your systematic review to provide the background and justification in this section.
- **Identify the limitations** in previous studies.
- Outline the **goal of your intended research**.
- Indicate **how your work will advance knowledge**.

### **Aims and Hypotheses of the Project**

- State the **main aim** of your project.
- Define the specific **research hypotheses** that will be tested.
- Describe the **specific objectives that will be measured** in testing the hypotheses.

### **Research Design**

**Define the research design**

- For example: observational study/RCT/survey etc.
- How will the design of your research counter potential sources of bias?

**Use checklists in Appendix 1** to limit the influence of bias on your research results.

**Define participants:**

- Eligibility criteria and exclusion criteria- defend these criteria.
- Define the number of participants- defend this number using power analysis. This analysis requires that you know which statistical test you plan to use, and the predicted effect size. How this is tackled will vary with each research question.
- If there are no participants, define the source of the data.

**Define the intervention** (if there is one)

**Baseline data** (if appropriate)

- What will be assessed at baseline.

**Outcome data**

- Define the key outcome of interest and secondary outcomes.
- How will outcomes be measured? Defend the selection of outcome measurements. Are they suitable/valid for the task, are they adequately reliable to detect the effects of interest.
- When will outcomes be measured? Defend the decisions.
- Who will collect outcome measurements (will they be blind to group allocation)?

**Data analysis**

- Define how each hypothesis will be tested (what test will be used) and how test results will be interpreted.

**Define costs** (see budget section below)

**Clarify how this research will contribute to knowledge**

Make brief comments about the following :

- Predicted Outcomes of Study.
- External validity of the study.
- Ethical considerations.

**References**

List the references referred to in your research proposal. This section can be in smaller font if space is limited. It is recommended that you use the latest edition of the American Psychological Association Style Manual for citation and listing of references. (Bibliographic references not included in word count).

**RESEARCH PROPOSAL**

**Budget**

Predict costs that will be incurred by your research. For higher degree by research students (PhD, Masters by Research, Professional Doctorate), refer to the School of Physiotherapy Postgraduate Handbook for information about funding of projects. Refer to RGSO (<http://www.latrobe.edu.au/rgso/>) for details of salary, per diem, on-costs, etc. If no costs are anticipated for a section please indicate by typing the word "NIL". Indicate priority for all items. A - considered essential for the project. B- necessary to maintain a reasonable rate of progress. C - Other items which would be useful. Please use numerical rankings eg. B1, B2, C1, C2, etc.

	Detailed Budget items	Priority (A, B, or C?)	Funding Source
Personnel			
Equipment (eg. low-cost equipment not currently within the School of Physiotherapy that is essential for your project?)			
Maintenance (eg. equipment maintenance)			
Travel (eg. does your project entail travelling into rural regions or interstate? Do participants need to be reimbursed for travelling expenses?)			
Other (eg. production & postal costs)			
		<b>Total⇒</b>	

**Justification of the Budget**

Using the following headings, explain why requested funds are necessary.

- Personnel
- Equipment
- Maintenance
- Travel
- Other

## Appendix to Research Proposal Form

Controlling for sources of bias that might influence results can strengthen the design of a trial. In the section that follows, questions that seek sources of bias in different trial designs are reported. Think through the questions relevant to your intended design and plan research methods that limit the potential for bias to affect your results.

### If you are planning an randomised controlled trial :

Study the PEDro scale at :

[http://www.pedro.fhs.usyd.edu.au/scale\\_item.html](http://www.pedro.fhs.usyd.edu.au/scale_item.html)

and make sure you protect yourself from the possible sources of bias that might affect your results.

Check list :

- Was the assignment to the treatment groups random?
- Was randomisation of the participants concealed from the allocating officer?
- Was relatively complete follow-up achieved (>85%)?
- Were the outcomes of people who withdrew described and included in the analysis?
- Were subjects blind to treatment or is it likely that both groups would have considered their treatment to be equally credible?
- Were those assessing outcomes blind to the treatment allocation?
- Were the control and treatment groups comparable at entry?
- Were the groups treated identically other than for the named interventions?
- Was an Intention to Treat analysis performed for at one least one key outcome measure?
- Were the results of between-group statistical comparisons reported for at least one key outcome?
- Were point estimates and measures of variability described?

The following checklist is from the CONSORT STATEMENT.

*David Moher, MSc, Kenneth F. Schulz, PhD, MBA, Douglas Altman, DSc for the CONSORT Group 2001 The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials JAMA.;285:1987-1991.*

This is designed to help people to adequately report their RCTs but is very useful when designing an RCT.

- How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").
- Scientific background and explanation of rationale.
- Eligibility criteria for participants and the settings and locations where the data were collected.
- Precise details of the interventions intended for each group and how and when they were actually administered.
- Specific objectives and hypotheses.
- Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).

- How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.
- Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).
- Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.
- Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.
- Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.
- Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.
- Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.
- Dates defining the periods of recruitment and follow-up.
- Baseline demographic and clinical characteristics of each group.
- Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).
- For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g: 95% confidence interval).
- Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
- All important adverse events or side effects in each intervention group.
- Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.
- Generalizability (external validity) of the trial findings.
- General interpretation of the results in the context of current evidence.

### **If you are planning a cohort study:**

What is a Cohort Study?

Cohorts are defined populations that, as a whole, are followed in an attempt to determine distinguishing subgroup characteristics.

*Example of a cohort study: Johansen C and Olsen JH. Risk of cancer among Danish utility workers—a nationwide cohort study. American Journal of Epidemiology 147(6):548-55, 1998 Mar 15.*

Advantages of cohort studies :

- ethically safe;
- subjects can be matched;
- can establish timing and directionality of events;

- eligibility criteria and outcome assessments can be standardised;
- administratively easier and cheaper than RCT.

Disadvantages of cohort studies :

- controls may be difficult to identify;
- exposure may be linked to a hidden confounder;
- blinding is difficult;
- randomisation not present;
- for rare disease, large sample sizes or long follow-up necessary.

Consider ways to counter these important sources of bias :

- Are the exposed people representative of the standard users of the intervention?
- Was the non-exposed cohort selected from the same population as the exposed?
- Was exposure reliably ascertained and verified?
- What factors (other than the exposure) may affect the outcome?
- Were the cohorts comparable on these important confounding factors?
- Was there adequate adjustment for the effects of these confounding variables?
- Was a dose-response relationship between exposure and outcome demonstrated?
- Was outcome assessment blind to exposure status?
- Was follow-up long enough for the outcomes to occur?
- Was an adequate proportion of the cohort followed-up?
- Were drop-out rates similar in exposed and unexposed groups?

Questions from <http://www.ncl.ac.uk/pahs/internal/ejr/CriticalAppraisal.htm>

- What kind of cohort study was it - historical, prospective, mixed?
- Was a cohort design the best one for the question addressed?
- Cohorts are suitable for studying natural history, causation and prognosis, but are generally not good for studying treatment effects.
- Who exactly was studied?
- How accurately was exposure measured?
- How accurately were outcomes measured and were relevant outcome measures ignored?
- Was loss to follow up a large problem and what efforts were made to reduce losses?
- Did analysis allow for the passage of time - for example increasing mortality during a long period of study?
- Were there other confounding factors that were not adequately allowed for?

### **If you are planning a Case-Control Study :**

What is a case-control study?

Studies that start with the identification of persons with a disease of interest and a control (comparison, referent) group without the disease. The relationship of an attribute to the disease is examined by comparing diseased and non-diseased persons with regard to the frequency or levels of the attribute in each group. Involves identifying patients who have the outcome of interest (cases) and control patients

without the same outcome, and looking back to see if they had the exposure of interest.

*Example of a case control study: Del Amo J, Petruckevitch A, Phillips AN, De Cock KM, Stephenson J, Desmond N, Hanscheid T, Low N, Newell A, Obasi A, Paine K, Pym A, Theodore C, and Johnson AM. Risk factors for tuberculosis in patients with AIDS in London: a case-control study. International Journal of Tuberculosis & Lung Disease 3(1):12-7, 1999 Jan.*

Advantages of a case-control study :

- quick and cheap;
- only feasible method for very rare disorders or those with long lag between exposure and outcome;
- fewer subjects needed than cross-sectional studies.

Disadvantages :

- reliance on recall or records to determine exposure status;
- selection of control groups is difficult;
- potential bias: recall, selection.

Consider ways to counter these important sources of bias in Case-Control Studies :

- Is the case definition explicit?
- Has the disease state of the cases been reliably assessed and validated?
- Are the cases representative of a series, or is there a potential for selection bias?
- Were the controls selected from a similar population as the cases?
- Is there evidence that the controls are free from disease?
- How comparable are the cases and controls with respect to potential confounding factors?
- Were hazards and interventions assessed in the same way for cases and controls?
- Was the response rate adequate?
- Were the non-response rates the same in both groups?
- Is it possible that over-matching has occurred in that cases and controls were matched on factors related to exposure?
- Was an appropriate statistical analysis used (matched or unmatched)?

Questions from <http://www.ncl.ac.uk/pahs/internal/ejr/CriticalAppraisal.htm>

- Is this design appropriate? Case-control studies are generally not suitable for measuring treatment effects. Cohort studies are better if the disease incidence is sufficiently high (common conditions).
- How were the cases obtained?
- Case definitions, referral sources.
- Incident or prevalent cases?
- How was the control group chosen and was it appropriate?
- Were data collected in the same way for cases and controls?
- Could there be other sources of bias?
- Ascertainment of exposure status, misclassification of cases.
- Recall bias, poor measurements.
- Could there be confounding?

- Was there "data-dredging" to look at multiple possible exposures?

### **If you are planning a Longitudinal Study :**

What is a longitudinal study?

In a longitudinal study subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both. Such investigations vary enormously in their size and complexity. At one extreme a large population may be studied over decades. For example, the longitudinal study of the Office of Population Censuses and Surveys prospectively follows a 1% sample of the British population that was initially identified at the 1971 census. Outcomes such as mortality and incidence of cancer have been related to employment status, housing, and other variables measured at successive censuses. At the other extreme, some longitudinal studies follow up relatively small groups for a few days or weeks. Thus, firemen acutely exposed to noxious fumes might be monitored to identify any immediate effects.

Consider ways to counter these important sources of bias in Longitudinal Surveys or Case Series :

- Is the study based on a random sample selected from a suitable sampling frame?
- Is there any evidence that the sample is representative of standard users of the intervention?
- Are the criteria for inclusion in the sample clearly defined?
- Did all individuals enter the survey at a similar point in their disease progression?
- Was follow-up long enough for important events to occur?
- Were outcomes assessed using objective criteria?
- If comparisons of series are being made, was there sufficient description of the series and the distribution of prognostic factors?

### **If you are planning a study of the utility of a Diagnostic Test :**

A diagnostic test is a measurement used to indicate the presence or absence of a specific disease or condition in a patient from a specific patient population. A study of the utility of a diagnostic test would seek to quantify the degree to which a test correctly identifies the presence or absence of disease. The preferred design is prospective. The new test is used and the (preferably gold) reference standard also used and the results compared.

In addition to choosing an appropriate comparative procedure, evaluating a new test involves choosing appropriate patients, specimens, and individuals performing the tests. Descriptions of comparative results should include a clear description of all methods used, and how and what data were collected.

This includes: patient recruitment procedures, patient demographics, patient and specimen inclusion/exclusion criteria, specimen collection procedures, time of specimen collection and testing, types of specimens collected, number of specimens collected and tested and number discarded number of specimens included in final data analysis, specimen collection devices (if applicable), and specimen storage and

handling procedures. The data description should include an accounting of all patients and test results (number of tests planned, tested, discarded, used in final analysis) and descriptive summaries of the final results. Results should be reported overall, by site, and by any other relevant categories. For qualitative tests derived from an underlying quantitative result, descriptive summaries should include ranges of results, histograms of results by disease state (if known), and Receiver Operating Characteristic (ROC) Plots (if disease state is known).

*STARD checklist for the reporting of studies of diagnostic accuracy.*

The STARD statement (The STARD Initiative -- Towards Complete and Accurate Reporting of Studies on Diagnostic Accuracy) with the checklist and flow diagram has been published in several journals including: Clinical Chemistry, Annals of Internal Medicine, Radiology, BMJ, Lancet, American Journal of Clinical Pathology, Clinical Biochemistry, Clinical Chemistry and Laboratory Medicine.

### *INTRO*

- Identify the article as a study of diagnostic accuracy recommend MeSH heading.
- 'sensitivity and specificity'.
- State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.

### *METHODS*

- Participants.
- Describe the study population: The inclusion and exclusion criteria, setting and locations where the data were collected.
- Describe participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?
- Describe participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in items 3 and 4? If not, specify how participants were further selected.
- Describe data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?
- Test methods.
- Describe the reference standard and its rationale.
- Describe technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.
- Describe definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.
- Describe the number, training and expertise of the persons executing and reading the index tests and the reference standard.
- Describe whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.
- Statistical methods.

- Describe methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).
- Describe methods for calculating test reproducibility, if done.

## *RESULTS*

- Participants.
- Report when study was done, including beginning and ending dates of recruitment.
- Report clinical and demographic characteristics of the study population (e.g. age, sex, spectrum of presenting symptoms, comorbidity, current treatments, recruitment centers).
- Report the number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended).
- Test results.
- Report time interval from the index tests to the reference standard, and any treatment administered between.
- Report distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.
- Report a cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.
- Report any adverse events from performing the index tests or the reference standard.
- Estimates - Report estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).
- Report how indeterminate results, missing responses and outliers of the index tests were handled.
- Report estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.
- Report estimates of test reproducibility, if done.

## *DISCUSSION*

- Discuss the clinical applicability of the study findings.

### *Hierarchy of evidence for test accuracy studies.*

- Level 1. A blind comparison with reference standard among an appropriate broadly defined sample of consecutive patients.
- Level 2, one of the following.
- Level 3, two of the following
- Level 4, three of the following: Narrow population spectrum, differential use of reference standard, reference standard not blind, case control study design.
- Level 5. Expert opinion with no explicit critical appraisal, based on physiology, bench research or first principles.

See notes sources of bias in studies of diagnostic tests in the document “Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Draft Guidance for Industry and FDA Reviewers”

<http://www.fda.gov/cdrh/osb/guidance/1428.html>

### **If you are planning an Economic evaluation :**

See phase 5, page 15: [http://www.york.ac.uk/inst/crd/pdf/crd4\\_ph5.pdf](http://www.york.ac.uk/inst/crd/pdf/crd4_ph5.pdf)

Consider how your design counters the following sources of bias.

- Is there a well defined question?
- Is there comprehensive description of alternatives?
- Are all important and relevant costs and outcomes for each alternative identified?
- Has clinical effectiveness been established?
- Are costs and outcomes measured accurately?
- Are costs and outcomes valued credibly?
- Are costs and outcomes adjusted for differential timing?
- Is there an incremental analysis of costs and consequences?
- Were sensitivity analyses conducted to investigate uncertainty in estimates of cost or consequences?
- How far do study results include all issues of concern to users?
- Are the results generalisable to the setting of interest in the review?

Based on Drummond's checklist

*Drummond M, O'Brien B, Stoddart G, Torrance G. Methods for the economic evaluation of health care programmes. 2nd ed. Oxford: Oxford University Press; 1997.*

### **Grading system for quality of economic evaluations**

*Medical Care 2003 41(1): 32-Qualitative research papers.*

*Medical Sociology News 1996;22.1*

- Are research methods appropriate to the question being asked?
- Is there a clear connection to an existing body of knowledge/wider theoretical framework?
- Are the criteria for/approach to sample selection, data collection and analysis clear and systematically applied?
- Is the relationship between the researcher and the researched considered and have the latter been fully informed?
- Is sufficient consideration given to how findings are derived from the data and how the validity of the findings were tested?
- Has evidence for and against the researcher's interpretation been considered?
- Is the context for the research adequately described and accounted for?
- Are findings systematically reported and is sufficient original evidence reported to justify a relationship between evidence and conclusions?

Are the researchers clear about their own position in relation to the research topic?

### **If you are planning qualitative research :**

*Mays N, Pope C. Qualitative research in health care. London: BMJ Publishing Group; 1996.1.*

- Adequate description: Is sufficient detail given of the theoretical framework informing the study and the methods used?
- Is the description of the context for the study clear?
- Is there an adequate justification and description of the sampling strategy?
- Is the description of the fieldwork clear?
- Data analysis:
- Are procedures for analysis clearly described?
- Is the analysis repeated by more than one researcher?
- Are findings from quantitative research used to 'test' qualitative findings?
- Is there evidence that the researchers have looked for contradictory observations?
- Link to theory:
- Is the study design and sampling strategy theoretically grounded?
- Does the link to theory inform the analysis and any claims for generalisability?
- Is sufficient original evidence provided to support relationship between interpretation and evidence?

### **If you are planning an Epidemiological study :**

Checklists for epidemiological studies that assess potential links between exposures to risk factors and harm.

*Fleiss Gross. Meta-analysis in epidemiology, with special reference to studies of the association between exposure to environmental tobacco smoke and lung cancer: a critique. J Clin Epidemiol 1991;44:127-1392.*

*Levine, Walters, Lee et al User's guide to the medical literatureIV:How to use an article about harm JAMA 1994;271:1615-16193.*

*How to read clinical journals,IV: To determine etiology or causation Can Med Assoc J 1981;124:985-9904.*

*How to read clinical journals, III: To learn the clinical course and prognosis of disease Can Med Assoc J 1981;124:869-872.*

Additional reading.

#### **Evaluating clinical practice guidelines**

<http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf>

#### **Evaluating Outcome measures**

<http://www.leeds.ac.uk/nuffield/infoservices/UKCH/review.html>

#### **Evaluating the quality of studies of prevalence**

<http://www.paho.org/English/DD/PUB/v10n3-Silva.pdf>