The Royal Australasian College of Physicians

The Joint Training Committee in Paediatric Emergency Medicine

How to manage a trainee research project (TRP): A guide for Royal Australasian College of Physician (RACP) trainees under the Joint Training Committee (JTC) in Paediatric Emergency Medicine (PEM)

Introduction

The Trainee Research Project (TRP) is intended to help you learn the correct way to do research so you can use your skills in future research or in the analysis of other people's research. Like many aspects of medicine, more is gained by active participation and experience, than by only reading and listening.

The JTC has reviewed and refined the requirements for the RACP PEM trainee projects to have equivalent requirements as the ACEM 4:10 requirements project. This includes clear information about the minimum criteria for a TRP against which a project will be adjudicated.

This guide aims to help you conduct a successful TRP. Although the advice it contains is not derived from data from multiple randomised controlled trials, it has come from the extensive experience gained by TRP supervisors and adjudicators over many years. For this area, it is the highest level of evidence available!

Project planning – be SMART
A successful TRP requires not only research related knowledge, but also effective project planning.
A "SMART" project is Specific, Measurable, Achievable, Realistic, Timely

Projects suitable for adjudication include:

- Small, compact clinical trials that answer a simple question relevant to paediatric emergency medicine. Very complex or long studies are very hard to complete.
- Well designed validation studies of a common or important clinical test/tool

- Retrospective studies that employ sound research methods and answer important/relevant questions
- Comprehensive literature reviews (at least 5 studies to analyse on the topic)
- Well-designed observational or cross-sectional studies, comparing patient groups
- An audit or quality project is only acceptable if it reports a full audit cycle (ie audit, intervention and re-audit) and associated with literature review

If you are training under 2 SACs the JTC PEM will not automatically accept a study considered acceptable by another SAC unless it meets the study design outlined above and minimum criteria specified below.

It is expected that your TRP will:
be original
be relevant to paediatric emergency medicine
meet all of the mandatory learning objectives
answer an important and relevant research question
employ sound research and statistical methods
be complete – an interim analysis or pilot study will be unacceptable
have been authorised (or given exemption) by a research ethics committee

Minimum Criteria for Completion of a TRP for JTC PEM trainee

These criteria will be used to adjudicate all JTC projects and will assist in making the expectations for the trainee project clear and also ensure standardisation of the adjudicating process. Each trainee should address these criteria with their supervisor before submission to ensure these criteria have been addressed.

	Criteria	**Met**	
1.	The research question asked is clear	Yes	No
2.	A literature search of the major healthcare databases has occurred	Yes	No
3.	Study methods appropriate to the research question are used	Yes	No
4.	A statement that local institutional ethics committee approval is provided or a statement why this is not required is made	Yes	No
5.	Inclusion and exclusion criteria are clearly defined and appropriate	Yes	No
6.	Methods to minimise bias (ie selection bias, measurement bias, confounding factors) have been used	Yes	No
7.	A primary outcome measure is defined	Yes	No
8.	There is a data analysis plan that contains: An appropriate justification of the sample size chosen	Yes	No
	Statistical methods appropriate for the type of data are used	Yes	No
	Results are reported as point estimates (eg mean, median,proportion) with measurement of uncertainty of point estimates (eg standard deviation, interquartile range, 95% confidence intervals)	Yes	No
	Statistical significance is reported where relevant	Yes	No
	The statistical software used is named	Yes	No
9.	Results: The study sample and the flow of participants through each stage is described	Yes	No
	A comparison of the baseline characteristics of the study groups is made when relevant	Yes	No
	All outcomes measured are reported	Yes	No

10.	Discussion: There is a concise summary of the main findings	Yes	No
	The relationship to existing knowledge is discussed	Yes	No
	The clinical relevance of results is discussed	Yes	No
	Potential biases and the extent and direction of their impact on the study findings are discussed	Yes	No
11.	Conclusions: Relate to the research question and are supported by the study results	Yes	No
12.	Additional Information: A declaration of competing interests (eg. funding sources) is made	Yes	No
13.	Clarity of presentation: The communication used to report the study is clear and concise	Yes	No

Tips on how to successfully manage a TRP

The most important factor for a successful TRP is adequate planning.

Time management

The project is likely to take 12-18 months from the first idea to the final judgment. This time frame is considerably longer than you may be used to dealing with. Most successful projects require about 200 hours of trainee input over the project's life, so you need to allow for this when organising your life.

When planning, you will need to consider the availability of your supervisor(s). Supervisors may take leave, attend meetings and/or have periods where they are temporarily unable to assist you due to other commitments. This can be particularly disruptive at key periods of the project. You can often avoid unexpected delays in your project by asking your supervisor(s) of their likely availability during the study period. Where possible, having more than one supervisor may help.

Before you start

Funding

Search for sources of funding, if required. Most TRPs don't require funding, just time and enthusiasm.

Familiarise yourself with the requirements

Read the relevant regulations on the RACP website. Clarify any areas you are unsure about with your educational supervisor. If you have time, read about commonly used study methods and analyses.

Get ready to use IT

Get acquainted with the software likely to be used before the study starts. You will need to be able to use the medical database search engine(s) used by your health service library – they usually have a guide that can be downloaded and studied, or seek help from your health service librarian. Being able to use word processing features such as change tracking, comment insertion and paragraph styles is very helpful. Familiarity with a spreadsheet or database program is also usually required and will be very important when it comes to data entry and retrieval.

Choose your supervisor

Choosing your project supervisor is very important for your learning and project success. Not all Consultants (either FACEM or FRACP) are equally skilled or comfortable with supervising TRPs. Choose a supervisor familiar with the JTC research requirements and who has experience in supervision of TRPs, whenever possible. Consider your personal compatibility with potential supervisors - you will have close contact with them during the project.

The role of the supervisor is to assist the trainee in the selection of the project, project design, and to guide the trainee in completion of the project. The supervisor is not a joint author.

The supervisor is asked to certify that the project is ready for submission. Trainees must allow adequate time for their supervisor to read and provide feedback prior to submission.

Some trainees work with project supervisors who are different to their educational supervisors. This can introduce problems if there is not clear communication between supervisors, and particular caution is required to ensure that the trainee's educational supervisor remains aware of the trainee's progress in their project work

Be prepared to act on advice
A significant proportion of TRPs fail because the trainee did not act on their supervisor's advice. If your project fails at initial adjudication, is absolutely critical you address all the issues raised by the feedback from adjudicators in the resubmission. If you do this adequately, you have the best chance of success.

Study site selection
When planning your TRP you should try to be in the department where the study is being conducted throughout the study. Everyone who works in Health is busy, and helping to conduct research projects is just one of the many demands they need to consider. Your strong presence in the department when the research is being conducted is a critical factor for success. If you are not working in the department for the duration of the study, you will need to be able to return to the department on a regular basis.

Project phases
This is only a rough guide as times for each section can vary considerably.

Developing research idea and determining authorship 4 weeks

Make sure the idea interests *you* – enthusiasm for someone else's idea is unlikely to last for long.

Study relevance

Choose to study something that has some relevance or importance and is not already self evident. For example, a study to see if patients triaged to the resuscitation room have a higher mortality rate than those triaged to the fast track area is a waste of time. It is like trying to find out if parachutes reduce mortality when jumping from a plane – it is obvious and already known.

Literature search / refinement of idea into a study outline 2 weeks

An adequate literature search is vitally important to find out if the answer to your research question is already known. If it is, you need to choose another idea. If someone else has done a similar study to the one you have planned, your study might not be considered to be original. If your research question has not been answered, use the information gained from other similar studies to develop the methods you will use.

Develop specific study objectives
Vague objectives lead to vague and inconclusive results, so it is important to be specific with your objective(s). For example, a study that aims to 'determine the incidence of post intubation hypotension in ED patients following poisoning and the factors associated with it's occurrence' is likely to be much better than a study that aims to 'determine if there is are any associations between airway manoeuvres and possible adverse effects'. As the former study defines the population, intervention, outcome and potential comparators much better than the latter, it is more likely to be able to achieve its aim.

Develop specific hypothesis – before data collection!
If you don't have a specific hypothesis, you are likely to end up data dredging. This occurs in studies with vague objectives that collect large amounts of data then

perform multiple comparisons between groups to find a statistically significant 'result'. The study is then written, pretending that the 'result' found was one of the study hypotheses. This usually produces false positive results and leads to erroneous conclusions. For these reasons, data dredging is a very serious error and should be avoided at all costs.

Check that you are heading in the right direction

It is vitally important you check that your proposed study will be able to meet the learning objectives at about this stage. Experienced advisors can usually detect the likely problem areas and help you to modify them – *but only if this occurs in the planning phase*. Receiving expert advice later in the process is of little use as the damage has been done. It is like taking a dying patient to a Pathologist - they are unlikely to be able to resuscitate it, but they will be able to tell you what it died from!

Development of study methodology, sample size calculation 4 weeks

Sample size calculation usually requires access to specialised statistical software and is an essential part of study planning. If your study is too small, you reduce the chance of being able to adequately see if your theory is right. If it is too big, you have wasted people's time and may have even potentially exposed patients to unnecessary harm.

Information from previous similar studies can be used to help with the sample size calculation. You can also conduct a pilot study to test the feasibility of your study plan or to collect data for a sample size calculation with the results being helpful in deciding whether to continue with your idea or not.

In clinical studies, many potential study subjects are not enrolled for a variety of reasons. Even in very well conducted studies, less than 50% of the eligible population will end up being enrolled. You need to allow for this when calculating how long your proposed study might take.

Deciding the methods you will use is the most important part of the study as it determines the quality of the information you collect. Studies with good methods collect more accurate information; therefore their conclusions are more likely to be correct. Make sure the methods you use are as good as they can be to minimize possible biases. Spend a lot of time getting this area right before considering anything else. Large, poor quality studies are less likely to pass at adjudication than smaller, (but still appropriately sized) high quality studies.

Research ethics committee approval and trial registration 6 weeks

Developing the ethics committee submission is well worth the effort it requires, as the submission usually forms the basis of the introduction and methods section of the manuscript. Once this is done, half of the manuscript is written! This process usually requires 2-3 revisions, with input from the supervisor. Most ethics committees meet monthly so try to submit your proposal at the right time to prevent unnecessary delay. A variety of trial registers exist (e.g. www.anzctr.org.au). Trial registration does not take long and is required by many journals if a study is to be considered for publication. It can also demonstrate that the study was not a data dredging exercise.

Study duration 6-12months

This varies considerably according to the nature of the study. It is rarely less than 3 months, and more commonly 6 - 12 months. Activity should be expected to be intense for the first month of the study so it is important that the commencement date is scheduled at a time when you and your supervisor are freely available. Unexpected problems always arise when putting study planning into practice. You should plan to conduct staff education sessions and generate material to promote awareness of your study. As no more than 2/3 of available staff are likely to be at any given session (due to shiftwork, leave etc), multiple education sessions are usually required. Following the start up period, you should focus on staff motivation and data collection for the remainder of the study.

If you are undertaking a retrospective study, be aware that retrieving case notes from medical records for review is often a very lengthy process. As many records are not available at any given time, requests for record retrieval need to be performed repeatedly and usually in small batches. If you are lucky you have electronic or scanned medical records!

Data analysis **6 weeks**

This usually requires one primary analysis and one secondary analysis (to deal with unexpected issues) and should be performed by someone with statistical expertise. Be prepared to modify the format of collected data so it can be used by the statistical software for analysis. This phase may be longer if external statistical advice is required. Be aware that availability of assistance from many University statistical departments is variable during the year, so you should check this prior to commencing the study. Prior to analysis you should meet the statistical advisor to discuss the study aims and methods. After the analysis you should meet again to discuss the results, statistical methods used and the reasons for their choice of methods. Taking notes on the methods used and the reasons for their use can be very helpful if your understanding of statistics is limited.

If you do not use a statistician, you must make sure you analyse the distribution of the data prior to performing any analyses. This is important to make sure the most appropriate statistical methods are used. For example, failing to recognise that data is not normally distributed can lead to the inappropriate description of its central tendency and spread (use of mean instead of median, standard deviation instead of interquartile range) and usually increases the chances of false positive results when subjected to statistical testing.

Manuscript preparation **3 months**

This is an intense period where supervisor availability and input is important. The methods section is the section most commonly underdeveloped in TRPs so requires special attention. The aim should be to describe the methods used in enough detail to enable someone else to repeat your study.

Most manuscripts require 2-3 revisions before being suitable for submission. Keep the language simple, write one idea in each sentence and have one theme for each paragraph. Check the manuscript for clarity, accuracy, coherence of ideas as well as the objectivity and logic of any arguments used.

Refer to Minimum Criteria for Completion of a TRP for JTC PEM trainee and discuss each item with your project supervisor.

Study reporting

No study is perfect and good research is about being honest. Make sure you consider the potential limitations of your study and are open about them in the discussion section of your report. It is particularly important that you consider all possible sources of significant bias. Trying to cover up major limitations of your study is much more likely to result in failure at adjudication than if you are open and honest about them.

Conclude only what is supported by your study data

Trying to make a ‘negative’ study appear like a ‘positive’ one is a lost cause in front of an experienced adjudicator. Whether the results support or reject your hypotheses has no effect at all on the adjudication result. Research is all about finding out if your theories are correct - but they can’t always be. If you were already sure of the answer to your research question when you started then you shouldn’t have done the study.

PROJECT MANUSCRIPT Template

The following guide is how you should prepare your manuscript for submission to the JTC. It is the same format if you were preparing a paper for publication. Comments in italics refer to preparing for journal submission rather than JTC manuscript submission.

Study Title

Investigators

Principal investigator: Trainee Name

For publication: include all authors who have contributed significantly to the study design, data collection, data analysis and manuscript preparation by order of contribution. Some senior authors may choose to be listed as last author but this is not consistently enforced

Institution where study was undertaken

Contact details for corresponding author

ABSTRACT – 250 words max

Introduction
Methods
Results
Conclusion

INTRODUCTION

Background

What is the problem?
What is the extent of the problem?

Research question

Must be relevant and important
Must be shown not to already have been answered (by literature search)

Hypothesis

What is your best guess to the answer to the research question?

Aims

What do you aim to do in this study in order to answer the research question?

METHODS

Study design

Eg. RCT, cohort study, cross-sectional study etc

Study setting
Where was the study undertaken?

Study period
When was the study undertaken?

Ethics committee authorisation
Every study must be authorised by a Committee or given exemption from review

Study subjects
Inclusion and exclusion criteria
Recruitment
Consecutive, random, convenience sampling
Advertisement details (if appropriate)

Endpoints
Primary and secondary

Data collection
Bias and confounding
Details of how these were minimized

Statistics
Sample size or power calculation
Methods of statistical analysis (and software used)
Statistical methods appropriate for the type of data are used.

RESULTS
Response rate (if applicable)

Description of the study sample
Usually this will be done in Table 1 – mainly subject demographics etc.
Description of the flow of participants through each stage of the study (eg CONSORT diagram)
Comparison of baseline characteristics of the study groups (when relevant)
All outcomes measured are reported
Results reported as point estimates with measurement of uncertainty (confidence intervals)
Statistical significance is reported where relevant

Primary endpoints
With statistical analysis
Use tables/figures if possible. However, summarize the data in the tables/figures in plain English in the text – **without repeating** the numbers etc

Secondary endpoints
With statistical analysis
Use tables/figures if possible. However, summarize the data in the tables/figures in plain English in the text – **without repeating** the numbers etc

DISCUSSION

First paragraph is a brief summary of main findings

Discussion of primary endpoints

What do they mean?
How do they compare with the findings of others?
How might they influence practice?

Discussion of secondary endpoints

What do they mean?
How do they compare with the findings of others?
How might they influence practice?

Limitations of the study

Participation rate / sample size / drop outs
Bias (selection and measurement), confounding – discuss the extent and direction of impact upon results
Internal and external validity

Recommendations and Implications for Emergency Medicine

Clinical practice
ED organization
Future research

Conclusion (one paragraph)
Relates to only the data presented
Is supported by the data presented

References

Relevant
Recent
From primary data sources (original articles)
Sequential

(Format varies with each journal's Author's Instructions - study these carefully and conform to their requirements)

Competing interests

Declaration of competing interests (eg. funding sources)