



## PLANNING A TRAINEE RESEARCH PROJECT: A GUIDE FOR TRAINEES

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### 1. 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 you should consider are:

- small, compact clinical trials that answer a simple question relevant to emergency medicine (very complex or long studies are hard to complete)
- well-designed validation studies of a common or important clinical test/tool
- retrospective studies that use sound research methods and answer important/relevant questions
- structured literature reviews
- well-designed observational or cross-sectional studies, comparing patient groups.

## 1.1 Projects best avoided

- (a) **Purely qualitative research** (i.e. without any numeric data or statistical analysis): Trainees cannot satisfy the minimum criteria that related to data and statistics by performing purely qualitative research. Mixed qualitative and quantitative research (i.e. transformation of qualitative data into quantitative data) with a hypothesis being tested and statistical analysis of data) would be able to meet the learning objectives, so would be acceptable.
- (b) **Purely descriptive studies** (ie “we looked at a lot of cases and this is what happened”) without any comparisons between groups or analysis of factors that may have contributed to an outcome. These types of studies do not have a hypothesis, so won’t be able to meet the learning objectives.

This does not mean that qualitative or descriptive research is not important (when done well and with clear objectives). However, the vast majority of medical research is quantitative and hypothesis-testing in nature, so it is essential that all Fellows have a good understanding of this type of research.

It is expected that your TRP will:

- be original
- meet all of the mandatory learning objectives
- answer an important and relevant research question
- employ sound research and statistical methods
- be complete – interim analyses or pilot studies are highly unlikely to be acceptable
- have been authorised (or given exemption) by a research ethics committee

## 1.2 Management Tips

The most important factors for a successful TRP are adequate planning, knowing the requirements, and seeking assistance from those with experience in supervising TRPs.

### Time management

The project is likely to take 12-18 months from the first idea to the final judgement. As an emergency doctor, this timeframe may be considerably longer than you are used to dealing with. Most successful projects require about 200 hours of trainee input over the life of the project, so you need to allow for this when organising your own life.

When planning, consider the availability of your supervisor(s). Supervisors may take leave, attend meetings and/or have periods where they are 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 to your project by finding out your supervisor(s) likely availability during the intended study period. Where possible, having more than one supervisor may help.

### Before you start

#### (a) Funding

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

#### (b) Familiarise yourself with the requirements

Read the relevant regulations in the Trainee and Examination Handbook. Clarify any areas you are unsure about with your DEMA or the College. If you have time, read about commonly-used study methods and analyses.

**(c) 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 you can 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. Familiarity with referencing software (eg EndNote) will also help you.

**(d) Choose your supervisor**

Making the right choice of supervisor is very important for your learning and the success of the project. Non-FACEMs are much less likely to understand the research requirement of the College than FACEMs, even when they are experienced and expert researchers. However, not all FACEMs and DENTs are equally skilled or comfortable with supervising TRPs. Choose a supervisor familiar with the College 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. You should encourage your supervisor and/or DENT to seek advice about the project from the local TREP member, Censor, or members of the panel of adjudicators, if required.

**(e) 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, it is absolutely critical that you address all the issues in the feedback from adjudicators in your resubmission. If you do this adequately, you have the best chance of success. Remember, you have only one chance to save the project or you will need to do another.

**(f) Be aware of how your TRP will be assessed**

The marking schedule reflects the minimum criteria. You need to demonstrate your understanding of this minimum criteria in your TRP.

**(g) 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 with your research project is just one of many demands on them. 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 at the time of the study, you will almost certainly need to return to the department to maintain the momentum of the project. Your role as a motivator of others will be very important.

## **2. PROJECT PHASES**

The times indicated should be considered only as a rough guide as they can vary considerably.

### **Developing research idea and determining authorship**

Timeframe: 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 the mortality rate of patients triaged to the resuscitation room is higher 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.

Whenever possible, be the primary researcher (ie. lead author)—you can then have more control over the study and make it do what you want it to.

### **Literature search / refinement of idea into a study outline**

Timeframe: 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 there is any doubt about this, you must check with the TREP that they will consider you as original before you go any further. 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 its occurrence’ is likely to be much better than a study that aims to ‘determine if there is any association between airway manoeuvres and possible adverse effects’. Because the first 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 (or minimum criteria). 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 them, but they will be able to tell you what they died from!

### **Development of study methodology, sample size calculation**

Timeframe: 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 finding out 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.

Involvement of your statistical advisor at this time is very important. You should discuss the study aims and methods with them so they can advise you of the best way to collect data that will be suitable for the type of analyses likely to be used. The types of statistical tests to be used in the data analysis phase should be determined at this stage—not after data collection. There are ample free statistical resources available on the internet for areas you find difficult. An excellent example on one of these is <http://statpages.org/>

You can also conduct a pilot study to test the feasibility of your study plan or to collect data for a sample size calculation. The results of the pilot study will be 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 be 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. Please be aware that very high levels of patient follow-up are required when conducting safety studies and that this can be difficult and time consuming if the patient has left the ED.

### **Research ethics committee approval and trial registration**

Timeframe: 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 (eg. [www.anzctr.org.au](http://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. As registration requires you to specify the outcomes you had planned to study before you started, it can prove that your study was not a data-dredging exercise.

### **Study duration**

Timeframe: 6–12 months

This varies considerably according to the nature of the study. It is rarely less than three months, and more commonly is 6–12 months. Activity should be expected to be intense for the first month of the study, so it is important that the start date is 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 two-thirds of available staff are likely to be at any one 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 the same time, requests for record retrieval need to be performed repeatedly and usually in small batches.

### **Data analysis**

Timeframe: 6 weeks

This usually requires one primary analysis and one secondary analysis (to deal with unexpected issues) and should be performed by the same statistical advisor you involved earlier in the project. If you have not involved anyone earlier, be prepared to modify the format of collected data so it can be used by the statistical software used 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. 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**

Timeframe: 3 months

This is an intense period where supervisor availability and input is important. If planning to present your TRP, you should finish your manuscript first, then use the relevant sections to create your presentation. The methods section is the section most commonly underdeveloped in TRPs, so requires special attention. The aim should be to describe the methods in enough detail to enable someone else to repeat your study.

Most manuscripts require two to three revisions before being accepted for publication, and journal reviewers will provide feedback on areas that need to be addressed on each occasion. Written submissions that accompany a presented TRP need to be of a similar standard so should undergo a similar process of development. Keep the language simple, write one idea in each sentence and have one theme for each paragraph. No one will be impressed by big words and tortuous themes. Check the manuscript for clarity, accuracy, coherence of ideas as well as the objectivity and logic of any arguments used.

If you have been unable to get your TRP published, you may want to consider presenting it instead.

### **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.

If you are planning to present your TRP, ask someone not directly involved in the project to help review it. This often helps improve the clarity of the manuscript.

## **3. PREPARATION FOR PRESENTATION**

Timeframe: 4 weeks

Successful presentations usually have the following:

- a limited number of slides (10-15 slides for a 10 minute presentation)
- a mixture of text and relevant images, diagrams and/or graphs
- an average of seven lines per slide and seven words per line
- no distracting transitional effects between slides or unnecessary animations
- light text on a dark background
- a logical flow of topic: introduction / aims, methods, results, discussion, conclusion.
- a presenter who talks fluently about the important issues and does not just read what is written on the slides
- simple concise wording without spelling mistakes.
- simple tables and charts (avoid small fonts and 'cluttered' tables) that ensure the results of the major outcome variable(s) are easily identified and emphasised
- appropriate conclusions for the study findings (shows perspective)

- free from obvious flaws in methodology and statistical analysis

### **Rehearsal**

It is advised that you present your study to, and get feedback from, an appropriate audience at least two weeks prior to presentation. Presentation to a group of FACEMs/trainees is usually a good forum for this. You should have at least one more 'dry run' in front of your supervisor. Make note of the questions asked and try to anticipate what the audience may ask you on the day of presentation. Practice presentations should be the same as allowed on the day—10 minutes for presentation and five minutes for questions.

Before leaving for the presentation venue, make sure you have appropriate backups in digital and paper format available in case of emergency.

On the day of presentation, get to the venue early and make sure you are familiar with the AV equipment to be used. This can usually be done at one of the breaks before your scheduled session. Before you present, identify yourself to the adjudicators. Following the presentation session make sure you are available to receive the adjudication result and any relevant feedback. Depending on the number of presentations, it may take up to an hour before the adjudicators can get to you.

### **Adjudication phase**

If this doesn't go well, it is likely to take a further three months to rectify the situation. Pay special attention to the feedback received and make sure that you act on it.

### **After your project**

If you presented your TRP, consider publishing it. You should already have a manuscript of suitable quality so it should not take much more effort to do this. You and others will have put a lot of effort into the project, so it is important that as many people as possible are aware of its results. Try to avoid the post-project celebrations and feeling of relief from stopping you from pursuing publication.

Consider continuing with further research in the same area.

Reflect on the improvements you have made in your knowledge of research and address any areas you are not yet comfortable with.

Provide feedback to your supervisor(s) and other relevant people

Pass on what you have learnt to trainees yet to complete their TRP, then help them with their projects when their time comes.

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