

## DEVELOPING A RESEARCH QUESTION

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### Introduction

The potential scope of Radiology research is wide. It encompasses activities as diverse as development of novel image acquisition and analysis methodology, non-invasive biomarker investigation and validation, using established imaging methods in clinical observational projects or as surrogate markers in therapeutic trials and population-based studies, and examining the process and role of imaging in wider patient care. Ideas for imaging research may be stimulated by awareness of a clinically-relevant research question that might be addressed by imaging, or an imaging technique that probes important pathophysiology, and might be applied clinically. In either event, such nascent ideas need to be formulated into well-defined research questions around which studies can be planned.

Developing a research question is the essential first step to prosecuting any meaningful piece of research as it establishes the reason for the study, considers its design, methods and sample sizes required to achieve meaningful conclusions, and the resources needed to support it.

Whatever the size and scope of a research study, a rigorous and structured approach at this initial stage defines the project and allows an early insight as to whether it might work. For those projects that are worth pursuing, it also provides essential information for more detailed study design, and on which to base ethics and funding applications.

***A one page structured proposal provides a useful template on which to base this process.***

*Try to write this as if for critical review by a sharp-eyed scientific reviewer.*

It should comprise:

#### a) Introduction/background

This provides the rationale and impetus for the research. It can usually be summarised in a referenced paragraph or two.

*Key questions:*

- What is the clinical context or importance?
- What has already been published on the subject? – see section on performing literature search.
- What is the unanswered clinical or scientific question?
- What new techniques or observations can be brought to bear to address it?

#### b) Purpose/Aim

This defines the specific question or questions addressed by the study:

Primary objective (main question to be answered – where relevant, a study will be powered statistically to address this).

Any secondary objectives (other research questions to be addressed).

*Key questions:*

- Is this a worthwhile question to address?
- Is it novel? Specifically, what does it add to established knowledge in the field?
- Are the aims achievable? (See below – this should become clear when methodological aspects have been considered.)

**c) Methods**

This defines what will actually be done, and how the project will run in terms of study design, subjects/patients, imaging methods, endpoints, and data analysis.

**Study design and type:**

*For example:*

Retrospective: existing data (already acquired but limited to what acquired) vs Prospective: new data (more time consuming and recruitment-dependent, but greater control over data).

Cross sectional: each subject studied at a single time point vs Longitudinal: study of individuals at more than one time point (e.g. pre and post intervention).

Pilot/exploratory: little or no background data on which to base cohort numbers vs Powered: study numbers predicated by power calculations.

Single site vs multicentre.

**Subjects:**

For clinical studies, define the subject group(s) and necessary control groups. These may include patients and/or healthy volunteers. Consider age and sex matching, and co-morbidities as potential sources of bias, although in practice these may be difficult to eliminate completely.

**Imaging Methods:**

How and what data will be acquired.

Other investigations: e.g. Blood or physiological tests, tissue analysis (histology, genetics).

Schedule of imaging and other investigations: when will these tests be performed?

**Analysis**

How exactly imaging data will be processed, quantified and analysed.

Consider how they will be compared to other endpoints.

What statistical methods will be appropriate.

*Key questions:*

- Can the method proposed meet the primary research objective – i.e. answer the question being posed? If not, can it be re-designed, or are there other useful questions that it might address?
- Consider confounders; potential sources of bias (selection, observation?). How may these be avoided or controlled for?
- How will subjects be recruited? For projects involving patients, consider relationship/collaboration with clinical teams and sometimes patient organisations.
- Are required subject numbers achievable within the timescale/budget of the study?
- What will actually be required in practical terms to conduct the project? Include personnel time and expertise, imaging time, equipment, consumables, other investigations.

- Are there likely to be problems around ethics approval? Many imaging studies are observational and therefore considered relatively ethically 'benign', although radiation protection and data control may be issues.

**d) Anticipated outputs**

Consider what your project will produce.

*Optimistic (best possible) vs likely vs pessimistic (worst scenario)*

- Publications in peer reviewed journals? Publication strategy.
- Proof of concept?
- Changes in clinical practice? Diagnostic or therapeutic.
- Intellectual property/patents?

**General points to consider**

- **Not every idea will lead to a workable research project.**  
Some may lead to good projects that are quite different from what is first envisaged.
- **Seek advice, experienced mentorship and critical appraisal of your proposal.**  
It is likely to require several iterations.
- **Balance novelty and scope with practicability.**  
Try not to be over-ambitious when starting out in research.
- **Get statistical advice early; ideally, at the point of study design.**