Research Design Service
South Central

NHS
National Institute for
Health Research

Information Pack for Health & Social Care Researchers

The Research Design Service (RDS) is funded by the National Institute for Health Research (NIHR).

The RDS supports research teams to develop and submit high quality applied health and social care grant applications to NIHR and other national peer-reviewed funding programmes.

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1. The Purpose of this Information Pack

This information pack is not a definitive guide to research – there are plenty of research texts 'out there' that perform that function. It is an attempt to highlight the important things you need to consider when you are putting in a grant application to fund your research.

Inevitably this will mean:

- Refining your research idea;
- Examining the current literature;
- Getting your methodology right

– so these are discussed, albeit briefly; but this pack also encourages you to think more pointedly about what a grant application should look like by:

- Taking you through the usual structure of a grant application, and what a reviewer would expect to see in each section;
- Encouraging you to consider the logistics of the work you plan, and what you should be catering for in terms of time and money;
- Defining for you the various costs you are asked for in a typical grant application
- Highlighting the ethics and governance procedures you are obliged to attend to in order to undertake research in the NHS.
- Getting you to think about Patient and Public Involvement
- Pointing out other organisations which may be useful to you.

In this way, we hope it will be a thoroughly practical document.

Research Design Service South Central[1], 2013

[1] Written by Sophie Hyndman & Helen Lloyd, with grateful thanks to: Carole Fogg, Ramon Luengo-Fernandez, David Morley, Claire Ballinger and Judy Robison

2. The National Institute for Health Research & the Research Design Service

National Institute for Health Research

In January 2006, the Government formed the National Institute for Health Research (NIHR) to support people within the NHS to conduct research focusing on the needs of patients and the public.

NIHR goals are to:

- Establish the NHS as an internationally recognised centre of research excellence
- Attract, develop and retain the best research professionals to conduct research
- Commission research focused on improving health and social care
- Strengthen and streamline systems for research management and governance
- Act as sound custodians of public money for public good

The NIHR wishes to encourage trusts and researchers to move away from small 'own account' research and towards more formal, larger research projects that can have a greater impact on the NHS and bring more benefit to patients.

The NIHR operates nine different funding streams offering grants ranging from under £100,000 to over £5,000,000. Each stream has its own area of speciality and brief details of these can be found later in the guidance booklet.

Research Design Service South Central

As part of the infrastructure of the NIHR, the Research Design Service South Central (RDS-SC) is one of ten regional RDS teams in England. Led by Mark Mullee, RDS-SC provides support across this region, with offices in Southampton, Oxford, Portsmouth and the Isle of Wight.

Our Aims & Scope

The RDS is funded by the NIHR to help researchers prepare research proposals for submission to national, peer-reviewed funding competitions for applied health and social care research. Priority is given to supporting proposals to be submitted to NIHR schemes.

How We Can Help

We have highly experienced Research Advisors and Senior Methodologists with expertise and experience in research design and applying for grants. We are able to provide practical advice and support when you are developing your grant application, and as the RDS is funded by the NIHR, our services are **free of charge**. Our multi-disciplinary team includes: statisticians, clinical trials specialists, epidemiologists, qualitative researchers and health economists. Specifically we can provide help with:

- Finding sources of funding
- Providing advice on conducting literature reviews
- Developing and refining research objectives
- Study design, including statistics
- Planning teams and budgets
- Patient and Public Involvement (PPI)

We can offer you:

- A dedicated Research Advisor, with access to specific experts as required
- One to one advisory meetings
- Research Design Advisory Panels (multi-disciplinary advisory group meetings)
- Pre-submission Review Panels (a reviewing service for submissions nearing completion)
- The potential for collaboration
- Communications: e-mail, newsletter, website

The RDS recognises that researchers will differ in the nature and amount of support that they require, and we aim to tailor the support that we provide to the specific needs of the researcher. For example, if researchers have the benefit of an experienced research team, they may only require support regarding lay involvement or to make use of our review service. In contrast, a more junior researcher may require more detailed support with study design.

Expectations

You can expect the following from the RDS:

- Professional advice about all aspects of developing a grant application and practical support for such development
- Face-to-face meetings at a mutually convenient time and venue, supplemented by other forms of communication as appropriate
- Support in co-ordinating the process of proposal development, as required
- Support in drafting relevant sections of proposals, as required

- Support in identifying and approaching potential lay collaborators and help in identifying professional collaborators, as required
- Support in identifying suitable potential funding bodies and advising on their application processes
- Financial support for funding appropriate user and carer involvement in project development
- All discussions regarding the proposal to be treated with appropriate confidentiality

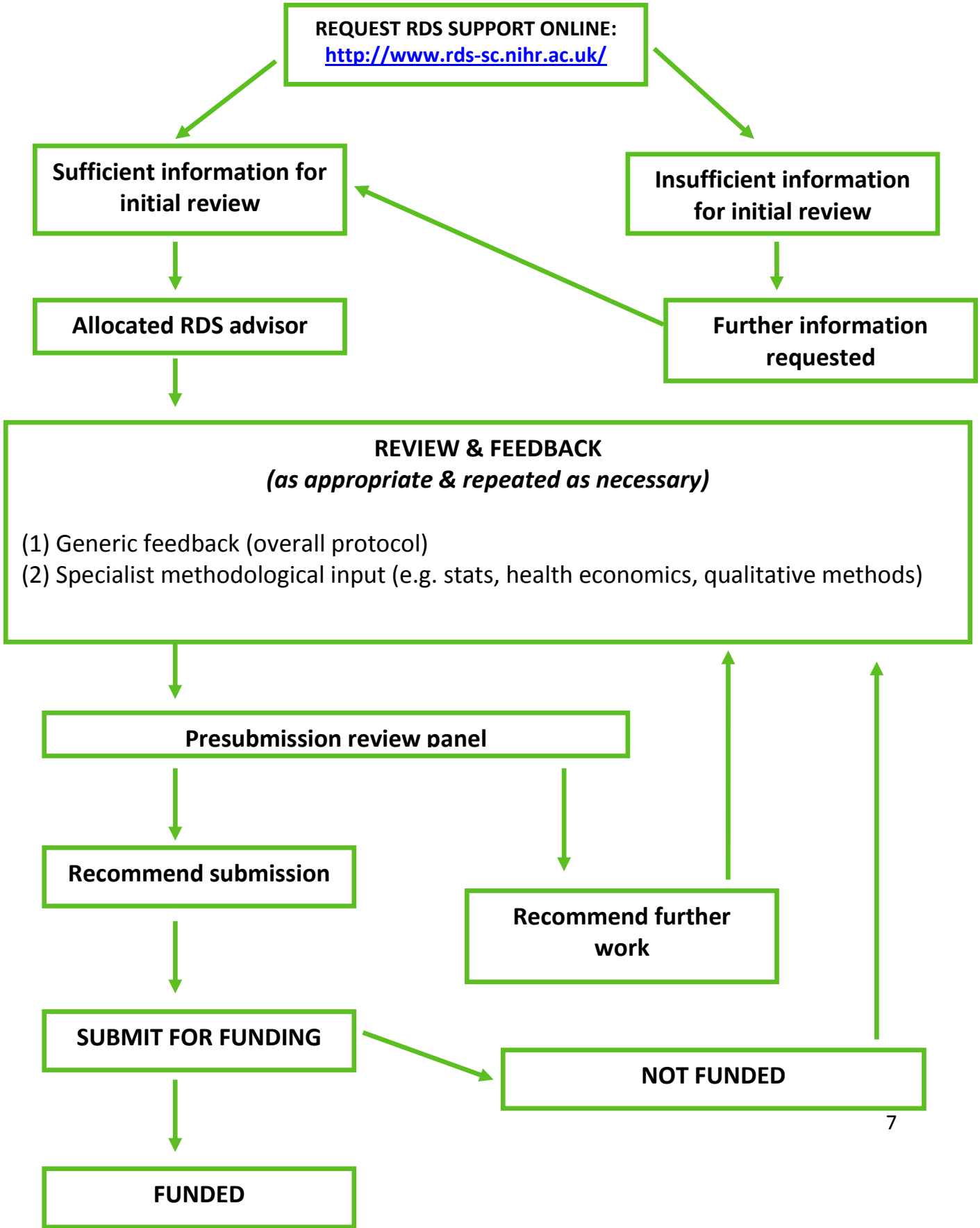
In return, the RDS expects that you will:

- Use the RDS only for eligible purposes
- Consider carefully proffered advice, discussing as necessary and accepting such advice except where there are compelling reasons not to do so
- Ensure that the research team includes, as a minimum, input from NHS staff and lay person(s)
- Where RDS staff agree to contribute to the execution of a research project (e.g. where specific consultancy is required, and staff are available), to agree to include appropriate costs in the grant to cover this work
- Consider sharing draft proposals with other RDS staff or lay members (with appropriate confidentiality safeguards) where to do so is likely to enhance the grant application
- Agree with RDS staff any wording to be included in a grant application about the nature of RDS involvement and support
- Let the RDS know of the outcome of any grant applications in which they have been involved.

Please bear in mind that for the RDS to provide you with the best support to develop your funding application, we need time to properly assess and advise on your needs. Ideally we would request that you contact us *at least 6 weeks* prior to the intended submission deadline. We acknowledge that there will circumstances where this might not be possible, and whilst we will endeavour to support all applications received within our capacity, please be aware that it is unlikely that we will be able to provide you with adequate support if your application reaches us close to the funding deadline.

We look forward to hearing from you!

3. Support Pathway for Researchers



4. Your Research Project

Successful health and social research routinely follows a set of predefined stages from conception through to completion, and in the case of applied research, from conception to implementation. Setting out your research as a staged process will help you plan and organise more effectively, but it is worth anticipating that stages in the research process may not always run according to plan. Furthermore the type of research proposed, e.g. qualitative or mixed methods designs, will necessitate different timings with regard to the stages which form the research process. Most research however will involve the following ten stages[2]:

I. **Ideas are transformed into research question(s) or aims**
II. **Literature/ available evidence is reviewed**
III. **Study design and methods are developed to suit the research question(s) or aim(s)**
IV. **A research proposal is written**
V. **Funding options are investigated**
VI. **Relevant approvals are sought**
VII. Data are collected and collated
VIII. Data are analysed and findings are interpreted
IX. Results are disseminated
X. Results are implemented into clinical practice or inform further research

Our role at the RDS is to help you through the early stages of your research to the point that you submit your proposal for funding (i.e. steps I-V). Before submitting your proposal for funding you will certainly have had to investigate or even begin the process of gaining the necessary approvals that your study may require (VI), so we highlight these for you later in the document.

TOP TIP! - Keep a research diary! Start your diary on day one of planning your project, and it will help you track progress, and remind you of why key decisions were made. For qualitative and mixed methods researchers, it will become invaluable for the reflexive process.

I. From Ideas to Research Questions

Until you have identified the focus of your research, further planning will be impossible. The focus of your research may have originated out of your own clinical or professional experience (e.g. the necessity to find a solution to a clinical or health problem), or through discussions with others both within and outside of your general field of interest. At this early stage it is enormously beneficial to discuss the focus of

[2] Extracted and adapted with kind permission from RDInfo.com (no longer available)

your research with other professionals and researchers, and with those who will be directly involved with the research i.e. service delivery teams etc. It is also now widely acknowledged that patients and members of the public have a role to play in research at this early stage. Further advice about involving patients and the public is provided later on in this document.

Where relevant and depending on the particular design of your study you will need to answer the following questions to help you focus the research:

- In **what** area do you wish to conduct research?
- What is your general aim?
- More specifically, what is your hypothesis? / What is your research question?
- **Why** do you wish to research it? Why does it matter?
- Is your idea novel?
- How will NHS patients or service users benefit from your research?
- **Where** should the research be conducted and on which population?
- **When** should the research be done?

The boxed text below provides a list of some of the key qualities for research questions for applied health and social research *(Adapted from Punch[3]& Lewis[4]).*

Fixed Design/Quantitative Research	**Flexible/Qualitative Research**
• Specific: sufficiently specific for it to be clear what constitutes an answer	• Focused, but not too narrow
Clear: unambiguous and easily understood	
Substantially relevant: they are worthwhile, non-trivial and worthy of research effort to be expended	
Relevant and useful	
Informed by day-to-day practice, research or genuine clinical research problem	
Feasible, given resources available	
Of interest to the researcher, public/patient and NHS	
Answerable: we can see what data are needed to answer them and how those data will be collected	

[3] Punch K. (2000). *Developing Effective Research Proposals*. London: Sage.
[4] Lewis J. (2003). *Design Issues. Qualitative Research Practice: A Guide for Social Science Students and Researchers*. Sage.

II. Performing a Review of the Literature/ Available Evidence

What is a literature review?

A literature review is '…a self-contained piece of written work that gives a concise summary of previous findings in an area of the research literature'[5]. A literature review is not a straightforward summary of everything you have read on the topic and it is not a chronological description of what has been discovered in your field. It is a select analysis of existing research which is relevant to your topic, showing how it relates to your investigation. It explains and justifies how your investigation may help answer some of the questions or gaps in your chosen area of research. Literature reviews vary from a superficial search to a scientifically rigorous 'systematic review'. Obviously, the more thorough and rigorous the review is, the more it will benefit the 'Background' or 'Rationale' section of your grant proposal.

A literature review is an *essential background document* relevant to your research. **The 'Background' or 'Rationale' section of a grant proposal** will be *based* on the literature review but is likely to be a carefully distilled and targeted version of it. It basically states the reason why someone should give you money – almost a sales pitch. It draws on the literature to create a clear, convincing argument for the importance and timeliness of your research, and its relevance to the potential funder.

Why do a literature review?

- To obtain an up to date picture of your area of interest
- To inform the methodology of your own work
- To make yourself aware of (1) possible problems, and (2) possible solutions concerning the research you are planning
- To examine (1) common findings and (2) inconsistencies in findings
- To show how your investigation relates to previous research
- To ensure you are not duplicating work
- To reveal the contribution that your investigation could make to the field (fills a gap, or builds on existing research, for instance)
- To identify specific populations who may have been excluded from previous research
- May help identify contacts, even collaborators
- To give you confidence in what you are planning

[5] Hewitt M. Carrying out a literature review. Chapter 2 in Saks, M., Williams, M., Hancock, B. (2000) *Developing Research in Primary Care*. Radcliffe Medical Press: Abingdon, p.29.

- To help to develop your ideas
- To provide evidence that may help explain your findings later

It is essential that existing sources of evidence, especially systematic reviews, are considered carefully prior to undertaking research, and updated as you develop your research, right up to publication of findings. Research which duplicates other work unnecessarily is unethical. A literature review shows how an investigation fits in with prior work; it demonstrates that you are able to source, select, understand and critically analyse relevant material to develop a context for your own project.

How to do a Literature Review

There are three stages to a literature review: (1) Searching, (2) Reviewing (and ideally, critically appraising), and (3) Writing.

1. Searching

Most NHS or academic libraries run short courses on how to conduct a literature search and it is advisable to make use of these. A proper literature review will consist of a planned search strategy. You can discuss strategies with your RDS advisor and local librarian, but most literature reviews will involve a structured search of relevant databases and citation indices with carefully chosen key words and search terms. Key journals and key authors will be identified through this process. Don't forget that systematic reviews in your subject area may recently have been done – so begin by looking for these. Be systematic in your searching, and record the process, so you don't waste time repeating yourself. The boxed text (*Resources for Literature Reviewing*) provides some useful information.

You should start your search by being broad and then narrow it down. If your search is too specific you will find you have no articles, or you will miss important ones; if it is too broad, you will find irrelevant articles. Always check your searches and be prepared to revisit your key words if necessary.

There is software available to help manage your references, for example, EndNote[6] and RefMan[7].

2. Reviewing

You can make some initial judgment of the relevance of the papers that you find by looking at the abstract. Remember - just because something is published does not mean that it is methodologically sound. Articles in peer reviewed journals have obviously had some review of quality, but the only real way to judge how good a piece of work is, is to obtain a copy and critically appraise it. In fairness, it is quite

[6] www.endnote.com/
[7] www.refman.com/

difficult to fully critically appraise a paper unless you have quite a good understanding of the potential pitfalls of research, but some at least relates to whether the paper makes overall sense given what has been done. Once you accept a research report is unlikely to be perfect, you will find it quite easy to be critical! There are courses on critical appraisal and much written guidance (see boxed text, *Useful References*), but the main issues are:

a) **Bias:** 'Deviation of results or inferences from the truth, or processes leading to such deviation'[8]
b) **Study validity:** The degree to which the inference drawn from a study is warranted, given the study methods.
c) **Measurement reliability** 'The degree of stability exhibited when a measure is repeated under identical conditions'[7]
d) **Measurement validity** 'An expression of the degree to which a measurement measures what it purports to measure.'[7]
e) **Rigour:** The degree to which the sample and methods used are appropriate.

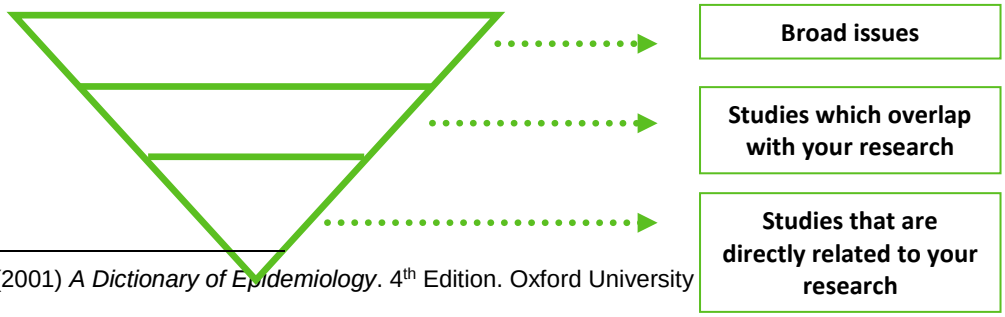
Different study designs will have different areas in which the above issues feature – a good introduction to appraising different designs can be found at the UK Critical Appraisal Skills Programme website - http://www.casp-uk.net/.

3. Writing

Reviews take different forms, from author's interpretation to statistical meta-analyses, but most will follow the following format: Introduction, Methods (including: indices searched, period covered, key words used, articles found but excluded), Results, Discussion, Conclusions.

A longer literature review may **have headings** to help group the relevant research into themes or topics. This gives a focus to your analysis, as you can group similar studies together and compare and contrast their approaches, any weaknesses or strengths in their methods, and their findings.

One common way to approach the writing of a literature review is to **start out broad and then become more specific**. Think of it as an inverted triangle.



[8] Last J. (2001) *A Dictionary of Epidemiology*. 4th Edition. Oxford University

For a basic literature review, first briefly explain the broad issues related to your investigation. You don't need to write much about this, just demonstrate that you are aware of the breadth of your subject. Then focus on the studies that overlap with your research. Finally, home in on any research which is directly related to your specific investigation. Proportionally you spend most time discussing those studies which have the most direct relevance to your research.

Most general research texts provide an overview of writing literature reviews. The RDS is happy to help you structure your literature review, but it is often most helpful to us if you have some knowledge of the literature that relates to your topic when you approach us.

Resources for Literature Reviewing

Libraries:

- You can find your local library from the Health Library & Information Services Directory (HLISD): www.hlisd.org/index.aspx
- NHS ATHENS: NHS Athens is an access management system which enables eligible users to access all the resources that have been purchased by the NHS for their use. See: www.evidence.nhs.uk/nhs-evidence-content/journals-and-databases/about-nhs-athens

The following websites are excellent for literature searching. In some cases you may need a password, which your library should be able to provide.

Links to useful websites:

- Social Care Online provides a complete range of information and research on all aspects of social care. www.scie-socialcareonline.org.uk
- PubMed -Searches MEDLINE and other life science journals for biomedical articles back to the 1950s: www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
- Intute - Major bibliographic database for biomedical sciences:www.intute.ac.uk
- Department of Health Library and Information Service and the Protection of Health (PH) Information Unit. The core subjects covered by the Department of Health Library are health service and hospital administration, with an emphasis on the British National Health Service. The PH Information Unit specialises in medical toxicology and environmental health.
- KING'S FUND - Focus on improving health and health care, covering policy and management of health and social care services in the UK rather than clinical issues and treatments. Core subjects include National Health Service (NHS) management, social care, health inequalities, urban health and regeneration, race and health, partnership working, primary care, mental health, public involvement, and workforce development in the NHS.
- The National Library for Health provides (free) access to 8 bibliographical databases and over 800 full text journals - excellent for literature searching. www.library.nhs.uk

Databases:
Of systematic reviews:

- Cochrane Collaboration: www.cochrane.org/reviews/clibintro.htm
- York Centre for Reviews and Dissemination: www.york.ac.uk/inst/crd/

Guidance on writing systematic reviews: www.york.ac.uk/inst/crd/index_guidance.htm

Other

- AMED - Allied and Complementary Medicine Database
- BNI - The British Nursing Index is a UK nursing database which covers British publications and other English language titles from over 220 related journals.
- CINAHL - Major bibliographic database for nursing and allied health
- EMBASE - Major bibliographic database for biomedical sciences www.embase.com
- DH-DATA - records relating to health and social care management information.
- MEDLINE - Major bibliographic database for biomedical sciences
- PSYCHINFO - Major bibliographic database for psychology. Coverage: 1887 to date. www.apa.org/psycinfo

Useful References

- Bury T, Jerosch-Herold C. (1998) Reading and critical appraisal of the literature. In Bury T. & Mead J. (eds.) *Evidence-based Healthcare: A Practical Guide to Therapists.* Butterworth-Heinemann: Oxford.
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- Crombie IK (1996) *The Pocket Guide to Critical Appraisal*. BMJ Publishing Group: London.
- Hewitt M. (2007) *How to search and critically evaluate research literature*. The NIHR RDS for East Midlands (www.rds-eastmidlands.nihr.ac.uk)

III. Developing the Study Design and other Methods to Suit the Research Question(s) and Aim(s)

The Research Design

> *Research designs are plans and procedures for research that span decisions from broad assumptions to detailed methods of data collection and analyses*[9]

The research design is the 'architectural' plan that links your research question to the procedures you will use to answer it. You should choose the best design to answer the question – not necessarily the most familiar to you, or your professional group. The RDS can advise you on the best study design to answer your question. If you have a design in mind, the RDS can discuss the appropriateness or otherwise of your choice. There are a number of general texts and resources that can help you decide if you have chosen the right design for your study. These are listed at the end of the section.

The three broad approaches to research design are qualitative, quantitative, and mixed-methods (see table for definitions). These are not discrete, and can be viewed as a continuum with mixed methods designs in the middle.

Quantitative[10]	***Qualitative***[11]	***Mixed methods***[12]
'Quantitative research is a means for testing objective theories by examining the relationship among variables. These variables, in turn can be measured, typically by instruments so that numbered data can be analysed using statistical procedures. The final written report has a set structure consisting of introduction, literature and theory, methods, results and discussion…those who engage in this form of enquiry have assumptions about testing theories deductively, building in protections against bias, controlling for alternative explanations, and being able to generalise and replicate the findings.'	'Qualitative research is a means for exploring and understanding the meaning individuals or groups ascribe to a social or human problem. The process of research involves emerging questions and procedures, data typically collected in the participant's setting, data analysis inductively building from particulars to general themes, and the researcher making interpretations of the meaning of the data. The final written report has a flexible structure. Those who engage in this form of enquiry support a way of looking at research that honours an inductive style, a focus on individual meaning, and the importance of rendering the complexity of a situation.'	'A mixed method design is one that incorporates qualitative and quantitative methods in parallel or sequential phases' 'Research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of enquiry'

[9] Creswell JD. (2009) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage, p.3
[10] Creswell JD. (2009) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage, p.4
[11] Creswell JD. (2009) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage, p.4
[12] Abbas T. and Creswell JW. (2007) Editorial: The New Era of Mixed Methods. *Journal of Mixed Methods Research, 1,1: 3-7.*

Quantitative Study Designs

Quantitative studies are those which use predominantly numerical and statistical data to examine a predetermined research question. They fall into two distinct categories – descriptive studies (often 'hypothesis generating') and hypothesis driven studies.

Descriptive Studies

Why conduct a descriptive study?
To explore an area for which there are little data
To look at current trends or patterns of health care/ disease

Statistical data can be used to describe a situation at a particular point in time (cross-sectional), looking back in time (retrospective) or looking forward (prospective). Studies may look at one or all of these. A typical example of a cross-sectional study, or survey, is any one UK census, but studies looking at more than one census can examine trends from the past to the present. Other descriptive studies may prospectively gather information relating to particular issues, for example, hospital admissions for a certain diagnostic group over a period of time.

In epidemiology there are a number of famous examples of hypothesis generating quantitative descriptive studies, often kick-starting long epidemiological investigations (e.g. Snow's study of cholera in London[13], the Barcelona asthma outbreaks,[14] the studies relating to Sellafield[15]). In health services research, descriptive studies can be used to examine trends and patterns in health and health care use that can help planning and monitoring (e.g.[16]).

Hypothesis-driven study designs

These study designs fall into two broad categories: experimental and observational. Both types are designed to test a hypothesis, usually the association between variables. In a health care scenario, this would typically be the relationship between a treatment (intervention) and an outcome. In epidemiology more broadly, hypotheses often relate to a potential aetiological (causal) factor and a disease.

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[13] Described in Cliff AD. & Haggett P. (1988) *Atlas of Disease Distributions*. Blackwell Reference, p.3-11.
[14] Anto JM., Sunyer JA (1986) Point source asthma outbreak. *The Lancet*, April 19th: 900-903.
[15] Gardner MJ. (1991) Father's occupational exposure to radiation and the raised level of childhood leukemia near the Sellafield nuclear plant. *Environmental Health Perspectives*, 94: 5-7.
[16] Hyndman SJ *et al*. (1994) Rates of admission to hospital for asthma. *BMJ,* 308: 1596-1600.

The distinguishing factor between experimental and observational studies relates to method of allocation to 'intervention' or 'cause'. In experiments, the researcher controls who/ what goes into which group; in observational studies, the researcher has no control. In health care research, experiments are common, as manipulation of participants by the researcher is considered ethical where there is a genuine lack of knowledge about which of, for example, two treatment interventions is the most effective. In aetiological research, observational studies are the norm, as it would clearly not be ethical to expose participants to a suspected disease causing agent.

Hypothesis-driven study designs attempt to isolate the associations pertinent to the study. They do this by trying to control the effects any other factors that may influence or bias the outcomes of interest. These 'other' factors are known as confounding variables. For example, a study examining the relationship between diet and health would have to take into account exercise and other aspects of lifestyle.

Experiments

Experiments are a key approach to examining associations between treatments and outcomes.

Why conduct an experiment?

- To question the assumption that an unevaluated treatment, which is in routine use, confers benefit
- To evaluate a new treatment, which theoretically offers benefit
- To evaluate a new treatment which promises to be less costly or less hazardous, but not necessarily less clinically effective than existing treatments

St Leger AS. *et al* (1992) *Evaluating Health Services' Effectiveness*. Open University Press: Milton Keynes

Randomised Controlled Trials

In randomised controlled trials (RCTs), individuals or study units are **randomly** assigned to, for example, two experimental groups, one with a new therapy (experimental group) and one with current therapy (control group). The great advantage of randomly assigning individuals to the groups is that it is possible (if the sample size is big enough) to show **clear cause-effect relationships.** This is because any other factors (known or unknown) which may affect outcomes of interest are randomly distributed between experimental and control groups. The only difference between the groups is the therapy under investigation. The RCT is the **only** study design that can clearly show cause-effect relationships.

The main disadvantages of RCTs relate to costs and the fact that those choosing to take part in the trial may not be typical of those with the condition in some way. As

with any research which takes place over time, people may withdraw[17] or be lost to follow-up.

It is very important that you **clearly specify your intervention, and any control or comparison interventions** you plan to use. For example, if 'usual care' is your comparator, make sure you define it clearly, preferably with reference to current standards or guidelines.

Advantages	Disadvantages
• CAUSE-EFFECT RELATIONSHIPS	• Generalisability of participants • Bias through chance (hence importance of sample size) • Bias through incomplete follow-up • Bias through withdrawals • Ethical objections

Other experiments

Other experimental designs exist. Some are elaborations of the RCT, for example, those attempting to take into account the preferences of professionals or patients. However, these tend to be more complex (simple is best). Where interventions are at an organisational rather than individual level, RCTs can be undertaken, but because large numbers of organisations would be required such studies may not be cost-effective as they would have to be very large. A compromise is the randomised cluster trial. These allow the randomisation of a smaller number of organisations, but statistically adjust for the fact that individuals within randomised organisations may share characteristics (which would otherwise bias the results).

Another common experimental approach is the quasi-experiment, where groups undergoing different treatments are compared, but are not randomised. Where interventions are community based, these are known as 'community trials'. Whilst these are often tempting (they may avoid disrupting normal care processes), they are inevitably open to confounding and therefore lack the rigour of RCTs. There are circumstances, however, where quasi-experiments and community trials are better than no evaluation at all, for example, a proper RCT or cluster trial is simply not cost effective (due to its required size) or where randomisation is not ethical, or logistically possible. Some potential confounding can be controlled by, for example, attempting to match groups being compared. In addition, refinements can be added – for example, where logistically and ethically possible, a cross-over can be undertaken, where those receiving the intervention cease to receive it at a later time point and *vice versa*. The effect of this change can then be noted. This approach, however, is not always possible, for example, where the intervention has longer term effects

[17] Data from RCTs should be analysed keeping participants in their *initially allocated group* to avoid biases arising via differential withdrawal from groups. This is known as 'intention to treat' analysis.

(which would run in to the 'new control' period). For an examination of biases in non-randomised intervention studies, see, for example, Deeks *et al.* [18]; and for general guidance on evaluating complex interventions, see the *MRC Developing and Evaluating Complex Interventions: New Guidance*[19]

A general rule is that if you cannot **design** out potential confounding you have to **measure** it, so that once the results come through, the role of other factors can be examined. Any quasi-experimental design, therefore, should attempt to measure all known confounding variables. As with RCTs, it is essential that you clearly define your intervention and control/ comparator groups.

The main advantages and disadvantages of quasi-experiments are shown below.

Advantages	Disadvantages
• Can be used where RCTs are unethical or impractical • Can indicate the effectiveness of an intervention, or an association between variables • Repeatable	• Difficulties in matching experimental and control groups
Therefore, Always a risk of systematic confounding *Therefore,* Causality/ associations not as strongly indicated as with RCTs	

Observational Studies

This group of designs have arisen largely through studies of disease aetiology, so they attempt to control confounding factors by methods other than randomisation. The two main designs are the case-control study and the cohort (also known as prospective or longitudinal) study. These terms are used rather loosely among researchers, but strictly speaking should be limited when describing specific research designs.

As observational studies cannot control for confounding in the way that RCTs can, epidemiologists often apply a number of criteria to help them judge whether or not any associations they see are in fact causal. The main criteria are as follows[20]:

- Consistency of association
- Strength of association
- Existence of a dose-response relationship

[18] Deeks JJ. *et al* (2003) Evaluating non-randomised intervention studies. *Health Technol Assess*, 7 (27):1-173
[19] www.mrc.ac.uk/complexinterventionsguidance
[20] E.g. Lilienfeld DE and Stolley PD (1994) *Foundations of Epidemiology*. Oxford: OUP.

- Specificity of association
- The biological plausibility of the association observed

Case-control studies

Why do a case-control study?

Where you want to determine the factors that have created a 'case'; or where you want to explore the effectiveness of an intervention and it is unethical to deprive patients of that intervention.

In case control studies, people with a disease or condition are compared with matched controls and exposure to the suspected aetiological factor is examined retrospectively in both groups. This type of design is more common in aetiological epidemiology, but the study of the effectiveness cycle helmets[21] is an interesting example of how case-control studies can be used in health services research. In this study, 'cases' were cyclists seeking emergency care with head injuries, and the main 'controls' were cyclists seeking emergency care with injuries other than those of the head.

Advantages	Disadvantages
• Can be used where RCTs are unethical or impractical • Can indicate the effectiveness of an intervention, or an association between variables • Repeatable	• Can be difficult to match cases and controls for other factors (i.e. risk of systematic bias) • Causality not as strongly indicated as with RCTs • Retrospective studies can be biased where they depend on recall • May be biased by early mortality among 'cases' (i.e. prior to selection)

Cohort Studies

Why conduct a cohort study?

Primarily, where you want to determine whether a suspected aetiological factor is linked to the later development of a disease or condition

Cohort studies involve taking a group or 'cohort' of people, some of whom have been or are being 'exposed' to a potential aetiological (or beneficial) agent as part of their everyday life. They are then followed over many years to see if they develop the

[21] Thompson RS. *et al*. (1989) A case-control study of the effectiveness of bicycle helmets. *New England Journal of Medicine*, 320: 1361-7.

disease (or are protected from the disease) hypothesised to relate to the exposure. Examples of studies of this nature include the United Kingdom Prospective Diabetes Study[22], the European Prospective Investigation into Cancer[23], the Framingham Study[24] and Doll and Peto's investigation into smoking and lung cancer[25].

Due to the very long time over which cohort studies run, they are of less practical importance than some other research designs for health services research.

Advantages	Disadvantages
• Can indicate an association between variables • Provide a direct estimate of risk, as prospective • Do not rely on recall • Can obtain information on people whose status has changed in relation to exposure during course of study • Can obtain information on other diseases • Will not be affected by early mortality of exposed group	• More difficult and more expensive to run • Causality not as strongly indicated as with RCTs • Participation in the study may influence participants' behaviour • Where different groups of the population are selected for comparison, this may lead to sample bias • Very inefficient in relation to rare diseases – would need a massive sample

Natural experiments

These are basically the observational equivalents of quasi-experiments, where, without manipulation, people are exposed or not exposed to a potentially good or bad agent. In the health services this may reflect the implementation of certain policies in one place rather than another; in aetiological epidemiology, it might relate to the natural presence or absence of substances, or the result of accidents (e.g. Chernobyl). Either way, the advantages and disadvantages are much the same as those for quasi-experiments and community trials, although there would rarely be an opportunity to perform any kind of cross-over with a natural experiment. The MRC have issued guidance on how best to reduce the potential biases inherent in natural experiments[26,27].

Qualitative Methods

[22] www.dtu.ox.ac.uk/ukpds_trial/index.php
[23] http://epic.iarc.fr/
[24] www.framinghamheartstudy.org
[25] E.g. Doll R. *et al*. (2004) Mortality in relation to smoking: 50 years' observations on male British doctors, *BMJ*, 328 (7455): 1519.

[26] Craig P. *et al*. (2012) Using natural experiments to evaluate population health interventions: new Medical Research Council guidance. *J Epidemiol Community Health*, 66: 1182-1186.
[27] Medical research Council (2011) *Using natural experiments to evaluate population health interventions: guidance for producers and users of evidence*. www.mrc.ac.uk.

Qualitative methods encompass a broad range of approaches, but they have the following in common:

- Based in the 'interpretivist' position (i.e. the subjective interpretation of data)
- Based on methods which are flexible and sensitive to social context
- Based on analytic methods which take account of complexity, detail and context

Qualitative methods are good at addressing 'WHAT' questions (e.g. what are older people's understandings about the goal setting process within rehabilitation?) and 'HOW' questions (e.g. How do clinicians prioritise when making decisions about service-user care?), and can be executed as standalone projects, as a component in a mixed methods study or as part of a larger quantitative study.

Like quantitative work, qualitative research in applied health research is more likely to be influenced by 'here and now' problems and less so with theory. Applied qualitative research should be: based on pragmatism, its methods should be transparent and rigorous, researchers should aim for objectivity and neutrality, and findings should be easily translated into policy planning and implementation.

Broadly speaking there are five main types of qualitative research methods:

- Ethnographic Research
- Case Studies
- Phenomenological Research
- Grounded Theory Studies
- Narrative Research

Ethnographic Research

Why conduct ethnographic research?

To gain an understanding of the meanings people attach to cultural phenomena, and what insights these provide about the subject of study.

Ethnographic research typically requires a researcher to study a group (cultural, patient, professional) over time, although an ethnographic approach could be used to guide in-depth interviews. The method was developed within the field of socio-cultural anthropology but is now used across the social sciences. Data are typically collected from primary observations and/or interviews in 'the field'. Ethnographic approaches are flexible and evolve in response to the lived realities encountered in

the setting[28]. For examples: See Estroff (1981)[29], Goffman (1961[30], 1963[31]) and Kleinman (1980)[32].

Case Studies

Why conduct a case study?

To explore, in depth, a person, program, event, activity or process in one or more individuals

Cases are defined by time and activity, and data are typically collected using a variety of procedures (e.g. qualitative interviews, analyses of official documents or policy material) to reflect the complexity of the subject under study[33]. Case studies are exploratory and are often used for theory generation. This approach is not new to medicine as case studies have long been used by clinicians to help understand disease. Case studies are often presented in a chronological or biographical format and/ or by the major components of a case. Vignettes are also commonly employed to illustrate the phenomena under study. For examples: Korman and Glennerster (1990)[34] and Sidell (1995)[35].

Phenomenological Research

Why conduct phenomenological research?

To identify the core or essence of human experience which relates to a phenomenon, as described by participants.

With this approach, an emphasis is placed on understanding 'lived experiences'. In phenomenology, 'experience' is considered in relation to 'being-in-the-world' i.e. embodiment. These types of studies typically involve small numbers of participants through extensive and prolonged engagement to develop patterns and relationships of meaning[36]. Researchers attempt to bracket or set aside their own experiences in order to understand those of the participants in the study[37]. Typical methods include

[28] LeCompte MD. and Schensul JJ. (1999) *Designing and Conducting Ethnographic Research*. Walnut Creek, CA: AltaMira.
[29] Estroff S. (1981) *Making it Crazy. An Ethnography of Psychiatric Clients in an American Community*. University of California Press.
[30] Goffman E. (1961) *Asylums : Essays on the Social Situation of Mental Patients and Other Inmates*. Penguin.
[31] Goffman E. (1963) *Stigma, Notes on the Management of a Spoiled Identity*. Penguin.
[32] Kleinman A. (1980) *Patients and Healers in the Context of Culture*. University of California Press.
[33] Stake RE. (1995) *The Art of Case Study Research*. Thousand Oakes, CA: Sage.
[34] Korman N. and Glennerster H. (1990) *Hospital Closure*. Open University Press. Milton Keynes.
[35] Sidell M. (1995) *Health in Old Age: Myth, Mystery and Management*, Open University Press. Cambridge University Press.
[36] Moustakas CE. (1994) *Phenomenological Research Methods*. Thousand Oaks. CA.
[37] Nieswiadomy RM. (1993) *Foundations of Nursing Research*. (2nd ed.) Norwalk, CT Appleton and Lange.

focus groups and interviews. For guidance on Interpretative Phenomenological Analysis (IPA), see: Benner[38].

Grounded Theory Studies

Why conduct a grounded theory study?

To derive a general, abstract theory of a process, action, or interaction grounded in the views of the participants

A range of data collection methods are employed in grounded theory (GT) but interviews and focus groups are most common. GT studies are characterised by multiple stages of data collection and the refinement and interrelationship of categories of information[39,40,41]. These studies employ the use of theoretical sampling, meaning that data collection is directed by evolving theory rather than predetermined population dimensions[34]. A further feature of GT studies is the constant comparison of data and the theoretical sampling of different groups to maximise the similarities and differences in the information. The emphasis of GT studies is on systematic research and analyses to generate theories. For example, key points drawn from the data (e.g. interview transcripts) are coded, collections of codes form concepts, broad groups of similar concepts generate theories and these are used to explain the subject of the research (See Glaser & Strauss[42]).

Narrative Research

Why undertake narrative research?

To study the lives of individuals by asking them to provide stories of their lives

Narrative research is often carried out using a narrative interview. Information is then retold or re-storied into a narrative chronology. This approach is particularly useful for creating powerful accounts of illness experiences and clinical practice often obscured from typical view. Another feature of this approach is that storytelling can be empowering and creative, helping to elucidate tacit processes and experiences. Like other qualitative strategies, narrative can be a method of data collection or analysis or both. See: healthtalkonline.org (formerly DIPEx).

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[38] Benner P. (1994). 'The tradition and skill of interpretive phenomenology in studying health, illness, and caring practices'. In P. Benner (Ed.), *Interpretive Phenomenology: Embodiment, Caring, and Ethics in Health and Illness*. Thousand Oaks, CA: Sage. pp. 99-127

[39] Charmaz K. (2006) *Constructing Grounded Theory*. Sage.

[40] Strauss A. and Corbin, J. (1990) *Basics of Qualitative Research*. Sage.

[41] Strauss A. (1987) *Qualitative Analysis for Social Scientists*. Cambridge, England: Cambridge University Press.

[42] Glaser BG. & Strauss AL. (1967). *The Discovery of Grounded Theory: Strategies for Qualitative Research,* Chicago, Aldine Publishing Company.

Essentially:

> '*A good qualitative research study design is one which has a clearly defined purpose, in which there is coherence between research questions and the methods or approaches proposed....'*[43]

There is a significant amount of overlap between the above types of qualitative methods and, as such, it is more appropriate to view them on a continuum rather than as discrete approaches. Whilst these approaches are more typical of theoretical/ pure qualitative research, we are now starting to see more varied qualitative strategies in health research.

Mixed methods

Whilst many studies fall firmly in the qualitative or quantitative camp, others will employ both qualitative and quantitative techniques of the types outlined above. Combining methods is necessary in research investigating the complexities of social interaction, particularly in social medicine where local and individual factors drive behaviour and form wider general patterns. However, there is a growing realisation in health research generally that the two approaches employed together can produce more 'complete' results, with sometimes confusing results from one being explained by the other. The way in which data or analyses obtained using one approach are validated by another is known as 'triangulation'. Triangulation is an attempt to employ 'more than one perspective, theory, method or analyses to get a better fix on the object of study'[44]. Quite apart from the benefits to the research *per se*, combining methods, where appropriate, will also allow the *researcher* to think beyond the confines of their own approach.

Whilst there is a continuum between qualitative and quantitative methods, for a study to be truly 'mixed methods' it should have significant components of both qualitative and quantitative approaches. For example, an RCT will collect a range of structured observations and patient data of a numerical nature. Should such a trial incorporate a semi-structured interview schedule about patient experiences this would not make it a proper mixed methods study. For this study to be so, it would need to have a *significant* qualitative component built into the design that provided a *textual* set of data to complement the numerical trial data.

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[43] Lewis J. (2003). *Design Issues. Qualitative Research Practice: A Guide for Social Science Students and Researchers*. Sage, p.47

[44] Robson C. (2002). *Real World Research*. Second Edition. Blackwell: Oxford.

It should be emphasised that mixed method designs are not a new phenomenon, and have been in existence for a long time, especially for instrument design where a qualitative component will often precede the quantitative psychometric development and testing of a measurement scale or questionnaire.

Issues to Consider when Planning Mixed Method Strategies

There are several important issues to consider that will no doubt influence the design of your mixed method strategy should you choose to adopt one. These are related to the **Timing** of different strands of the research (i.e. will your qualitative and quantitative data collection run sequentially or concurrently?), the **Weighting** applied to different strands of the research (the priority given to quantitative or qualitative data collection, or equality of both methods), and **Mixing** - when and how to mix the different strands of the research (i.e. the research question, data collection, analysis, interpretation). Issues of timing, weighting and mixing in mixed methods studies will be influenced by the nature of the topic of study, practicalities of the research environment, the philosophy of the researchers and in some cases the requirements of funders. These issues will need to be considered and presented carefully to convince potential stakeholders and funders that this is indeed the best approach to take. See Creswell (2003) for more detail on this.[45] For published examples of mixed methods procedures, see: Kushman[46], Hossler and Vesper[47] and Bhopal[48].

Feasibility and Pilot Studies

Feasibility and pilot studies are projects that are designed to take place prior to main studies. The two terms have been used fairly loosely in the past but, from the point of view of the NIHR at least, the differences are now clearly defined[49].

Feasibility Studies: "Can this study be done?" Used to estimate important parameters needed to design the main study, e.g. standard deviation of the outcome measure; willingness of participants to be randomised and clinicians to recruit them; number of eligible patients; characteristics / design of proposed outcome measures; follow-up rates, response rates, adherence/compliance rates

Pilot studies: are a version of the main study that is run in miniature to test whether the components of the main study can all work together, e.g. to test recruitment, randomization, treatment, and follow-up assessments

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[45] Creswell JD. (2009) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage.
[46] Kushman JW. (1992) The organizational dynamics of teacher workplace. *Educational Administration Quarterly*, 28(1): 5-42.
[47] Hossler D. & Vesper N (1993) An exploratory approach of the factors associated with parental savings for postsecondary education. *Journal of Higher Education*, 64(2): 140-165.
[48] Bhopal K. (2000) 'Gender, "race" and power in the research process: South Asian women in East London', in Truman DM. & Humphries B. (eds) *Research and Inequality*, London: UCL, pp.67-79.
[49] www.netscc.ac.uk/glossary/#glos6

Feasibility studies, therefore, may use a variety of methods, both qualitative and quantitative (often truly 'mixed methods' research) aimed to explore the best way to run a larger study. Pilot studies will use the same methodology as the trial whose methods they are testing.

Health Economics

Why do economic evaluation in healthcare?

'Securing the provision of comprehensive, high quality care for all those who need it, regardless of their ability to pay or where they live'[50]… is the aim of the NHS. However, whether we like it or not, there is a limited pot of money which can be spent on health care. Given limited funds, trade-offs have to be made between breadth of healthcare provision, quality and equity. This means that decisions have to be made about who gets what treatment. Rationing can take many forms: based on need, discrimination, 'personal merit', 'social esteem', via a lottery, or ability to pay (free market). One could simply choose the lowest cost treatments, but these may not be effective; one could choose treatments that are known to be effective – but these may be very costly. Health economics aims to take into account both the effectiveness and the cost of treatments in order to decide whether or not they should be endorsed, and it does this by undertaking economic evaluations of treatments.

Economic evaluation in health care is: "The comparative analysis of alternative courses of action in terms of both their costs and their consequences"[51] Its premise is that health care resources are scarce; its aim is to maximise health gain with the available resources; and it does this by comparing the costs and outcomes of interventions. Thus, heath economic evaluation provides an explicit way for making choices about treatment availability, and an alternative allocation system to a market, which many consider undesirable.

When to do health economic evaluation in health care

You should include an economic analysis in any study evaluating the effectiveness of a treatment/ intervention. The reasons for this are as follows:

- The new intervention could be more costly. Therefore is this extra cost worth the additional effectiveness?

[50] Quotation taken from Department of Health aims and objectives http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/Browsable/DH_4928731

[51] Drummond M. *et al* (2005) *Methods for the Economic Evaluation of Health Care Programmes* 3rd Ed, Oxford University Press.

- Although the intervention could cost the same or less, it might have other cost implications (e.g. patients are discharged later or require extra community support)
- The two interventions under study could be equally effective, but one could be less costly

For feasibility studies, health economics should also be included to see whether it is possible to collect the health economic data (questionnaires, patient diaries, hospital records) which you will need for your main study, should it go ahead.

Who should you consult?

A health economist. The RDS employs a number of health economists to help develop the health economic sections of grant proposals and you will be referred to one during the course of grant application development if it is considered necessary. As with the RDS generally, they should be consulted early on to ensure that you:

- Include the most appropriate methods of collecting quality of life, resource use and costs
- Embed the health economics aspects of the project in the application
- Cost any health economist to be employed on the study appropriately

Types of economic evaluation

There are various types of health economic analysis. Their characteristics are defined in the table below. In a typical study of alternative interventions for a specified condition (e.g. an RCT), the usual analyses undertaken would be *cost effectiveness* or *cost utility analyses*. Given the choice, a health economist would opt for a cost utility analysis, as the outcome used is the Quality Adjusted Life Year (QALY) – a combined measure of life expectancy and quality of life. QALYs are useful as they are a standard measure of outcome that can be used across studies as well as between interventions within one study. To calculate a QALY, health economists will need to measure quality of life. A commonly used measure of quality of life in economic analyses is the EQ-5D[52], but other measures of quality of life can be used, if they have been designed for use in economic studies. *Cost analysis* provides no information about effectiveness so is not very useful in studies where health outcomes need to be considered. *Cost benefit analyses* are unpopular because they rely on determining people's 'willingness to pay' for a specified health gain – not an easy thing for people to define.

Cost analysis	Simple costing (£) of intervention. No comparable evidence on effectiveness of interventions. E.g. comparing the cost (only) in £ of two different interventions for a condition

[52] www.euroqol.org/

Cost-effectiveness	Costing (£) of alternative interventions along with information on outcome based on natural units (e.g. number of symptom free days)
Cost-utility	Costing in (£) of alternative interventions along with information on outcomes in the form of QALYs.
Cost-benefit	Costing (£) of alternative interventions along with a monetary value for health gained (£)

What is needed to perform a cost utility or a cost effectiveness analysis

In order to undertake these types of health economic analyses, you need firstly a consideration of outcomes, which will depend on the context. For example, one would need data on cases detected (for an assessment of breast screening), cases prevented (for an assessment of cholesterol lowering drugs), symptom-free days (for a treatment for asthma). Years of life gained would be another measure.

Secondly, you need a consideration of costs. This will not simply be monetary costs, but opportunity costs. These are the potential benefits which are sacrificed when resources are committed to one purpose rather than another, i.e. the opportunity cost of investing in a healthcare intervention is the health benefit that could have been achieved had the money been spent on the next best alternative intervention.

What you include in your costs will depend on the perspective you take: costs to the individual, the health provider, Government or society as a whole. Whilst it would be tempting to try and measure everything, this is not practical, with many economic evaluations measuring only those costs that are most likely to be affected by the interventions under study.

When is an intervention cost-effective?

The Role of the National Institute for Health and Clinical Excellence (NICE)

NICE is part of the National Health Service. Established 1999, it provides:

- Advice to health professionals in England and Wales on highest attainable standards of care for NHS patients
- Guidance, based on best available evidence, on: individual health technologies, including screening, diagnostic, therapeutic and the management of specific conditions.

Health economists calculate Incremental Cost Effectiveness Ratios (ICERs) (Cost 1 - Cost 2)/(Effect 1 – Effect 2) which provides an incremental cost per QALY gained or incremental improvement in other outcome for the new treatment when compared to an alternative. A ‘maximum acceptable ICER’ cut off point can then be defined to determine whether or not a new or alternative intervention is cost effective.

In the UK, NICE usually defines 'cost-effective' where the cost per QALY is around £20,000 or less: "NICE should explain its reasons when it decides that an intervention with an ICER below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective"[53]

Useful Health Economics Texts

Main textbooks

- Kobelt G. (2002) *Health Economics: An Introduction to Economic Evaluation*. Office of Health Economics (£5 from www.ohe.org).
- Donaldson C., Gerard K. (2005) *Economics of Health Care Financing: The Visible Hand*. Palgrave MacMillan.
- Gold MR., Gold SR. & Weinstein MC. (1996) *Cost-Effectiveness in Health and Medicine.* Oxford University Press.
- Drummond M. *et al* (2005) *Methods for the Economic Evaluation of Health Care Programmes.* 3rd Ed, Oxford University Press.

Other references

- BMJ, EDUCATION AND DEBATE, Economics Notes http://www.bmj.com/bmj-series/economics-notes
- Claxton,K., Sculpher,M. & Drummond M. (2002) A rational framework for decision making by the National Institute For Clinical Excellence (NICE), *Lancet*, 360:711-15
- Petrou S, Gray A. (2011) Economic evaluation using decision analytical modelling: design, conduct, analysis, and reporting. *BMJ,* 342:doi:10.1136/bmj.d1766
- Petrou S, Gray A. (2011) Economic evaluation alongside randomised controlled trials: design, conduct, analysis, and reporting *BMJ*, 342:doi:10.1136/bmj.d1548

Your Sample

Sampling is the process of selecting units (e.g. people, organizations) from a population of interest for involvement in your study. Under the methodology section of most grant applications you will be expected to describe who exactly the participants in your study are to be (your **sample**), the population (**sampling frame**) and **setting** from which you will be recruiting them (e.g. which hospital *etc*) and also

[53] www.nice.org.uk/media/C18/30/SVJ2PUBLICATION2008.pdf

how many you intend to enrol into your study (**sample size**). This information is essential for both qualitative and quantitative studies. It enables reviewers to see whether the group you have chosen relates to the research question you have posed, and whether the numbers you propose are enough from a statistical point of view (quantitative studies) or a data saturation perspective (qualitative studies, see below).

Eligibility Criteria

The usual way of defining your patient group for a study is to use eligibility criteria. These state clearly the inclusion and exclusion criteria you are applying. Inclusion criteria may include a diagnostic and/ or demographic group among other things; exclusion criteria will list patients who you are not including either because they are not of interest to you, or because they have, for example, co-morbidities that may make it unsafe for their inclusion in a trial of a particular intervention.

Samples and Sample Sizes for Quantitative Research

It is usually unrealistic (and in fact, unnecessary) to sample everyone (100% sample) in a research study, so it is important that any group examined is *representative* of the overall group of interest, so that results from your study are *generalisable*. If the sample is not representative, you can immediately introduce biases into your study, which may compromise (or completely scupper) the results (right at the start!). A common way to select participants is to take a random sample. A complete listing of those to be sampled is usually obtained (1 to x), random numbers are generated, and applied to the list. This is only one common method and there are variations upon it, depending on what you are trying to achieve (e.g. stratification). Another common approach is to try and enrol concurrent patients meeting your eligibility criteria over a fixed period of time.

As well as deciding who you sample, the number you sample is also important. For descriptive studies, if the sample size is too small, you may under or over-estimate the presence of the variable of interest in the population. In small studies of the effectiveness of interventions, you may conclude a treatment is ineffective when a larger sample size may in fact have shown an important effect and thus patients may continue to receive an inferior treatment. For both types of study, you waste people's time and money on a study that was destined to show nothing – essentially an unethical study. If sample sizes are too big – you are simply wasting participants' time and funders' money, although the consequences for your results are less devastating than when sample sizes are too small.

In descriptive quantitative studies (e.g. a prevalence study) the primary aim of sampling is to obtain a representative sample of the population of interest from which inferences about the general population can be made.

Sample size calculations for surveys rely on knowledge of:

(1) The total number in the population being surveyed
(2) An estimate of the prevalence of the main variable in question
(3) The required degree of precision (i.e. the confidence you wish to have in the results). E.g. for a rate this might be +/- 2%.

A formula, or tables are used to determine the sample size.

***In hypothesis-driven studies**,* you are often comparing groups undergoing different experiences either in a health care or natural setting. In an intervention study such as an RCT, it is important to have a sufficiently large sample size to ensure that any differences you see between groups (i.e. as the result of the intervention) can be detected over and above the normal variability seen in the outcome of interest. For a very variable population, for example, a group of patients on a surgical ward (with different diagnoses and surgical experiences), variability, say in pain experienced, will be large and a sample size would have to be correspondingly large to take this into account. For a much more homogeneous population (e.g. a specific group of surgical patients, such as men undergoing a trans-urethral resection), the variability in an outcome such as pain is likely to be smaller, therefore the sample size is likely to be smaller.

If you are consulting a statistician about sample size in a study comparing groups, you will need the following information:

(1) Information on your main outcome measure – (a) An idea of the usual means (and standard deviations) or proportions for your main outcome measure (depending on the measure) in a population like the one you are examining. This could come from the literature or pilot work; (b) What would be considered 'clinically important' in terms of the difference seen between groups in your main outcome, should a difference exist. (a) and (b) are used to calculate the anticipated standardised difference (i.e. the difference to be tested between the two groups, taking into account the variability in outcomes).

(2) The level of statistical significance you are looking for - This indicates the probability of getting a false positive (i.e. rejecting the null hypothesis[54] when in fact it is true). E.g. where p=0.05, there is a 1 in 20 chance of concluding a treatment is effective, when in fact, it is not.

(3) The power you want to detect the specified difference - Power is the probability of rejecting the null hypothesis correctly. By maximising the power, you minimise the false negative rate. E.g. where the power is set at 80%, 4 times out of 5, on average, a difference will be detected when it is *really* there.

[54] The null hypothesis states that there are no differences between the groups being compared.

These pieces of information (standardised difference, level of statistical significance and power) can be used in a formula (often in a computer package), or applied to relevant statistical tables, to inform the sample size.

To determine the sample size properly, you should **always consult a statistician**. Hopefully you will have the clinical/ subject area knowledge, and a clear idea of your primary outcome, and the statistician will have the statistical knowledge required, so together you should be able to sort out the sample size needed for your study.

Samples and Sample Sizes for Qualitative Research

Purposive sampling is the most commonly used sampling strategy in qualitative research. The selections of units (e.g. people, organisations, documents, departments *etc.*) are made with direct reference to the research questions being asked and units have particular features and characteristics (socio-demographic, experiences, behaviours, roles) to enable detailed exploration of central themes of interest. There are several different approaches to purposive sampling:

- **Homogenous:** detailed picture of particular phenomenon by selecting participants from same subculture/same characteristics
- **Heterogeneous/ Maximum Variation:** deliberate strategy to include phenomena that differ from each other to identify themes that cut across the variety of cases and groups
- **Extreme Case/ Deviant Case:** cases chosen because they are unusual or special and therefore potentially enlightening
- **Intensity:** focus on cases that strongly represent the phenomenon of interest
- **Typical:** Focus on cases that typically represent the phenomenon of interest
- **Stratified:** hybrid approach – selection of groups that display variation but each of which is fairly homogenous so that subgroups can be compared
- **Critical:** selection of cases that are critical to convey understanding of central themes of research

There are other types of sampling strategies used in qualitative research such as theoretical sampling. This type of purposive sampling is mainly associated with development of grounded theory and is based on sampling incidents, people or units on the basis of their potential contribution to the development of testing theoretical constructs. It is an iterative process linked with data analyses (sample-analysis-re sample-analysis) which continues until data saturation (no new insights to be gained from expanding the sample further[55]). 'Opportunistic Sampling' and 'Convenience Sampling' strategies are also used in qualitative research. With the former the researcher takes advantage of unforeseen opportunities that arise in the course of

the fieldwork – the sample is thus moulded around the fieldwork. In the case of the latter, a clear strategy is often lacking and the sample is chosen by ease of access - this is the less commonly used approach to sampling[56].

Information on sampling

- Sampling methods from the National Audit Office Sampling Guide: http://www.nao.org.uk/report/sampling-guide/
- Probability methods: www.socialresearchmethods.net/kb/sampprob.php
- Non-probability methods: www.socialresearchmethods.net/kb/sampnon.php
- Ritchie J., Lewis J. & Elam G. 'Designing and selecting samples'. In Ritchie J. and Lewis J. (eds) (2003) *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: Sage. pp.77-108

Data Collection

Sources of data

There are two broad categories of data: primary and secondary (or routine). The former relies on the researcher obtaining data first hand while the second relies on material collected by someone else. Common sources of secondary data include censuses, surveys and organizational records. There are advantages and disadvantages to these different data sources:

Advantages of individual data

- Can control data collected
- Gets direct experience
- Potential for much richer 'in-depth' information

Disadvantages of individual data

- Expense
- Reliability
- Bias & expectations
- Time consuming (tool design, fieldwork)

Advantages of routine data

- Easily accessible, e.g. published
- Regularly updated
- Inexpensive
- Large numbers, e.g. health region

Disadvantages of routine data

- Interpretation
- Completeness and accuracy
- Delay in getting up-to-date data
- Relatively inflexible
- Reliability/ validity of coding
- Confidentiality (depends on dataset)
- Lack of overlap in datasets, (e.g. geographical area)
- Differing age/sex breakdowns to those desired

[56] Ritchie J. and Lewis J. (eds) (2003*) Qualitative Research Practice: A Guide for Social Science Students and Researchers.* London: Sage

Primary and secondary data can be made up of information from numerous sources. For example, both may be derived from interviews and/or questionnaires. For example, direct one to one interviews (primary), census data (secondary). Both can be derived from records, for example, direct data collection by the researcher from medical records (primary), hospital admissions based on Hospital Episode Statistics (secondary). These data may, themselves, arise through observation. Primary data may also include group work, the gathering of testimonies, anthropological and other observations.

Data collection methods

The data collection method that you choose to use for your study will largely depend on the design that you have selected.

If your research is a quantitative study you may use questionnaires and observations and recordings of clinical and biological data. If your research is qualitative in design you will most likely make use of interviews, which can range from structured to unstructured ones, focus groups, and observational techniques. Most importantly, the choice of data collection methods should be appropriate for the design and aims of the study. Availability and practicalities will also (inevitably) influence which methods are used. Data collection should only be conducted by appropriately trained individuals for ethical, safety and scientific reasons.

Data Collection in Quantitative Research

Data collected in quantitative studies are inevitably reducible to numbers that can be examined statistically. Such data will include measures of structure, process and outcome. They may take the form of questionnaires which can be administered face-to-face, telephone or internet (there are inevitably pros and cons to these different approaches), and will usually be highly structured. Such questionnaires might measure disease specific or more generic health outcomes. Other measures used in quantitative research are: biomarkers, scans and other forms of clinical and biological measurements and observations, specific event data, such as admission to hospital or visit to GP, death *etc*. Generally the issues to consider when considering a measure for a study are: its appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability and feasibility.[57]

As well as data collected concerning your primary outcomes of interest, you also need to consider collecting the data required for administrative purposes; and contextual data (e.g. potential confounding variables such as socioeconomic status) which may shed light on the results you have, and will often be included in statistical models to adjust for any factors you have been unable to control through the research design.

[57] Black N. *et al.* (1998) 'Patient-assessed outcome measures'. Chapter 2 in *Health Services Research Methods: a Guide to Best Practice*. BMJ Books: London.

Pre-validated Tests & Scales

Tests and scales are often self report measures although some are completed by the researcher, and are aimed to test or measure people's abilities, views, opinions, attitudes and propensities. Such tests have also been developed to measure service use experience (e.g. satisfaction), patient reported outcomes (PROs) such as quality of life (QoL) and for patients' resource use, for health economic analyses. There is increasing recognition that NHS research should include a PRO measure to reflect outcomes and experiences relevant to the patient, and there is increasing use of such measures in clinical trials. Measures used in such trials are now heavily regulated by licensing bodies such as the United States Food and Drug Administration. It is therefore imperative that any outcome measure used in a clinical trial complies with the regulations of such bodies.

Tests and scales are also used extensively in psychology and psychiatry and range from those which measure the relatively short term effect of something that has happened by using a 'state' measure (such as a depression inventory to measure the effect of an intervention in a trial), or those which measure relatively stable dispositions, or 'traits' (e.g. personality or intelligence).

There are different types of scales but the most widely used are summated such as Likert scales[58]; these are also relatively cheap to administer. The website and references below provide more information on tests and scales.

When you are considering which outcome variables to use in your research, make sure you do not 'reinvent the wheel'. If a well validated tool measuring your area of interest exists, consider using it. The great advantage of pre-existing tools is that many have been rigorously examined for their validity and reliability. If you try and construct a tool (e.g. a questionnaire) of your own you can run into difficulties. Whilst individual questions in a questionnaire may have face validity (i.e. they make obvious sense) and be useful in themselves, any attempt to scale them up into some sort of numerical score is likely to be methodologically flawed, making assumptions about the relative value of categories. The development of scales is a complex process, which requires input from health outcome experts and statisticians.

- The American Psychological Association: http://www.apa.org/science/programs/testing/find-tests.aspx
- Bellack MS., *et al*. (eds) (1998) *Behavioural Assessment: A Practical Handbook*, 4th edn. Boston, Mass.: Allyn and Bacon.
- Oppenheim AN. (1992*) Questionnaire Design, Interviewing and Attitude Measurement*. London: Pinter; New York
- Bowling A. (2005) *A Review of Quality of Life Measurements Scales*. Open University

[58] Likert, R. (1932) A technique for the measurement of attitudes. *Archives of Psychology*, 22, 140: 55

Data Collection in Qualitative Research

Interviews

Qualitative data collection methods typically involve some form of interview. These are often conducted face-to-face and one-to-one to establish trust and rapport, but can also be conducted via telephone or email. Qualitative interviews encourage interviewees to use their own language, can make use of a range of probes and are aimed at encouraging reflection. They are able to combine structure and flexibility and can therefore range in degree of structure from unstructured and exploratory to semi-structured and topic guided[59]. Interviews are usually audio or video recorded and transcribed verbatim for analysis.

Focus Group Interviews

Group interviews or focus groups have become increasingly common in health research and typically consist of 6-8 people who are assembled to discuss a topic decided by the researcher. Focus groups normally last between 1-2 hours, and vary in the extent to which discussion is structured. Members are selected because they have something in common and the researcher/ moderator/ facilitator poses questions to probe the subject of interest. Active promotion of interaction in the form of dialogue between respondents is one of the key aims of focus group interviews and they are often used to test the construction, utility, and validity of a research instrument at a preliminary research stage. They are also useful when individual interviews are difficult[60], or to explore a new research area, particularly in feasibility designs.

Observations

Observations can be used in qualitative enquiry in a variety of forms[61]. These range from observer as participant (role of researcher is known), participant as observer (observer's role is secondary to participant role) and complete observer (without participation). Some of the advantages of using observational methods are:

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[59] Ritchie J. and Lewis J. (eds) (2003*) Qualitative Research Practice: A Guide for Social Science Students and Researchers* London: Sage

[60] Ritchie J. and Lewis J. (eds) (2003*) Qualitative Research Practice: A Guide for Social Science Students and Researchers* London: Sage

[61] See: Hughes D. 'Participant Observation in Health Research' (2007) Chapter 6 in Saks M. and Allsop J. (eds.) *Researching Health: Qualitative, Quantitative and Mixed Methods,* & Becker HS. *et al.*'s (1961) early work on medical socialisation is a fascinating read – *Boys in White*

- First-hand experience (if participating) of behaviour, process and events
- Data are not filtered through an interviewee (respondent bias)
- Useful where issues are not suitable for discussion

Observational methods are also best suited to research that takes place in naturally occurring situations; to observe natural processes i.e. those which cannot be adequately captured by interview methods. Researchers often use field notes and record sheets when observing in the field. These can be inclusive in that they record everything that is happening or they can be time, event, or process sampled.

Data Analysis

Quantitative Research

Always seek statistical advice at an early stage of research planning if you are collecting quantitative data. A statistician can help you consider what you are trying to achieve with your data collection, and give you guidance on the type of analyses you will have to do and the software you may need to do it. Think about how the data will be managed. Will you have sets of questionnaires and other measurements for each patient? How will clinical data translate into the numerical data that will be entered onto the computer?

Check your data

Once data are collected the first data analysis job is to take a look at what you have and check for inconsistencies and inaccuracies. This is usually done by using simple descriptive statistics (frequencies, means, standard deviations) and cross-tabulations which will pick up on unexpected values that may need double checking.

Type of data

You may already have information on the statistical profile of the specific measures you wish to use (e.g. from manuals or the literature). This can also be examined looking at your basic descriptive statistics. Statistical data are broadly classified into those that are continuous measurements (e.g. height) and those that are not (e.g. sex). The statistical methods used to analyse the data are dependent on the type of data and whether or not (if continuous) they are also normally distributed. Always consult a tame and friendly statistician for advice before proceeding. The RDS has a number of them!

You need to think about what you want to examine or demonstrate. In a descriptive study, you may simply be looking at the prevalence of a particular characteristic in your sample. This can be looked at using descriptive statistics. Often, for example in a trial, your main interest lies in the difference between groups, or the change in score over time between groups. These can be examined using change scores and comparative tests. If other variables need to be taken into account (e.g. potential

confounders), more complex statistics may be undertaken which can model the statistical contribution of a variety of factors to an outcome.

It is not possible to cover here the range of statistical tests which are commonly used in quantitative studies. The important thing to stress is that you need to know what you are looking for, and you need to consult with a statistician to come up with the right way to deal with your data at the proposal writing stage.

Data Analysis in Qualitative Research

Approaches to data analysis in qualitative research will vary according to the aims and focus of the study. Common approaches are often based on identifying common themes (Thematic) and constructing analytical frameworks (Framework), or those based on conversation analyses and grounded theory approaches. There are a number of different tools available to help the process (see CAQDAS[62]).

A qualitative data analysis is best understood as a process of data transformation. For example, if employing a thematic analysis, the raw data (e.g. interview transcripts) will be subject to cleaning to ensure readability and to correct errors (typos *etc*.). This process will be followed by detailed scrutiny and reading to identify themes and concepts. Following this, repeated reading will occur to *assign meaning* and to label the data by theme or concept. This is often followed by a degree of sorting of the data by theme or concept (to allow cross sectional analysis). A process of synthesizing the data will follow, that results in the presentation of descriptive accounts with categories and classifications further refined to assign and establish typologies. This will facilitate the detection of patterns to develop explanations (answering how and why questions).

Qualitative data analyses are often underspecified in research proposals, but will require considerable forethought. It is important that you consult with and involve an experienced qualitative researcher if this is to be a component in your study.

[62] www.surrey.ac.uk/sociology/research/researchcentres/caqdas/

Study Design Literature:

Abbas T. & Creswell JW. (2007) Editorial: The New Era of Mixed Methods*. Journal of Mixed Method Research* 1: 3-7
Adamson J. (2005) 'Combined qualitative and quantitative designs'. In Bowling A. & Ebrahim S. (eds*.) Handbook of Health Research Methods: Investigation, Measurement and Analysis*. Berkshire UK: Open University Press.
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Baum F. (1995) Researching public health: behind the qualitative–quantitative methodological debate. *Social Science & Medicine*, 40, 4: 459-468.
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Czaja R.& Blair J (1995) *Designing Surveys: A Guide to Decisions and Procedures.* The Pine Forge Press Series in Research Methods and Statistics, Pine Forge Press.
Fink A. (ed.) (1995) *The Survey Kit: The Complete Survey Kit.* Thousand Oaks, London and New Delhi: Sage Publications, Vols. 1-9.
Hulley SB., *et al*. (2006) *Designing Clinical Research: An Epidemiologic Approach*. Lippincott Williams and Wilkins; 3rd revised edition
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Mason J. (2002) *Qualitative Researching* (2nd edition) London: Sage Publications.
McCain A., Nicholl J. & Murphy E. (2009) Structural issues affecting mixed methods studies in health research: a qualitative study. *BMC Medical Research Methodology*, 9:82.
Medical Research Council (2000) *A Framework for the Development and Evaluation of RCTs for Complex Interventions: Guidance on Incorporating Qualitative Studies in Designing Complex Interventions to Improve Health.* London. Medical Research Council.
Medical Research Council (2008) *MRC Developing and Evaluating Complex Interventions: New Guidance. London:* MRC
Medical research Council (2011) *Using natural experiments to evaluate population health interventions: guidance for producers and users of evidence*. London: MRC
Neale J (ed.) *Research Methods for Health and Social Care.* Palgrave Macmillan
O'Cathain, A*. et al.* (2009) Structural issues affecting mixed methods studies in health research: a qualitative study. *BMC Medical Research Methodology*. 9:82.
Ritchie J. and Lewis J. (eds) (2003*) Qualitative Research Practice: A Guide for Social Science Students and Researchers* London: Sage.
Robson C. (2002) *Real World Research. A Resource for Social Scientists and Practitioner-Researchers*. Blackwell
Sackett D. & Wennberg J. (1997) Choosing the best research design for each question: It's time to stop squabbling over the "best" methods. *BMJ*, 315: 1636:
Strauss A. & Corbin J. (1990) *Basics of Qualitative Research*. Sage.
Walker R. (2009) Mixed methods research: quantity plus quality. In Jo Neale (ed.) *Research Methods for Health and Social Care*. Palgrave Macmillan.

Link to useful websites:

Survey Research: www.socialresearchmethods.net/kb/survey.php

Training & Support:

Economic and Social Research National Centre for Research Methods: http://www.ncrm.ac.uk/
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IV. Writing a Research Protocol

What is a research protocol?

People use the terms 'research proposal', 'research protocol' and 'research grant application' rather loosely. Perhaps the most useful distinction is made between a 'research protocol' and a 'research grant application'.

Q. What is the difference between a research protocol and a research grant application?

A. A research protocol is the *definitive document* that will inform the process of the research. Some R&D offices will insist on a Good Clinical Practice (GCP) approved protocol*, and provide templates for this (regardless of whether the project is a Clinical Trial of an Investigational Medicinal Product (CTIMP) or not)

The research protocol can be used as the *basis* for applying for ethics (through the Integrated Research Applications System – IRAS – part of the National Research Ethics Service) and funding (your grant application), and there will be an overlap, but these latter documents will have different emphases, so it is not simply a matter of cutting and pasting.

Be aware that funding, ethics and other processes are likely to lead to adjustments in research related documents. It is important to keep tabs on versions and ensure the research protocol to be operationalized for the actual study is approved by all relevant organisations (funder, ethics, governance etc.)

A word about GCP:

Definition from EU Directive 2001/20/EC, article 1, clause 2:
"Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects."

Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible and accurate.

The principles of good clinical practice are outlined in articles 2 to 5 in the EU Directive 2005/28/EC.

(From www.mhra.gov.uk)

Who to talk to

You as the researcher have the responsibility for developing a proposal that is scientifically sound and ethical. First talk about your research proposal with colleagues (including your manager), and make contact with the RDS when you have something in writing (however basic). It is quite easy to become entrenched in your own ideas, and nearly always beneficial to talk to others about your plans. You should contact your proposed sponsor (see definitions below) and discuss your proposal. R&D Offices will vary according to staffing and workload as to what stage they wish to discuss your proposed work, but it is worth letting them know you are planning some research early on. Consider how you get input from users (e.g.

relevant patients or carers – see later) and ideally have several involved throughout the development process.

The Structure of a Research Protocol

It is worth bearing in mind that no two proposals are the same, but they will all have a similar structure[63]:

1. Title
2. Abstract/summary (often a lay summary as well)
3. Background/rationale
4. Aims/objectives
5. Design and methods
6. Ethical considerations
7. Benefits of the study
8. Resources and costs
9. Logistics and Gantt chart

When writing a proposal it is important to consider who will be reviewing it (e.g. for funding and/or peer review) as often it will be scrutinised by lay members of committees.

Tips on grant application sections

The distinction between a research protocol and a research grant application has already been drawn. The primary aim of the RDS is to help people apply for grants. This next section therefore concentrates on what should be in a *grant application*, rather than the definitive 'research protocol'. Good examples of GCP approved protocol templates can be found on the Oxford University Hospitals R&D website.[64]

What should be in some of the most common sections of a research grant application is shown in the following table. Resources, costs and Gantt Charts are also requested in applications, and these are discussed a little later in the section.

[63] Adapted from material by Keith Chantler, R&D Manager, Central Manchester and Manchester Children's Hospitals

[64] www.oxfordradcliffe.nhs.uk/research/downloads.asp - Clinical Research Protocol (non-CTIMP) and Clinical Trial Protocol (CTIMP) templates.

Title	• Descriptive, yet concise • Contains keywords relevant to the research • Study question and main outcome measure to be included • If a trial, also include intervention and population • State if pilot/ feasibility • Clear from title that study is in scope for funder
Abstract/ Summary	Concise, convincing summary of: • Problem (e.g. disease burden) • Research question and rationale • Design and method • Expected outcomes • Expected impact A 'Mini-Me' of the main protocol! For a **lay summary**, all of the above **BUT** absolutely understandable to the lay person: • **No** clinical or research jargon • **No** difficult words • Involve a PPI representative to review or even WRITE this section!
Background/ Rationale	This section needs to **PACK** a **PUNCH**! Using the literature: • Define the research issue. Justify **WHY** the research is necessary – build a clear case for clinical importance and impact, for example, disease /condition burden (local / national figures) • Back up the logic of aims and objectives • Provide evidence of the best design approach • Stress the relevance of your proposal to chosen funding scheme. Highlight if the study fits into a desired but under-represented area.
Aims/ Objectives	• Need absolute clarity of objectives / primary outcome / secondary outcomes, and ensure that these relate to funder scope and are not contradicting the title • Is this definitive or exploratory / preliminary work? What would the upshot be if it is successful in the case of the latter? • If there is a null hypothesis[65], is it clear and appropriate? • Do any qualitative aspects of the research have clearly stated objectives / questions / intentions? • If a pilot or feasibility study, make this clear, and also how it would lead on to full trial
Design & Methods	Cover the following: • Actual **study design**, for example, randomised controlled trial, ethnographic study. Make sure the design is appropriate to the aims and objectives • Specify the **setting** (location). • Specify the **sample**, including the **sampling frame** (population from which you are sampling) and **eligibility criteria**. These should be clearly defined

[65] The null hypothesis states that there are no differences between the groups being compared.

Design & Methods cont'd	and consistent with study title/ objectives. The results should be generalisable to the overall population of interest. • Specify the **sample size**, and if this is statistical, make sure a proper power calculation has been undertaken • Be very clear about any **proposed intervention**(s) and a good, evidence-based rationale for its (their) duration; provide a clear description and evidence-base for **control** or **comparator groups**. • Where relevant, give details of **randomisation**, for example, block, stratified, or use of minimization techniques, and **allocation concealment** • Specify appropriate **data types and sources** and make sure any **specific outcome measures** are validated and appropriate for the population (remember to reference them). Measurements must accurately reflect the impact of the intervention. If surrogate / proxy measures are used, give evidence that these can accurately predict long-term outcomes. Specify appropriate and clinically relevant follow-up periods. • Give details of **procedures** • Give details of **data analysis** methods • Make sure you have considered how potential sources of bias will be avoided or taken care of, e.g. **details of blinding** • A **flow chart** showing the progress of participants through the project always helps to clarify pre-intervention tests/measures, study interventions, post-intervention tests/ measures and follow-up times • Guidelines exist for accurate reporting of types of research study (e.g. CONSORT for trials, STROBE for observational studies, STARD for diagnostic studies *etc.*). These specify a minimum set of items for clear, complete accounting of processes. We recommend you consult a relevant guideline early in research planning to ensure you will have the data you need to report the study properly.
Ethical considerations	• Are you gathering information from a vulnerable group? If so, what are the ethical (and legal) implications? • You will almost certainly have to submit an ethics committee application (now done through the IRAS[66]) • Remember that ethics committees and R&D Departments have only approved the protocol they have seen. They should be informed of any changes to protocols.
Benefits of the study	• Think of the likely benefits to patients • Think of the potential impact of your proposed research on policy / service delivery *etc*., should it show what you think it may. • Make sure you specifically show how your work fits in with the funder's research remit detailed in the guidance notes.
Intellectual property	• Increasingly funding bodies are asking applicants to fill in a section on IP. Most projects will generate IP – even if it is simply a new dataset, but some studies will produce copyrightable (e.g. teaching pack, outcome measure) or patentable (e.g. a new medical device or drug) outputs. Try and show that you have at least thought about IP in your answers to questions, and always refer to your R&D or Technology Transfer Office if you need to seek clarification about IP in relation to your study.

[66] Integrated Research Application System.

Resources and costs

You need to justify the funds you are requesting and how you are allocating them.

The costs of R&D in the NHS are split into three categories:

- **Research Costs**, which will be met by the research funder(s)
- **NHS Service Support Costs** which will be met by the NHS through the Comprehensive Local Research Networks[67] (CLRNs), who transfer these funds to the relevant trust when the study is funded. Once researchers have considered possible service support costs, these should be discussed with their R&D Office. They may be advised to check that their plans are sensible and feasible with the CLRN, who are usually happy to discuss these costs with PIs once they have a reasonably clear idea of what they are. They can also discuss with CLRNs about how the latter can help with actual research (e.g. availability of CLRN nurses). See later section on 'Involving Other Organisations' for more on this.
- **NHS Treatment Costs** will usually come through normal commissioning processes via the Trust; however, in some circumstances, extra support will have to be applied for from the NIHR ('subvention support'). This is something the researcher will have to do, if advised by the R&D Office.

There are three stages to sorting out your costs (non-commercial studies):

(1) **Carefully think through the logistics of your research** (see next section) and for each activity relating to your project, consider what is required in terms of personnel (including grade and time commitment), equipment, travel, etc. The RDS can help you with this.
(2) **Look carefully at the new AcoRD document**[68], which gives you guidance on how to determine which of the three categories above (Research, NHS Service Support and NHS Treatment) each cost should fall into.
(3) **Consult with your Finance Office** (which may be University or NHS Trust or both) to talk through your costs and to allocate actual pounds and pence to the activities *etc.* you have identified. Finance Officers will have a list of costs for human resources and NHS Trust Finance Officers will also have lists of costs for all the clinical elements of the research – e.g. tests, diagnostic procedures. Where the research involves more than one institution (academic

[67] if your project counts as part of the Clinical Research Network (CRN) Portfolio. See www.ukcrn.org.uk/index/clinical/portfolio_new/P_eligibility.html for details of what counts as a portfolio study. If your project is considered 'non-portfolio', then these costs will have to be obtained from elsewhere, most likely the Trust where the research is taking place, or Sponsor.

[68] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133882. You can also find a useful presentation about AcoRD, by Trudi Simmons, Senior Manager – Research Finance & Programmes (NIHR) here: www.rdforum.nhs.uk/confrep/annual2012/TSimmons.pdf

and/or NHS), the funds suggested for each site need to be signed off by the Finance Officers of each site prior to submission, so you need to leave yourself plenty of time to ensure this. Should you be successful, formal collaboration agreements will have to be in place before funds are released. Beware - these types of arrangements can take a long time to set up.

The application guidance will specify how they wish funds to be broken down, for example, by project year or calendar year. There will usually be a number of headings. The table shows the commonest categories of funding you are asked to give, and what they mean – but your Finance Officer should be able to advise you.

What should you budget for?

(1) Salaries

Salaries are exceedingly important. They are often the most substantial part of a grant application. If you underestimate the salaries, you could find you have a research project with no researchers or data collectors! Anyone mentioned as a co-applicant on the grant application would be expected to have an associated cost in the budget – even if it is very small (in this case, perhaps more useful to indicate in days or weeks per year, rather than as a percentage of Full Time Equivalent). As indicated, obtain help for costing personnel through your institution's finance office. Note that staff from academic institutions often cost more than NHS staff, due to the larger overheads. Don't forget to also include a budget for your PPI representatives – they will also require a *per diem* rate and travel expenses (see INVOLVE – www.invo.org.uk – or contact the RDS for a list of costs related to PPI).

(2) Materials and consumables

(a) Stationery
For example: think about how many questionnaires or data collection schedules you need. How long are they? How many times will they be required? Remember that postal questionnaires may not be returned immediately - you will have to send reminders, and usually another copy of the questionnaire to some study participants. Remember the need for stationery to cater for: invitations, information sheets and general correspondence. For larger, longer-term studies, you may wish to consider how to represent the study to the public/ participants (e.g. using a logo). For a relatively small study, expect to fill at least one four drawer filing cabinet with administrative information!

(b) Printing
For example, as above, think about how many questionnaires or data collection schedules you will need, how long they are, how many times they will be needed. Cater for invitations, letters, information sheets etc.

(c) Postage

For example, think about how many mailings you need including follow-ups and reminders. Remember to budget for Stamped Addressed Envelopes or pre-paid envelopes (which are better as you are not paying for non-responders). Budget for considerable general correspondence postage costs. Don't forget to include postage costs for disseminating your research results to patients and other relevant organisations!

(d) Travel
For example, researcher to participant, participant to researcher, meetings to sites to set up and run the project, dissemination (some funding bodies will allow you to budget for conference costs)

(e) Tests
For example, clinical tests, laboratory tests

(f) Equipment
For example, monitoring instruments, computing equipment (including software), desks, chairs, renting room space

(g) Telephone costs
For example, your finance office may have a standard recommended rate for telephone costs for which they would like you to budget.

(h) Miscellaneous
For example, staff training, running costs of equipment, advertisements for staff.

Tip:

Give yourself some leeway - always err on the side of caution (i.e. round up) when you do your costs. It is almost certain that something will crop up which you cannot foresee.

Cost	Definition	Examples	Funded by:
(1) RESEARCH COSTS **(a) Directly incurred costs**	Costs of people/ other things that are being employed/ used *exclusively* to answer the research question. Activities falling into this category would end when the research ends.	Research, technical and other staff, travel and subsistence, equipment, consumables, PPI,	Research grant
(b) Higher Education Indirect (HEI) costs	For universities only, (i) the overheads associated with employing someone, (ii) the costs of people already employed taking 'time out' for the purposes of the study (e.g. supervision) , (iii) estate costs for staff, i.e. physical environment required for general staff support, & (iv) university-based technical support (e.g. laboratory costs)	E.g. For Oxford University, for 2010/11, the additional costs (or 'overheads') associated with employing a full time member of staff, regardless of grade, is £48,889; the estate charges, per full time member of staff per year, regardless of grade, are £4,420	Research grant
(c) Commercial/ Other Partner Organisation Indirect Costs	The costs of resources used by the research that are shared by other activities.	Similar to HEI indirect costs above	Research grant
(d) NHS Overheads	Costs of resources used by a project, but shared by other activities	Estates charges, telephone rental etc.	Research grant
(2) NHS SUPPORT COSTS	An activity comes under this category if it concerns patient care, but is primarily undertaken to facilitate research, or is driven by the NHS duty of care to a patient, e.g. to ensure their safety whilst participating in the research.	Extra patient tests, extra in-patient days, extra staff time, e.g. consultants or nurses taking consent, extra attention to patients due to the research.	Comprehensive Local Research Network
(3) NHS TREATMENT	An activity comes under this category if it is integral to the provision of a treatment regime, whether the treatment is	Research treatment compared to standard NHS care	Normal patient care commissioning

COSTS	standard or experimental. It is possible that the experimental treatment is in fact cheaper than standard care, and therefore presents a saving to the NHS.		

Logistics and Project Management

Often neglected by research textbooks, the actual planning and logistics of a research project are crucial to its success. Logistics are concerned with the materials, equipment, space, personnel and time you need to successfully run a project, and how all of these things are organised. Basically, the: Who? What? When? Where? For how long? of research.

In order to put in a grant application, you need to know the logistical implications of your proposed research. Without such forethought you may underestimate the funds you require.

Tips:

- Think about what will need to be done on a day to day basis in order to successfully run the study.
- Think about **maximising benefits to all involved***, within the confines of the study design, Research Governance and ethics guidance.

* Suzy Oakes (1950-2011), an experienced research co-ordinator with the UKPDS and EPIC (*Personal Communication).* Perhaps we could call this 'The Oakes Principle'?

Who should be on a research team?

A small research project may involve just one person; others may involve a large team of researchers. There are a number of distinct roles undertaken by people doing research, for example:

(1) Collaborators

Collaborators bring the right skill mix to the research team. Research funders will want to see that the study team has the expertise to carry out the proposed work. If you have a study with a large statistical or qualitative element, for example, you should collaborate with a statistician or qualitative researcher. Collaborators may have varying degrees of involvement in a study, but it is important to involve people with a genuine interest in what you are planning, who will be available to help you when you need them. Remember that each collaborator will require funding, so a realistic estimate of the time they will need to complete their allocated tasks is important to ensure quality.

(2) Steering committee/ overseer

Many studies have steering committees, basically a group of fairly senior people (in addition to, for example, a lay or consumer representative), who take responsibility for overseeing the work, and ensuring that the study happens as intended. They will keep an overall check on the project timetable, and help with specific problems and issues when they arise. If there is no steering committee, this job would usually be

undertaken by an experienced, senior individual, usually a manager. Again, steering committees require time and therefore funds, so include a schedule and resource allocation in the grant proposal.

(3) Day to day project manager/ co-ordinator

This key person would be responsible for the day-to-day management of the study. They would normally have considerable research experience. Their tasks might include: keeping up to date with the literature, planning and implementing the study, establishing communication with sites and other researchers, co-ordinating the data collection, undertaking data analysis, and writing reports.

(4) Research assistants

These might include data collectors, professional interviewers, or technicians. They would be responsible for the collection of data, or the processing of samples, among other things.

(5) Administrative staff

Basically for administrative support: answering queries, assisting in literature reviews, keeping in touch with participants, document management, data entry, making copies of documents, making appointments, taking messages.

(6) Patient and Public Involvement (PPI) representatives

Funding bodies are very keen to know that what you are planning is relevant and useful to patients. All NIHR and most other funding schemes wish to see that relevant patient groups or individual patients have had input into your research proposal and will be involved in the research project, for example as a member of the steering committee. The input will vary according to the project itself (see PPI section) but what is certain is that, for the NIHR, if you have no PPI associated with your study (and no good reason for not having it), it is far less likely to get funded.

(7) Support staff

Generally people external to the study, but whose help may be needed, for example, staff on wards, in libraries, on ethics committees, local data protection officers, research governance officers.

(8) Consultants

For specialist help and advice, for example, statisticians, health economists, qualitative researchers. Where your project has a methodological element requiring support at a level less than co-applicant, you can pay for a consultant to do the work. Remember, though, that if the methodological input required from these specialists is

significant, funders will feel more comfortable if you have a co-applicant with the skills needed for the study.

(9) IT Support

You may need to consider involving a data manager. A decent database design and a good data management system are often overlooked in studies.

(10) Data Monitoring and Ethics Committee (DMEC)

Clinical trials will often have an independent Data Monitoring and Ethics Committee whose primary task is to periodically check on the data being collected for the purposes of patient safety. In particular, they undertake interim data analyses to detect either unexpectedly beneficial or detrimental effects of experimental treatments. Finding either may mean the trial is curtailed. They may also undertake more broad-ranging monitoring of data quality and integrity.

How should a research team be organised?

Planning in advance to ensure a good management structure for your research project is essential. It is very important that all co-applicants have clearly designated responsibilities and know what their role in the study will be. Everyone involved with the study should be committed in terms of interest and time. By looking at roles and responsibilities you can determine what other staff may be required to deliver the research successfully.

Good staff management is crucial. People should know what is expected of them, feel confident about what they are doing, and have easy access to advice and support when necessary.

The importance of communication issues

You need to consider who should know about the study. Examples of who may need to know are: your R&D office, senior managers, the National Research Ethics Service, medical (including GP, even if hospital based study) and other health professionals likely to be caring for patients involved in your study, local patient groups or national/ international charities for people with the condition, medical records officers, Information Commissioner/ local data protection officers (Data Protection), clinic/ward clerks.

For study sites, and some other relevant organisations (e.g. charities), the more evidence there is that people are ‘on board’ with the project (e.g. letters of intent, support), the more organised your proposal will look to a funding body.

For some aspects of the research (e.g. finances), formal agreements will have to be made before any funds are released (e.g. between collaborating sites). Formal agreements may also be advisable for things like data ownership and the authorship

of future reports and papers. Showing that you have considered these things will indicate that you are organised, and therefore fundable.

It is worth considering external communications, for example, advertisements for participants, websites, press releases, and if, when and at what stage these might be appropriate (and how to manage them successfully).

The importance of on-going communication

Between researchers

You need to have thought through how your team will relate to each other and that you have sufficient structure to run a successful study. It is important that research staff, in whatever project role, have ready access to support and advice from those at a more senior level. If a problem in the field occurs, for example, it may not be appropriate to expect a data collector to deal with it. Systems should be in place to ensure that the problem is relayed up to the appropriate level of seniority. Those working on the project at all levels should have the background and/or training to recognize potential issues. Bear in mind that apparently small problems, issues or omissions, if ignored or unrecognized, can lead to bigger problems later on (e.g. data problems, or disgruntled research sites).

With study participants

The funding you request must be enough to ensure that all participants in the study are provided with appropriate levels of contact with study staff. For example, contacts might range from 'on-call' doctors (for certain trials), to just having a name and number to contact during office hours. Studies which run over a long period of time may benefit from regular updates to participants, for example, newsletters or the provision of a website, to maintain interest and possibly enhance recruitment and retention.

With study sites and personnel

Bear in mind that even once a study is set up, you should have the capacity built into your team to keep in touch with study sites on a regular basis. This will ensure that any issues arising from the research can be dealt with before they become problems.

Other logistical on-going communication issues

- Provision of ‘back-up’ information may be useful, within the confines of the study design, Research Governance and ethics guidance. If you are interviewing people at length all sorts of issues may arise. It is sometimes useful to have ‘to hand’ information on, for example, support organisations, local council services *etc.*
- Suitable identification for researchers on wards *etc.* to avoid any confusion by participants or NHS staff.

- Have the capacity always to answer queries, trouble-shoot and engage in general information exchange
- Have the time to provide appropriate feedback to, and acknowledgement of, all those involved in the research you undertake, obviously bearing in mind confidentiality and ethics issues.

Recruitment issues

Staff

You need to have a clear idea about the logistical implications of recruitment, both of staff and study sites/ participants. You should bear in mind that recruiting can take time, and this has to be built into your research trajectory. For example, to recruit staff you will need to:

- Liaise with personnel
- Develop job descriptions
- Advertise (which can cost substantial amounts)
- Interview
- Get proper references - remember that your project may involve confidential information and vulnerable people.

To recruit study sites, you will need to:

- Liaise with management at research sites, including Research and Development departments
- Contact the Comprehensive Local Research Networks for advice and support
- Liaise with health professionals working in sites where data are being collected
- Share appropriate information about the study, what it will entail for the study site, the information being collected *etc*.
- Look at recent throughput/ numbers of the care group you are interested in to give you an idea of how long it will take to obtain the numbers required for your study.

To recruit study participants, you will need to:

- Establish how the eligibility criteria will be checked – i.e. how this information will be elicited through screening, who will do this and how long it will take
- Think carefully through issues relating to first contact and informed consent and the time it takes to do this properly.

It is worth considering all these things at the application stage, as they may have time, and therefore cost implications.

Logistical Issues Relating to Study Design

Types of study design are briefly discussed elsewhere. Different study designs have different logistical (and therefore cost) implications. It is very helpful to those reviewing grant applications to see visually the plans you have in mind. Researchers often use **flow diagrams** to show how patients travel through the research design, and these usually include the consent procedure, randomisation (where applicable) and when and what patients get in terms of interventions and outcomes.

Here are some examples of how study design influences logistics.

(1) Sample selection and recruitment

The type of sample you wish to recruit will determine the number of study sites you need and how long it will take to recruit your sample in these sites. For example, if your sample consists of individuals with a rare condition, you may have to involve a large number of sites, recruiting a small number of patients in each (or take a very long time to recruit your sample with smaller numbers of sites). If your sample consists of a common condition, you may be able to identify all your participants in one site (as long as they are representative of the care group in question).

In research, you usually wish to recruit a representative sample of the care group of interest. The results from the research can then be generalized to similar patients elsewhere. This section does not deal with sampling, but the method of sampling used clearly has logistical implications. For example, you may have to undertake certain procedures to ensure a sample is representative. This may require the help of a statistician, whose time will need costing in any grant application.

(2) Randomisation

If you are conducting a randomised controlled trial, it is important that you have a robust procedure of randomisation. This needs to be set up in advance, and should be discussed with a statistician when the project is being planned. Some funding bodies now encourage the formal involvement of a Clinical Trials Unit for this type of statistical input. Obviously this has cost implications.

(3) Arranging an intervention

Some projects may require researchers to organize the intervention being evaluated. Clearly this has to be well co-ordinated and fit around pre and post-tests and will affect the proposed project timetable.

(4) Data Collection Issues

There are a number of logistical issues relating to data collection that you need to consider when planning your grant application.

- *How will data be recorded?* What information do you need for administrative purposes? Should you be collecting information on possible confounding factors?
- *Measuring outcomes* -There are many validated tools available already but these need finding. It is also worth bearing in mind that permissions may need to be sought, and sometimes a fee paid to use these tools. If you are developing your own measurement tools, be very aware of (a) the time it can take to do this, and (b) issues of validity and reliability (especially in tools where answers are scored up - here tool development may require statistical reliability and validity testing). The timing of assessments needs to be carefully considered, and should be sensible given what the research is trying to show. Obviously the timing and frequency of outcome measurements will have logistical implications
- *Non-English speaking issues* - do you need to make provision for translations or interpreters?
- *Coding for the computer*, for example, are your tools easy to interpret for someone entering the data onto a computer?
- *Database development*, for example, which software will you use? If you are not using a statistical package for data entry, can entered data be transferred easily to a statistical package for analysis (without re-interpreting your coding, for example, for missing values, which can cause havoc!)? Who will enter the data? Double punching (double key verification) is a method of ensuring data are entered accurately but will have to be costed for.
- *How will the data be collected*: By whom? Where? When? For example, what is the best time of day from the ward's point of view? Will this affect the speed at which data can be accumulated?
- *Bear in mind the effect of holidays* on recruitment, and bank holidays on postage times.
- *Have in place a mechanism for data checking and quality control*. It is important to catch problems early. This should be catered for in the grant application
- *Think carefully about data storage*, in particular how to ensure data confidentiality and what mechanisms need to be in place. To ensure valuable time is not lost through accidental data loss, whatever system you plan should include some sort of back up data facility (including careful labelling of versions).

(5) Piloting

Always pilot! It checks that everything works. Make sure you have time to do it.

- Management and personnel arrangements
- Data collection methods
- The feasibility of the study: technical, political, logistical, and methodological considerations

- Highlights any fieldworker training needs
- Illustrates whether sample identification and selection methods work
- Provides information on the timing and content of questionnaires and interviews
- Provides an opportunity for examining the validity of tools and data sources. For example, you can obtain feedback from participants on questionnaires.
- Gives you an idea of the overall likely time-scale of the study
- Gives you a 'dry run' at data entry, cleaning and analysis

Unless you are planning a separately funded pilot study, some time for piloting should be built into the trajectory and costs of your application.

(6) Data analysis issues

Overall data analysis methods, whether qualitative or quantitative, should be planned before the study has started. The amount and complexity of analysis required will determine the degree of statistical, health economic or qualitative expertise you will need for your study, hardware and software requirements, and whether you need help with transcribing or other data entry. All these have implications for the amount of money you request in your grant application. Any proposal with a substantial statistical, health economic or qualitative component will have a better chance of success if a co-applicant or designated team member has the relevant expertise.

Dissemination issues

Ensure that the project timetable allows for sufficient time to disseminate the work. It is basically a waste of time if you undertake a project and then have no time to tell people about it. Dissemination may occur at several levels:

- Local dissemination to study sites and, where appropriate, to study participants, and PPI representatives
- Dissemination to national patient groups
- National dissemination to funding body and colleagues
- International dissemination at relevant conferences and meetings, and through publication

Dissemination may involve:

- Individual feedback
- Local workshops
- A report for the funding body
- Academic and health services related conferences and meetings
- Journal articles
- Dissemination through websites
- Dissemination through the press. This may result from the presentation of findings at conferences or through journals. Be prepared with a press

release (most organisations can provide advice on this to their employees), and do your best to control how your results are presented!

Ethics Committees will also expect reports (at various stages of the research, but including a final report).

It is very important that you have sufficient time in your project plan for these activities.

Timetables and Gantt Charts

Timetables help you to plan - they are not an after-thought! Most grant applications will ask for some sort of timetable. Timetables are very useful in helping to clarify what has to be done when. NIHR funding schemes ask for a Gantt Chart, which is basically a bar chart which, if you wish, allows you to link items, specify lag and lead times, indicate critical tasks and critical paths *etc.*

References for Logistics

- Crombie IK. & Davies HTO. (1996) *Research in Health Care*. Wiley and Sons Ltd.: Chichester. Chapter 14, pp.223-242
- St Leger AS, Schnieden H. & Walsworth-Brown JP. (1992) *Evaluating Health Services' Effectiveness*. Open University Press: Milton Keynes. Chapter 3, pp.15-28
- Hulley SB, *et al*. Implementing the Study and Quality Control'. Chapter 17 in *Designing Clinical Research*. Wolters Kluwer, Lippincott Williams and Wilkins. 3rd Edition. pp.271-289

V. Funding options are investigated

There are a large number of schemes that provide funding for health and social care research. One of the most important is the National Institute for Health Research. Others include charities[69], which can be specific to disease, demographic or geographical group, or generic in their scope. Government funded research councils are also a good source of funding, and for health, the Medical Research Council[70] (MRC) is the biggest. It is important that you read the scope of any funding body carefully and target your research accordingly.

Another option for smaller research projects is to include them as part of a fellowship application, for example, for a PhD. There are several NIHR fellowship schemes available, as well as MRC and Wellcome Trust fellowships, depending on your background. These fellowships require a clear plan for the academic training of the main investigator and also a consideration of the suitability of the institutional

[69] E.g. See www.amrc.org.uk
[70] www.mrc.ac.uk

expertise and context in relation to the professional development needs of the applicant.

National Institute for Health Research Funding Streams

NIHR commission and fund NHS and social care research that is essential for delivering their responsibilities in health and personal social services. The NIHR's role is to develop the research evidence to support decision making by professionals, policy makers and patients. A key objective of the NIHR is to improve the quality, relevance, and focus of research in the NHS and social care by distributing funds in a transparent way after open competition and peer review.

The NIHR funds a number of research programmes addressing a broad range of health priorities. Funding is channelled through the following streams which have various research emphases:

- Invention for Innovation (I4i)
- Efficacy and Mechanism Evaluation (EME)
- Programme Grants for Applied Research (PGfAR)
- Health Technology Assessment (HTA)
- Public Health Research (PHR)
- Health Services & Delivery Research (HS&DR)
- Research for Patient Benefit (RfPB)

- Information on NIHR fellowship schemes and clinical lectureships (which also include research) can be found at: www.nihrtcc.nhs.uk/nihrfellow; the academic pathway for nurses, midwives and allied health professionals can be found at www.nihrtcc.nhs.uk/cat/.

Whilst the NIHR fund research, they **do not** fund independent implementation of research or service development.

NIHR are expanding existing research programmes and new funding streams are being introduced. Systems for processing research funding applications and the commissioning of research are currently being standardised. NIHR programmes are co-ordinated and managed by the NIHR Central Commissioning Facility (CCF) and the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). For brief details of NIHR funding schemes, see:

http://www.nihr.ac.uk/research/Pages/programmes_research_programmes.aspx

TIPS

- Target project to the most suitable stream
- Meet the scope and objectives of stream
- Get the timing right – different streams have different deadlines
- And different guidance.....
- Each scheme has a telephone helpline – make use of them!

A Word about Peer Review

Every proposal for health and social care research must be subjected to independent peer review by experts in the relevant fields and others who are able to offer advice on its quality and suitability. Projects that are externally funded will usually undergo peer review as part of the funding process. Where this is not the case, other arrangements have to be made (your R&D Office should be able to advise you on these). For student research projects the university supervisor will normally provide an adequate level of review. Many organisations allow established research teams to determine details of the elements of an overall programme of research, which has been reviewed externally. Arrangements for peer review must be commensurate with the scale of the research.

The following websites provide information on peer review:

Websites providing guidance on peer review:

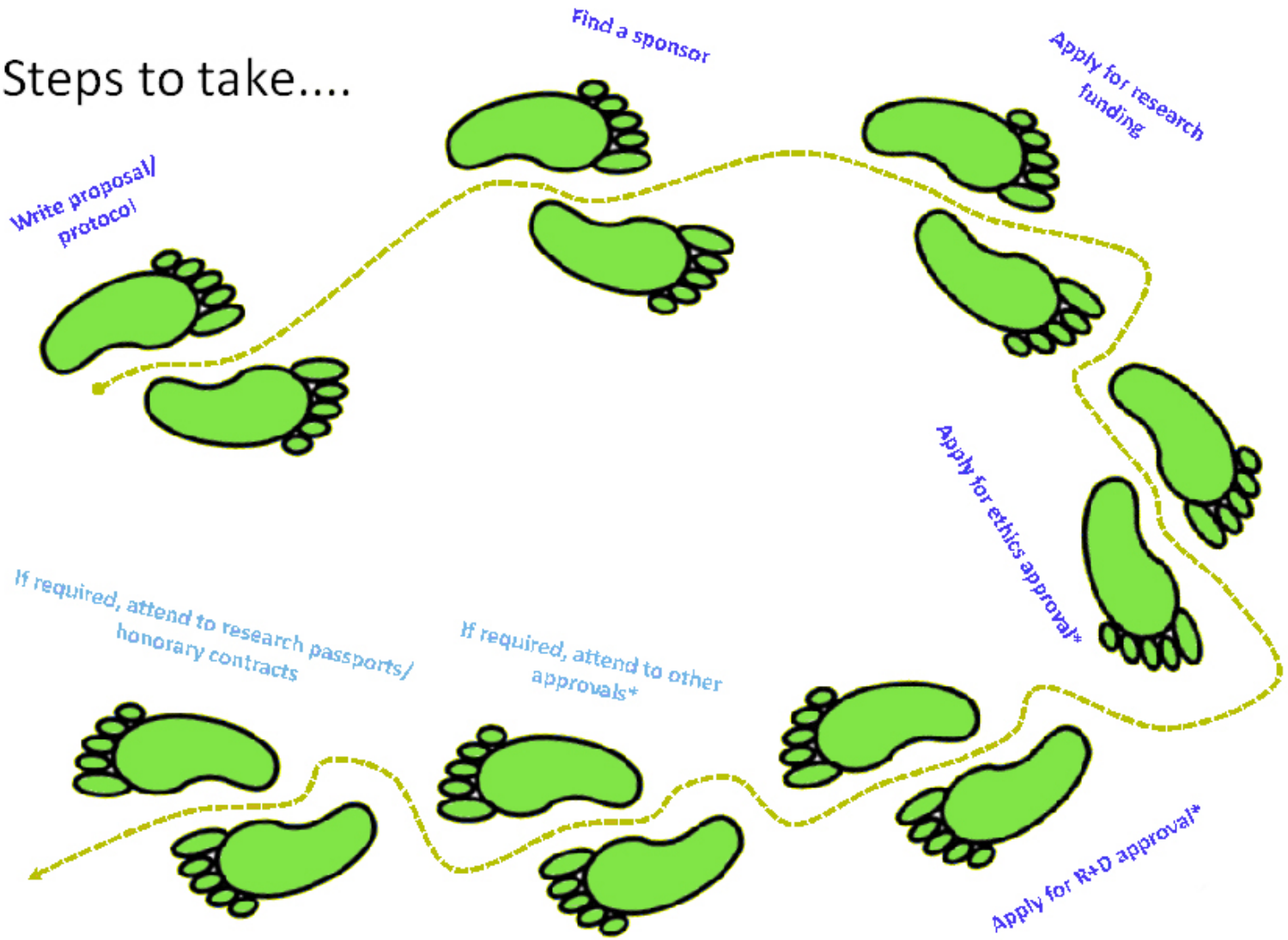
- MRC Reviewer's Handbook www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003184
- AMRC section on peer review has a number of documents to download such as 'Principles of Peer Review' and 'Guidelines on the Implementation of Peer Review' www.amrc.org.uk/HOMEPAGE
- EPSRC: Reviewing proposals: http://www.epsrc.ac.uk/funding/peerrev/review/Pages/proposals.aspx
- Responding to reviewers' comments: http://www.epsrc.ac.uk/funding/peerrev/Pages/responding.aspx
- Parliamentary Office of Science and Technology report on Peer Review : http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/peer-review/

VI. Relevant approvals are sought

There are a number of ethics, governance and sometimes other approvals that have to be sought when you are developing your research and applying for funding. It is a common misconception that only approval from the Research Ethics Committee needs to be obtained. An overview of these approvals is presented here.

The next page shows the various steps you have to take during the development of your research. They are not necessarily done in a particular order although the order presented overleaf makes some sense. Often approvals will be sought simultaneously.

Steps to take....



Finding a sponsor for your research

The Research Governance Framework for Health and Social Care for the NHS[71] makes it clear that no research with human participants, their organs, tissue or data, may begin or continue in the NHS until a sponsor accepts responsibility. A sponsor is the organisation which is ultimately accountable for your research. A sponsor must:

- Accept responsibility for the initiation and overall management of the research, including quality assurance (research protocol, team, and research environment)
- Accept responsibility for the finances associated with the study
- Ensure all approvals are obtained, e.g. ethics, clinical trial authorisation, NHS permission.
- Make arrangements for the handling of any Investigational Medicinal Products (IMPs)
- Ensure that Good Clinical Practice (GCP), monitoring and reporting (including safety reporting) occurs as it should

Sponsors are usually:

- The Chief Investigator's employing institution, e.g. a university or NHS trust
- A funding organisation
- Where research is for training purposes, the research supervisor (on behalf of their employer)
- Private sector e.g. pharmaceutical industry

Ethics Approval: National Research Ethics Service

The National Research Ethics Service (NRES)[72] has a dual mission: to protect the rights, safety, dignity and well-being of research participants; and to facilitate and promote ethical research that is of potential benefit to participants, science and society. You apply online for NHS research ethics approval (which includes the R&D and Site Specific Information forms) via the Integrated Research Application System (IRAS).[73] IRAS also captures the information required for various other permissions, namely:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Justice (National Offender Management Service)
- Health and Social Care Research Offices and Ethics Committees
- National Information Governance Board for Health and Social Care (NIGB).
- Social Care Research Ethics Committee

[71] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962
[72] http://www.nres.nhs.uk/
[73] www.myresearchproject.org.uk/

Local Research & Development Approval

Whilst the sponsor is the main organization that takes responsibility for the research and is often a health trust, many other organizations may be involved with the research, for example, as collaborating sites, or sites for the collection of data. In most cases local R&D Approval is required. The role of the local R&D office is to give permission for the research to take place and, if the trust is hosting research (i.e. not the sponsor), to undertake an audit of a proportion of studies, and to ensure that all research related contracts are in place.

Some R&D offices offer advice and support, but this will depend on the training and availability of staff. Some will offer help with ethics applications, the financial aspects of the study from the trust perspective, and more general research advice. It is best to inform them of your plans at an early stage. They will certainly want to see you as soon as you have a protocol, especially if you are undertaking high risk/ drug related/ device related studies. Some offices may be interested in these and other studies at the development stage.

You apply for ethics and local R&D permission as follows: (1) For research qualifying for the NIHR Clinical Research Network Portfolio,[74] via IRAS Coordinated System for gaining NHS Permission (CSP)[75]; (2) For all non portfolio research, also via IRAS, but not through CSP (you have to copy the forms and send them to R&D and Ethics separately, in the format they request – hard copy or electronically).

Research Passports and Honorary Contracts

- **A research passport is a** set of signatures and checks from **your employing organisation** required *prior* to issuing an honorary contract or letter of access. It consists of a single standard form for each researcher, which provides evidence of one set of checks on a researcher conducting research in the NHS.
- **An honorary research contract** is a contract with an NHS trust for a researcher whose employer is not that NHS trust. An honorary contract is required when (a) the research is hosted in the NHS **and** (b) the researcher has no contract with the NHS **and** (c) the researcher's activities in the NHS site will involve interacting with individual patients in a way that has a *direct bearing* on the quality of their care. You usually apply for an honorary contract via the Human Resources Department/ R&D Department of the NHS Trust where you wish to do the work.
- **A letter of access is a** letter permitting a researcher whose employer is not that NHS trust into the trust. Letters of access are required when (a) and (b) above are present, but not (c).

[74] www.ukcrn.org.uk/index/clinical/portfolio_new/P_eligibility.html.
[75] www.crncc.nihr.ac.uk/about_us/processes/csp

You should **always** check with trusts what level of access **they** consider you need, and to find out the procedures you need to follow locally.

5. Public and Patient Involvement

Patient and Public Involvement (PPI) is an increasingly important component of research grant applications with some funding organizations, such as the NIHR, placing a great deal of weight on the presence of consumer input. It is fair to say that unless there are very good reasons, an absence of PPI in an NIHR application would count against it.

Who are the 'PP' in PPI exactly?

'Patients' and the 'Public' include users of health and social care services, informal (unpaid) carers, parents/ guardians of health service users, organisations representing consumers' interests, the general public, as potential recipients of health promotion, and groups asking for research relating to specific exposures.

What is PPI?

PPI is when patients and the public become active partners in the research process rather than simply 'subjects' of research. Patients might come up with research ideas, sit on steering committees, even collect data.

Why have PPI?

PPI can enhance research in many ways, from conception to dissemination. The patient's view on what constitutes an 'important research question' may differ from, but be just as valid as, the view of the professional – in some cases – more valid. Patients can therefore be invaluable sources of research ideas and useful when trying to prioritise what really matters. The type of health outcomes considered important in assessing the success or otherwise of an intervention may vary between clinician, patient and carer. In some circumstances it may be helpful for patients to actually assist in recruitment and it is always important to disseminate results to relevant patient groups.

How to do PPI

The RDS has a dedicated PPI Officer to advise on all aspects of involving service users or their representatives in research. Advice given may include how to find the most appropriate PPI representatives, how to support those people already identified by researchers or how PPI might be sourced via adverts, word of mouth etc.

PPI works on three levels: *consultation*, where the views of service users are sought and used to inform decision-making; *collaboration*, where there is a more active, on-going partnership with members of the public in the research process; and *user controlled* research where the locus of power, initiative and decision-making lies with service users rather than professional researchers. When and where these different

levels are appropriate will obviously depend on the context (researcher, topic, method, funder) of the research being undertaken. Whatever the level, input would be required from both professional researchers and patients/ the public.

- INVOLVE (2004) *Involving the public in NHS, public health, and social care research: Briefing notes for researchers.*
- Consumers in NHS Research Support Unit (2001) *Getting involved in research: A Guide for Consumers.*
- www.involve.org.uk

6. Involving Other Organisations

Research Networks

There are three types of research network:

- Topic specific
- Primary care
- Comprehensive

How can they help?

Basically the funding which used to go to NHS trusts to fund local research (former 'Culyer' funding) has now been channelled to the networks, which will only assist projects of a certain standard, and prescribed area of care, that is, falling within the remit of the **Clinical Research Network (CRN) Portfolio**[76]. In England, the Department of Health has determined that studies (clinical trials and other well designed studies which involve the NHS) that are funded by NIHR, other areas of Government, and NIHR non-commercial partners are automatically eligible to be included in the CRN Portfolio. NIHR Partners are those organisations that:

- award research funds as a result of open competition across England with high quality peer review
- fund research that is of clear value to the NHS
- take account of DH and NHS priorities and needs in their research funding strategies.

Full details are included in:
www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/

If you are eligible for the CRN Portfolio and your project is 'adopted' by one of the networks (something for which you apply), they may be able to assist with a variety of things:

- Funding the NHS Support Costs (see earlier for definitions) of research studies. This is a tremendously important role. If your study is not considered within the CRN Portfolio, your NHS support costs will not be covered by the Comprehensive Local Research Network, and you will need to find funding for these costs from an alternative source.
- Facilitating the necessary permissions for your work;
- Recruitment of clinical personnel, patients and other participants;

[76] www.crncc.nihr.ac.uk/about_us/processes/portfolio/portfolio

- Helping with data collection. Whilst you should apply for funding to cover all your research salary requirements, studies on the CRN portfolio (see footnote, previous page) will be eligible for CLRNs to provide research nurses who will be able to assist you with recruitment, and this will be counted as an NHS Service Support Cost.[77] Most application forms ask for these costs to be separated from the research costs. Nurse time for the remaining elements of the study (e.g. follow-up visits) will need to be covered by the research grant. If the study is not on the CRN portfolio, this nurse capacity needs to be 100% funded from the study budget.
- General advice on the research process in their area of expertise.

If you have a project which the CRN may be able to adopt, contact the relevant network, at the development stage of your study, to find out what may be available to you. For more information, see: http://www.crncc.nihr.ac.uk/about_us.

Clinical Trials Units

It is important to note that some grant awarding schemes (e.g. the NIHR Health Technology Assessment scheme) expect that a CTU would be formally involved with projects, and generally speaking, for quantitative studies, the involvement of a CTU is likely to enhance your application, and therefore increase your chances of success in funding.

CTUs are being set up regularly. For the latest information on regional and national CTUs, and what they offer, please see: http://www.ukcrc-ctu.org.uk/

[77] See the ACoRD document www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133882) for more detail on how to allocated these costs.

7. Overall Tips for Grant Applications

Make sure:

- You submit your proposal on time
- It is complete!
- It is a ‘well-crafted’ proposal – in terms of argument and presentation
- Your proposal is understandable to a diverse audience
- You have shown the relevance of the study to the NHS
- You have had adequate lay involvement
- You have the right skill mix
- You have made the necessary research partnerships
- You have demonstrated a need for the study, and your knowledge of the area
- Any necessary pilot work is undertaken or planned appropriately
- Interventions (e.g. for RCTs) are clearly described. This includes good descriptions of ‘control’ or ‘usual care’ groups.
- You have an appropriate study design
- Other aspects of the methods and procedures are clear
- You have consulted appropriate experts and incorporated their suggestions
- You have given yourself a realistic timetable
- Your study is sensibly funded
- You are not being over-ambitious!