

Making Your Research Project Happen – Challenges, Facilitators and Tips for Planning

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ABSTRACT

This article describes some of the important processes to consider when planning the implementation of a research project. Key organizations and external links are identified, including the roles of ethics committees and regulatory organizations. In addition, organizational elements which need to be given careful thought in the planning stages are discussed. Finally, steps to successful dissemination are outlined. (J Clin Prev Cardiol. 2013;2(3):162-7)

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Introduction

So you want to do research? You have selected a topic for your research and developed your ideas into focused research question(s) with clear objectives. You know which data you will collect and how you will collect it. It is tempting to rush out and start collecting data. **WARNING:** research is a slow process, patience is crucial, and careful planning is the key to success.

It is easy to be wise after the event! At the end of your research study you will know how much time and effort it took. Hopefully, you will not be disappointed with the final results. Sadly, many researchers are finding it difficult to understand why the findings are not what they had hoped for, often as they had not achieved the quality project they initially had in mind. Achieving excellence in research involves patience; a good beginning to implementing the project requires a careful, considered process - if activities are rushed and uncoordinated,

shortfalls will occur. Is your research feasible given the time and resources you have available? It is important to identify risks in implementation and when these might occur, and put into place contingency plans. Be clear from the beginning about the legal and ethical responsibilities and accountability of the research team. Who are the important people to involve from the outset? Do you or your team have training needs? How will you fund training, buy equipment and the resources required? Asking and seeking answers to these questions now may seem unnecessary, time-consuming bureaucratic steps, but early planning can save time and resources in the long run, and lead to a better quality project.

In this article, we have set out to provide a comprehensive, although not exhaustive, discussion of research project planning in order to illustrate the bigger picture of what you need to consider ensuring the successful completion of your research study.

Feasibility of Delivery

It is important to consider how feasible a proposed research project is at the outset. Being focused, realistic and aiming to achieve what can reasonably be done within the time, expertise and resource constraints under which you are working are all important factors to consider. It is easy to overestimate how much can be accomplished and it is crucial to ensure the research plan is actually achievable. Considering some of the points

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below should help with this:

- Can the project be completed within the time available? You will need to take account of time for all aspects of setting up (including gaining permissions), piloting, data collection and coding, analysis, writing up and dissemination. Allowing leeway for unforeseen circumstances is advisable.
- Is the study too complex and over ambitious given the resources available? It is easy to get overenthusiastic and be under the impression that your study will answer many more questions than it realistically can.
- Are the required resources available? Most projects require a range of resources, some more obvious than others. These will vary enormously depending on the nature of the research but may include access to literature, equipment, participants, data, expertise, funding and so on. You need to bear in mind the availability and accessibility of the resources for any given project.
- What skills are needed by staff working on the project and are there training needs associated with these? You need to identify these as early as possible and make an informed judgment about whether the necessary training can be provided within the available time and funding.
- Are the recruitment procedures going to work? Most research involves inviting participants, either patients, carers, or healthcare professionals, to consent to undergo research-related procedures, for example questionnaires or interventions. However, the rate of recruitment is often over-estimated, leading to a lengthened period required to complete the study, or the study having to finish data collection before the desired sample size is reached. This is often referred to as Lasagna's Law (Day, 2007). Disappointment on this account can be avoided by careful attention to study design and early discussion with stakeholders regarding the recruitment process.

Patient and Public Involvement

It is now widely acknowledged that patient and public involvement (PPI) in research is important to ensure the relevance, applicability, and appropriateness of research activities (Brett *et al.*, 2012). Many funding bodies now include an assessment of how well you are

incorporating PPI into your research when they decide if your study is worth funding. PPI should be a meaningful activity, incorporating the knowledge and experience of those with interest in your research. PPI can take many forms, and the level of engagement varies from involving people in an advisory capacity, to more active 'co-production' of the research. PPI should take place from the very beginnings of your research when you are shaping the research question, deciding on the important outcomes, and explaining the research plan in ways that are clear, non-patronizing, and free of medical jargon. At a later stage, PPI actions can include having members of the public sitting on steering committees and informing decisions, helping with the recruitment strategy (for example by designing the information sheets and letters of invitation), co-producing the research with you (for example through peer-to-peer interviews), right through to facilitating with the dissemination activities. In the UK, the advisory group 'Involve' offer many guidelines and resources for involving members of the public, and these contain useful messages applicable to other settings as well (www.invo.org.uk/). One example of a project involving members of the public is an interview study carried out in Manchester, UK, exploring the factors influencing how people undertaking caring activities for someone with vascular disease come to be defined as a carer (<http://www.invo.org.uk/resource-centre/research-project-database/research-project/?id=743>). In this project members of the public were involved in finding and designing appropriate ways of approaching participants, prioritizing topic areas, planning the research, managing the research, analyzing the research, and applying for funding.

Building an Experienced and Qualified Team, and Nurturing Juniors

When carrying out research, it is important to have a good team around you with the necessary skill mix, expertise, and capacity to contribute to the research design chosen to address your question. Consider complementary skill sets when formulating your team, for example, you may need to bring together varied skills such as clinical leads, methodology experts, statistician, laboratory scientists, patient public involvement member, project manager and ethics and governance expert. Some team members may have expertise across these domains, and others may require training, for example in 'Good Clinical Practice'. The 'International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use' (ICH) developed the E6 Guideline for Good Clinical Practice

(1996), known as ICH GCP. This is an “international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3/>), and that the clinical trial data are credible.” (ICH Guideline For Good Clinical Practice E6(R1), 1996). Having a mix of junior and senior researchers facilitates learning and capacity building. Additionally, identifying areas of the research project that could be carried out by juniors and written-up as part of an educational qualification is a worthwhile investment for the institution.

Budgeting a Study

Every research project has associated costs. If you are applying for a grant to cover the study, or requesting the resources from your institution, it is important to have a well-planned budget (Hulley *et al.*, 2006). Costs fall into six main areas: staff, equipment, consumables, costs for participants, administrative and dissemination costs. Your institution may also apply ‘overhead’ costs (i.e. to cover the office/laboratory space, energy usage, etc.), so it is important to work with the professional services within your institution in order to gain approvals for your proposed work and budget plan.

Staff costs are often the largest expense for any research project. Most projects require a multidisciplinary team and may need small amounts of time to be contributed from a large range of people – for example qualitative researchers, statisticians, health economists – who will need to plan how much time their individual contribution will require, and assign a cost to it. There will also be staff, who need to be recruited and paid full-time for the study duration, for example research assistants, data entry clerks and laboratory technicians. PPI members also need their costs considered – for example their time, travel expenses, reimbursement for child/spouse whilst they attend activities. Members of any groups, who are supporting the study, for example the Data Monitoring Committee or the steering group, will also require reimbursement for time and travel.

Equipment costs will depend on what is already available and what you need to purchase for the study – ensure that if equipment is currently in use for clinical activities and is also intended to be used in the research project

that the workload and planning for the equipment and the operator is feasible availability of equipment does not necessary mean that it will be free for use for the research project. If you are collecting and analyzing large data sets, you may need to consider access to networked computer systems to share data. It might be necessary to buy a new computer with sufficient memory or purchasing additional high volume storage devices. The purchase of a laptop for collecting data in the field might be useful. Some further considerations, related to the data type:

Quantitative Data:

- If you do not currently have the support of a statistical advisor, will you need to pay for statistical advice, for example a consultant?
- Do you require specialized computer software (such as SPSS) for analyzing your quantitative data and will you require training to use it?

Qualitative Data:

- Do you need to purchase video or audio equipment to record observational or interview data?
- Lengthy audio recorded interviews will require transcribing; do you have the time to type up the interviews or will it be possible to pay somebody else to do this for you?
- For qualitative data storage and analysis you might benefit from using qualitative computer software (such as NVivo (<http://www.qsrinternational.com/>), or MAXQDA - <http://www.maxqda.com/>) for which you will need to purchase personal or multiple users license and relevant training. Such training may be costly and will require appropriate funding.

Consumables need to be estimated based on the number of participants you require for the study, and the number and type of tests or procedures they will undergo. Any additional consumables for the research project over and above those used for routine clinical care need to be costed. It is common for participants to be reimbursed for their travel expenses, and sometimes for their time, or provided with a token of thanks for their participation, such as a small gift.

All research generates a considerable amount of paperwork and communications – costs for an administrative assistant and all necessary office supplies are therefore vital to provide an administrative hub for

the study. Disseminating the results of the study is also an important activity – funds for printing posters, travel expenses and subsistence for conferences, publication fees and organizing dissemination workshops need to be included in the budget. Other miscellaneous costs may include fees for approvals from regulatory bodies, fee to register clinical trials, purchasing of clinical datasets, and advertisements and website information about the study.

Funding

Given the numerous costs of a study, funding is crucial - without it, research cannot take place. The cost of carrying out a study will vary according to its size, nature and length of time. During the planning stage of a potential study, it will be necessary to forecast its potential cost and for many studies, this will be greatly supported by advice from a finance officer who is aware of local costs and formulae for calculating them. Fortunately, there are numerous funding options available to researchers. These include local, national and international bodies who seek to support the generation of new knowledge about healthcare, such as government agencies, charities and Universities. Typically, these different providers of funding will have an area of clinical or social interest they wish to support and it is important when considering who to apply to for funding whether a proposed study falls within one of the funder's areas of interest. This is because, unfortunately, there is not a limitless supply of research funding and therefore funding committees make judgments about a potential study's overall likely benefit and value for money.

There is usually an application process to a funding body, which is likely to include a requirement for information about the justification for a proposed study, how the study will be conducted and managed, and how much it will cost – i.e. what they are being asked to fund. This is a competitive process that requires time and expertise in both the clinical field of study and the research itself; for these reasons successful applications are often made by teams of individuals with a range of knowledge and experience. Funding applications need to contain a rigorous discussion of the current literature regarding the area of interest and show where the proposed study fits within this. It also requires significant amounts of technical information regarding the research methods proposed, such as sampling, data collection and analysis and how the findings of a study may influence future clinical practice. This level of knowledge and detail indicates why it is useful to assemble a team of colleagues to prepare and conduct a study, and also justifies seeking

the advice of specialists such as statisticians, economists and research methodologists.

Ethics and Governance

An important principle and process of the research journey are ethical considerations and opinions. All research, and particularly that including human participants, should be underpinned by accepted ethical principles. Research ethics are universally accepted ideas and approaches to the justification and conduct of a study and are principally concerned with the interests of society and human participants within any research study. Ethically, research is expected to have a potential benefit to a society and should aim not to harm any participants within it. Although the moral values guiding ethical opinion are relative, an excellent source of guidance for cardiologists are the World Medical Association's principles enshrined in the Declaration of Helsinki (2008). In addition to these international guidelines are a range of interpretations of research ethics found in professional guidance such as the General Medical Council in the UK and research funding and governance agencies such as the UK's Medical Research Council and the American Psychological Association.

All of these various guidelines resonate a fascinating history of medical and research ethics since the time of Hippocrates over two thousand years ago. However, it is interesting that the core ideals have remained largely unchanged over this period of time and focus on minimizing any harm experienced by research participants. Research ethics therefore seeks to protect the individual and society and defines harm broadly. For example, harm can include physical pain, psychological distress and or a lack of respect for a participant's dignity. Fortunately, there are numerous practices that help researchers reduce potential harm. In terms of distress and physical pain, it is useful to consider what is known as the *risk benefit ratio*. This test considers that research with an elevated risk of causing harm should be balanced by a higher likelihood of leading to benefit for research participants. Conversely, studies with minimal or even potentially no benefit are justifiable on the grounds that they also are unlikely to lead to any harm. The idea of harm also includes an individual's *dignity and respect*. Here researchers can firstly consider whether the participants they seek to include are in any way *vulnerable*, for example in the case of children and mentally incapacitated adults. Vulnerable members of society should not be excluded from research, indeed

it would be unethical to do so, however, their inclusion should be well justified and their involvement supported accordingly.

This latter point leads to a central principle of reducing the risk of harm to a person's dignity and respect, which is that of *informed consent*. Informed consent to participate in a research study is a universal ethical principle and in many countries can also be a legal requirement. It concerns the idea that human participants should, in some way, be aware that they are participating in research, that they have the right not to participate, or withdraw once they have started, and should be provided with sufficient information and time to consider it before independently deciding and agreeing to take part. Ultimately this means that individuals cannot be compelled to participate in research and should be provided with clear information about the study and what their participation will involve. In the case of vulnerable groups, this has to be considered carefully according to the reason for vulnerability and therefore the individual's ability to understand the implication of their inclusion and provide a truly informed, independent and reasoned opinion. Finally, research respects dignity when it protects information about participants and it is always important to maintain high levels of *confidentiality*, particularly with patient data that has been collated for reasons unrelated to any treatment they may be receiving.

Ethical principles, such as those illustrated above, should be considered during the planning stage of a study and certainly discussed in a research proposal. However, in the case of research, before a study may commence it will require a favorable opinion from an ethics committee. Research ethics committees should reflect the diversity of individual's within a society and take on the responsibility of providing an opinion about the ethics of a proposed study that would be reflected in the wider community. Researchers should identify the relevant committee (Hospital, University, Funder) that they should consult for an opinion and complete an application for an opinion. This usually involves detailing the justification for the proposed research and the nature of involvement of any human participants, in particular who will be approached to participate, how they will be approached and what they will be asked to do during their participation. Committees consider these points against accepted principles of research ethics and ultimately form an opinion of the risk benefit ratio. The committee will communicate their decision to the research team, who are hoping it will be favorable

and therefore allow them to pursue other areas of research governance. There are close links between the ethics committee and the 'sponsor' of the study – i.e. the organization who takes overall responsibility for conducting the study (e.g. a pharmaceutical company, a University or a healthcare delivery institution). Issues arising from the study delivery which may affect patients' rights and safety, for example serious adverse events, are reported regularly to the ethics committee by the sponsor, and the ethics committee is always available to provide advice on study conduct post-approval.

Regulatory Aspects

All research normally takes place within a national framework. For example, the UK government produced the Research Governance Framework for Health and Social Care which outlines the standards to which the research structure should operate, where responsibilities and accountabilities lie, what the systems are for research delivery, and monitoring and inspection processes to detect failures (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962). Bodies such as Ethics Committees, Research and Development departments within health delivery institutions and the Medicines and Healthcare Regulatory Agency work together to form a system of processes and approvals to ensure that research carried out is safe for patients, is appropriate to take place within the health structure and is properly resourced.

There are other international forms of guidance relating to health research and clinical trials in particular, notably the International Conference of Harmonisation (ICH) Good Clinical Practice (GCP) guidelines (<http://ichgcp.net/>). Although this document was developed to guide the requirements for pharmaceutical products for human use, it has been widely adopted as a standard for investigators for all types of research. It provides a structure for investigators to ensure that the rights and safety of trial participants are protected, and contains much detail relating to appropriate documentation for studies, so that an appropriate audit trail could check whether the data and reported results are credible and accurate. This guidance was adopted as a legal requirement for clinical trials of investigational medicinal products (CTIMPs) in Europe in 2005 (http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm). This means that the sponsors of the studies have to put in place monitoring procedures to ensure that these principles are being adhered to for the course of the study.

Dissemination

You should plan your dissemination strategy before you even begin your research. Consider where you will publish, agree who will be included as authors (or at least the principles that will govern this decision), and what will be the different modes of dissemination. When it comes to writing up your research, it is important to consider who you are writing it for. You will want your research to have an impact, to inform practice and further research in the field. You should be transparent about what you did and did not do, and remain true to your original research plan (i.e. do not switch your original primary outcome for one that shows a more favorable result!). It may be tempting to put a positive spin on results, which actually showed no significant difference; however this can result in bias, making it harder for people to determine what actually does not work (or is even harmful), and what may be worth disinvesting in. A well planned and conducted study will be informative regardless of the findings, and you have a duty to those who took part in and supported the research to get the results out in the public domain to help inform future decisions. There are reporting guidelines to help with writing up all manner of study design types; you should plan to utilize the relevant guide and ensure that you are collecting the appropriate information throughout the research to accomplish this. The EQUATOR network (Enhancing the QUALity and Transparency Of health Research) has compiled these guidelines in an online resource centre (<http://www.equator-network.org/resource-centre/library-of-health-research-reporting/>). Also consider the different routes to dissemination; as well as researchers, you will probably want to consider policy makers, practitioners, and members of the public. Different audiences may read different types of journals or magazines, or prefer different modes of delivery. Although the high impact factor journals will

most likely be a place you want to publish in order to progress your own career and reach your peers, you may also want to consider the use of newsletters/magazines, public seminars, and social media as additional methods of getting your message out to those whom the research can have most impact. Another important consideration is how accessible your chosen journal is; does it operate an 'open access' policy which will enable the end users to access the paper (either immediately on publication or after some delay), or will your research be hidden behind a pay-wall making it less accessible and less likely to reach your target audience. Some journals provide a payment option for making your research open access (indeed some funders now require you to publish in an open access resource); a well-planned study will have considered this, and incorporated the publishing costs into the funding plan.

In short, careful planning and consideration of all stages of the research journey, will help overcome potentially stressful situations, and provide you with the best opportunity for smooth transition through the research project. There will be the inevitable unexpected eventualities; however with a good team around you, and support systems in place, you may experience the rewards of undertaking research in a field that you feel passionate about.

References

1. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, Suleman R. Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expect.* 2012 Jul 19. doi: 10.1111/j.1369-7625.2012.00795.x.
2. Day, S. 2007 Dictionary for Clinical Trials, Second Edition. Wiley.
3. Gray, D. 2008 Doing Research in the real World. London, Sage.
4. Hulley S, Cummings SR, Browner WS, Grady D, Newman T. 2006. Designing Clinical Research, Third Edition. Lippincott, Williams & Wilkins.
5. ICH Topic E 6 (R1) Guideline for Good Clinical Practice Step 5.