



Human Subjects Research

Research Proposal/Research Protocol Guide

How to write a research proposal

The purpose of the proposal is to ensure that

- Principal Investigators have done sufficient preliminary reading/research in the area of their interest
- Principal Investigators have thought about the issues involved and are able to provide more than a broad description of the topic which they are planning to research.

The proposal is not a fixed blueprint. One cannot predict one's findings beforehand or mechanically stick to an argument since the research will inevitably alter or even unseat one's initial expectations. There is no fixed formula for writing a proposal.

However, your challenge is to convince members of the scientific community that you:

- have identified a scientific problem
- have a theoretical background and a methodical approach to solve the problem
- have a realistic time frame and at reasonable expenses.
- Have research that will add a new aspect to the scientific discourse.

Title Page:

Personal data (name, academic title, your position at your institution, date of birth, nationality, your contact information, institutional contact.

Title:

It should be concise and descriptive. For example, the phrase, "An investigation of . . ." could be omitted. Often titles are stated in terms of a functional relationship, because such titles clearly indicate the independent and dependent variables. However, if possible, think of an informative but catchy title. An effective title not only pricks the reader's interest, but also predisposes him/her favorably towards the proposal.

Abstract:

It is a brief summary of approximately 300 words. It should include the research question, the rationale for the study, the hypothesis (if any), the method and the main findings. Descriptions of the method may include the design, procedures, the sample and any instruments that will be used.

Introduction:

The main purpose of the introduction is to provide the necessary background or context for your research problem. How to frame the research problem is perhaps the biggest problem in proposal writing.

If the research problem is framed in the context of a general, rambling literature review, then the research question may appear trivial and uninteresting. However, if the same question is placed in the context of a very focused and current research area, its significance will become evident.

Unfortunately, there are no hard and fast rules on how to frame your research question just as there is no prescription on how to write an interesting and informative opening paragraph. A lot depends on your creativity, your ability to think clearly and the depth of your understanding of problem areas.

However, try to place your research question in the context of either a current "hot" area, or an older area that remains viable. Secondly, you need to provide a brief but appropriate historical backdrop. Thirdly, provide the contemporary context in which your proposed research question occupies the central stage. Finally, identify "key players" and refer to the most relevant and representative publications. In short, try to paint your research question in broad brushes and at the same time bring out its significance.

The introduction typically begins with a general statement of the problem area, with a focus on a specific research problem, to be followed by the rationale or justification for the proposed study. The introduction generally covers the following elements:

1. State the research problem, which is often referred to as the purpose of the study.
2. Provide the context and set the stage for your research question in such a way as to show its necessity and importance.
3. Present the rationale of your proposed study and clearly indicate why it is worth doing.
4. Briefly describe the major issues and sub-problems to be addressed by your research.
5. Identify the key independent and dependent variables of your experiment. Alternatively, specify the phenomenon you want to study.
6. State your hypothesis or theory, if any. For exploratory or phenomenological research, you may not have any hypotheses. (Please do not confuse the hypothesis with the statistical null hypothesis.)
7. Set the delimitation or boundaries of your proposed research in order to provide a clear focus.
8. Provide definitions of key concepts. (This is optional.)

Literature Review OR Background and Significance:

Sometimes the literature review is incorporated into the introduction section. However, most professors prefer a separate section, which allows a more thorough review of the literature.

The literature review serves several important functions:

1. Ensures that you are not "reinventing the wheel".
2. Gives credits to those who have laid the groundwork for your research.
3. Demonstrates your knowledge of the research problem.
4. Demonstrates your understanding of the theoretical and research issues related to your research question.
5. Shows your ability to critically evaluate relevant literature information.
6. Indicates your ability to integrate and synthesize the existing literature.
7. Provides new theoretical insights or develops a new model as the conceptual framework for your research.
8. Convinces your reader that your proposed research will make a significant and substantial contribution to the literature (i.e., resolving an important theoretical issue or filling a major gap in the literature).
9. Ensures that previous, similar research did not cause harm.

Most literature reviews suffer from the following problems:

- Lacking organization and structure
- Lacking focus, unity and coherence
- Being repetitive and verbose
- Failing to cite influential papers
- Failing to keep up with recent developments
- Failing to critically evaluate cited papers
- Citing irrelevant or trivial references
- Depending too much on secondary sources

Your scholarship and research competence will be questioned if any of the above applies to your proposal.

There are different ways to organize your literature review. Make use of subheadings to bring order and coherence to your review. For example, having established the importance of your research area and its current state of development, you may devote several subsections on related issues as: theoretical models, measuring instruments, cross-cultural and gender differences, etc.

It is also helpful to keep in mind that you are telling a story to an audience. Try to tell it in a stimulating and engaging manner. Do not bore them, because it may lead to rejection of your worthy proposal. (Remember: Professors and scientists are human beings too.)

Methods or Outline of the project- Methods would be used for a more research oriented project while an Outline would be used for a project that is more programmatic. Please read the description of the two to decide which best fits your project. If applying for a grant, funders often will tell you the specific sections they are requesting.

Methods:

The Method section is very important because it tells your Research Committee how you plan to tackle your research problem. It will provide your work plan and describe the activities necessary for the completion of your project.

The guiding principle for writing the Method section is that it should contain sufficient information for the reader to determine whether methodology is sound. Some even argue that a good proposal should contain sufficient details for another qualified researcher to implement the study.

You need to demonstrate your knowledge of alternative methods and make the case that your approach is the most appropriate and most valid way to address your research question.

Please note that your research question may be best answered by qualitative research. However, since most mainstream psychologists are still biased against qualitative research, especially the phenomenological variety, you may need to justify your qualitative method.

Furthermore, since there are no well-established and widely accepted canons in qualitative analysis, your method section needs to be more elaborate than what is required for traditional quantitative research. More importantly, the data collection process in qualitative research has a far greater impact on the results as compared to quantitative research. That is another reason for greater care in describing how you will collect and analyze your data. (How to write the Method section for qualitative research is a topic for another paper.)

For quantitative studies, the method section typically consists of the following sections:

1. Design -Is it a questionnaire study or a laboratory experiment? What kind of design do you choose?
2. Subjects or participants - Who will take part in your study? What kind of sampling procedure do you use?
3. Instruments - What kind of measuring instruments or questionnaires do you use? Why do you choose them? Are they valid and reliable?
4. Procedure - How do you plan to carry out your study? What activities are involved? How long does it take?

Outline the project:

This is the central part of your research outline.

- Detail your research procedure within the given time.
- List sources and quality of evidence you will consult, the analytical technique you will employ, and the timetable you will follow.

Depending on the topic, suitable research strategies should be defined to ensure that enough and adequate empirical data will be gathered for a successful research project.

- Describe the intended methods of data gathering, the controls you will introduce, the statistical methods to be used, the type of literature or documentary analysis to be followed, etc.

Consider your work to be a Work-in-Progress and allow yourself a flexible planning:

Stay ready to revise the proposal according to new insights and newly aroused questions and keep on modifying the working hypothesis according to new insights while formulating the proposal and the working hypothesis. Once you have a useful working hypothesis, concentrate on pursuing the project within the limits of the topic.

Timetable:

Develop a time table (if possible in table form), indicating the sequence of research phases and the time that you will probably need for each phase. Take into account that at this stage, it can only be estimated, but make clear that you have an idea about the time span that will be needed for each step.

Selective research bibliography OR References:

List academic works mentioned in your research outline as well as other important works to which you will refer during your research

Attachments:

List other documents attached to your proposal.

Principal Investigators or Collaborators

References, CV, etc.

Support for the project

Results:

In many cases you may have preliminary results that could be given in this section, if not, you need to have some idea about what kind of data you will be collecting, and what statistical procedures will be used in order to answer your research question or test your hypothesis.

Discussion:

It is important to convince your reader of the potential impact of your proposed research. You need to communicate a sense of enthusiasm and confidence without exaggerating the merits of your proposal. That is why you also need to mention the limitations and weaknesses of the proposed research, which may be justified by time and financial constraints as well as by the early developmental stage of your research area.

Common Mistakes in Proposal Writing

- Failure to provide the proper context to frame the research question.
- Failure to identify reasonable scope for your research.
- Failure to cite landmark studies.
- Failure to accurately present the theoretical and empirical contributions by other researchers.
- Failure to stay focused on the research question.
- Failure to develop a coherent and persuasive argument for the proposed research.
- Too much detail on minor issues, but not enough detail on major issues.
- Too much rambling -- going "all over the map" without a clear sense of direction. (The best proposals move forward with ease and grace like a seamless river.)
- Too many citation lapses and incorrect references.
- Too long or too short.
- Sloppy writing.

*Formatting- for Research/Compliance review by ACOM please format in APA. For submission of manuscript for publication, please see the appropriate journal guidelines

Additional Components for a Research Protocol

Study Population:

Describe the number of subjects to be included in the study, and describe the characteristics of the subject population, including the following:

1. Identify the criteria for inclusion or exclusion (especially women and/or minorities).
2. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, or others who are likely to be vulnerable, especially those whose ability to give voluntary informed consent may be questionable. If any inclusion/exclusion criteria are based on age, gender, racial/ethnic origin, pregnancy or childbearing potential, explain and justify.
3. If any specific classes of persons who might benefit from the research will be excluded from participation (e.g., pregnant women, particular gender, particular races, etc.), provide a scientific and ethical justification for the exclusion.
4. Detail the power analysis.
5. If non-veterans will be recruited, explain why you cannot accomplish your study aims with only veterans as research participants. REQUIRED
6. If this study focuses on a disease, disorder, or condition that disproportionately affects women and/or members of a minority group, describe the special efforts that will be made, as scientifically appropriate, to include women Veterans and/or Veterans who are members of minority groups affected by the disease, disorder or condition. Note that if there are insufficient Veterans to complete the study, every effort must be made to enter non-Veteran subjects who meet the demographic profile of the Veteran population. REQUIRED
7. If this study will recruit those who are non-English speakers, what accommodations will be made to assure that these subjects are fully informed during the course of the study.
8. Include the number of volunteers, age ranges, sex, ethnic background, and health status.
9. Explain how many subjects will be consented for this study (including screen failures). If this is a retrospective records review and/or specimen analysis only, indicate how many records and/or specimens will need to be reviewed/collected, including possible screen failures.

10. How many subjects will be enrolled (i.e. – information is used and/or procedures are performed beyond screening). If this is a retrospective records review and/or specimen analysis only, indicate how many records and/or specimens will be included in the study's data set,

Subject Identification/Recruitment:

Explain how potential subjects will be identified, and what recruitment strategies will be used in the study.

1. Will advertisements be used? If so, they should be referenced in the protocol and included with the submission to the IRB.
2. Explain how you will ensure that the recruitment and selection of subjects is just, fair and equitable (this applies to both prospective and retrospective studies, including studies that use clinical or administrative databases or bio-specimens). REQUIRED
3. Describe any other recruitment materials or methods that will be used, such as brochures, posting to craigslist, etc.
4. Describe or explain how eligibility will be determined. Include eligibility checklists or other tools in the appendices.

Risks and Side Effects:

1. Describe any potential risks to subjects or others --physical, psychological, social, legal, or other - and assess their likelihood and seriousness. Describe the alternative treatments and procedures that might be advantageous to the subjects. REQUIRED
2. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Describe the provisions for monitoring the data to ensure the safety of subjects. REQUIRED
3. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. REQUIRED
4. List all risks that are more than minimal (no greater probability or magnitude than those ordinarily encountered in daily life or during routine medical tests). Include physical, psychological, social, economic, legal or other risks, where present.

5. Describe the severity and probability of all material risks, and the implications, in understandable terms. Use a table for Common (21-100/100), Occasional (5-20/100) and Rare (<5/100) risks sorted by Immediate (1-2 days of treatment), Prompt (within 2-3 weeks before next course), Delayed (any later time during treatment) and Late (after completion of treatment) onset wherever possible.

Participant Safeguards:

Describe the safeguards that will be put in place for participants. Consider addressing the following:

1. If the study includes vulnerable populations, what additional safeguards are included to protect their rights and welfare? If no additional safeguards are included, explain why not.
2. If the study population includes those with impaired decision making, describe the process to determine how decision-making capacity will be determined. Will this be done once for the population/group as a whole, or for potential participants individually? What process or tool will be used to determine decision-making capacity? (Remember that a note must be placed in the medical record for each subject indicating their lack of decision-making capacity).

Suicidality:

If the population for this study includes those who are potentially suicidal, become familiar with the method of conducting a “warm transfer” when a suicidal participant is on the phone. Include language in your protocol regarding when a “warm transfer” will be conducted. Also include language in the risks sections of the informed consent form to inform potential participants that, if they indicate during a phone call that they are suicidal, then a “warm transfer” will take place.

Benefits:

1. The risks must be reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge reasonably expected to result.
2. The use of modest compensation for the burdens imposed by the research may be permitted, especially if benefits are minimal, but should be incremental and not conditioned on completion of the entire study. (See “Subject Compensation” section below.)
3. Explain the expected benefits, if any, and their likelihood. If none, say so.
4. You may mention general benefits for science, or for other persons, if any.

Protected Health Information:

Explain which HIPAA identifiers will be utilized (in any way) in this study and be sure to be consistent with the HIPAA authorization, if applicable. Explain here why the identifiers and health information you will collect (i.e., the PHI that will be utilized for this study) are the minimum necessary needed to conduct the research and can't be further reduced.

Multi-Site Study Concerns:

If the research will be conducted at multiple sites state explicitly what will be conducted at each institution. Identify what components of the study will be conducted at VAPORHCS and what components will be conducted elsewhere. If it is, indeed, a multi-site study, it is REQUIRED that the protocol/addendum list the other sites and their contact information, which can be accomplished in this section.

Resources Available:

Describe the resources available to conduct the research, including clinic space, office space, PI time, and study coordinator time (if applicable). If the PI or coordinator are working on multiple studies, address why there are enough resources to add this study.

Costs to Subjects:

The Research Plan and the consent documents must describe the compensation plans in detail, including the provision of free care or medicines related to the study. See the informed consent form template for specific language, as appropriate.

Subject Compensation:

If subjects will receive compensation for participating, the Research Plan must describe such compensation plans in detail, including the provision of free care or medicines related to the study. If compensation will be provided, it is REQUIRED that the following are addressed:

1. Substantiation that proposed payments are reasonable and commensurate with the expected contributions of the subject.
2. The amount of payment and terms of the payment.
3. Why the payments are fair and appropriate and do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for or continue participation in the study.

Privacy and Confidentiality:

Include appropriate provisions to protect the privacy of subjects and maintain the confidentiality of information and safeguards to protect the rights and welfare of vulnerable subjects or those who may be susceptible to coercion or undue influence.

Certificate of Confidentiality:

If this project will collect sensitive information from research subjects (such as information about sexual attitudes, use of drugs or addictive products, or information about illegal conduct), which could reasonably lead to social stigmatization, discrimination, or legal proceedings and which would need to be protected against subpoena or forced disclosure in order to protect the participants, consider obtaining a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) or other Human Health Services (HHS) agencies to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. A Certificate of Confidentiality is not required solely by virtue of collecting sensitive information from research subjects. Further information can be found about NIH Certificates of Confidentiality at: <http://www.grants.nih.gov/grants/policy/coc/>. If applicable, the protocol should address the need for a Certificate of Confidentiality and how and when it will be obtained.

Information and/or Specimen Management:

Explain how the information and/or specimens will be managed. Indicate their level of identifiability throughout the study. Include statements on where electronic and hard copy information will be stored (be as specific as possible). Identify the building and room number in which hard copy information and/or specimens will be stored, and what measures will be used to secure the information/specimens (e.g., locked office, locked filing cabinet, etc.). If study information will be maintained outside the VAPORHCS, address which institution will maintain information, specifically how the information will get there, whether or not such transfer is addressed in the informed consent form and, if applicable, the HIPAA authorization, for what purpose it will go to the other institution, and who will view the information at the other institution. If the information and/or specimens are to be kept for future uses, specify the repository to which they are to be contributed.

Transfer of Data Ownership:

If applicable, include this section if ownership of the information will be transferred away from the VA Portland Health Care System. The protocol, informed consent, and HIPAA authorization must be consistent with regard to how and to whom ownership will be transferred.

Even if data ownership is transferred, please note that the protocol must indicate one of the following options:

- A copy of any electronic data, and originals of paper records will be maintained concurrently at _____ over the course of the study,
Or
- if the option above is not done, the electronic copies and originals of paper records must be returned to _____ at the time of study closure.

Data and Safety Monitoring Plan:

REQUIRED: Describe the data and safety monitoring plan.

For interventional studies, include, at a minimum, the following REQUIRED items:

1. What safety information will be collected including serious adverse events and unanticipated problems involving risk.
2. How the safety information WILL be collected, e.g., case report forms, at study visits, by telephone, etc.
3. The frequency of data collection including when safety data collection starts.
4. The frequency or periodicity of review of cumulative safety data.
5. If there will not be a data monitoring committee, and if applicable, what statistical tests will be used to analyze safety data and determine if harm is occurring?
6. Who will oversee safety data?
7. Which conditions would trigger an immediate suspension of the research, if applicable.

For retrospective studies, including studies involving pre-existing data and biological specimens, include a discussion of potential study outcomes that may have an effect on the subject's health or well-being and a procedure to determine when and how to notify individual subjects or their health care providers of findings that may affect the subjects' health.

Follow-Up:

The research protocol must give a clear indication of what follow up will be provided to the research participants and for how long. This may include a follow up, especially for adverse events, even after data collection for the research study is completed.

Data Management and Statistical Analysis:

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analyzed.

Quality Assurance:

The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.

Expected Outcomes of the Study:

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

Dissemination of Results and Publication Policy:

The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where

relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

Duration of the Project:

The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

Problems Anticipated:

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

Project Management:

This section should describe the role and responsibility of each member of the team

Ethics:

The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).

Informed Consent Forms (PLEASE SEE OUR CONSENT FORM TEMPLATE):

The approved version of the protocol must have copies of informed consent forms (ICF), both in English and the local language in which they are going to be administered. However translations may be carried out after the English language ICF(s) have been approved by the ERC. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form. For guidance on how to write an informed consent form