Qualitative Methods In Health Research

Opportunities and Considerations In Application and Review

Office of Behavioral and Social Sciences Research
National Institutes of Health

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Background and Introduction

The Office of Behavioral and Social Sciences Research sponsored a workshop on September 30 and October 1, 1999, entitled *Qualitative Methods in Health Research: Opportunities and Considerations in Application and Review*. The workshop was organized by the National Institutes of Health's (NIH) Culture and Qualitative Research Interest Group[1] and was supported by the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism.

The workshop brought together 12 researchers who served on NIH review committees or had been successful in obtaining funding from NIH. This document, a product of the NIH Culture and Qualitative Research Interest Group, is based on discussions and written comments from the expert working group. The purpose of this document is to assist investigators using qualitative methods in submitting competitive applications for support from NIH. The document is not intended to be comprehensive, but rather, to assist applicants in thinking about qualitative research issues to be addressed when applying for NIH funding. While the perspective is on qualitative research, many of the general issues discussed apply to both qualitative and quantitative methodologies.

The organization of this document follows the structure for the **Research Plan** that is described in the instructions for the Public Health Service Grant Application (PHS 398)[2]. Each section begins with the format and number of pages recommended in the PHS 398, and follows with a discussion of the issues to be considered and addressed. Information on the Human Subjects and Budget sections of an application follows the sections of the Research Plan. The final section of this document provides an overview of the NIH grant review process. A caveat to readers is to always consider the information and instructions given by NIH on its websites and official documents such as the PHS 398 as taking precedence over the present document in case of any unanticipated conflict. NIH grant application instructions must be followed carefully.

The Research Plan

The Research Plan, which is the main body of the PHS 398 application, includes four items: (a) Specific Aims; (b) Background and Significance; (c) Preliminary Studies/Progress Report; and (d) Research Design and Methods. The PHS 398 instructs applicants to:

> *Organize Items a–d to answer these questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work? (The Research Plan may not exceed 25 pages, including tables, graphs, figures, diagrams, and charts.)*

Specific Aims

> *List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypotheses to be tested. (One page is recommended.) PHS 398 Instructions*

[1]Organized in 1998, the central mission of the interest group is to promote greater awareness of the use and contribution of appropriate and rigorous qualitative methods in research on health and disease, within both the NIH and the extramural research community.

[2]The PHS 398 is the application form used for research grant and career development award applications to the NIH. (The PHS 416-1 is used for Individual National Research Service Award fellowship applications.) The application instructions and form pages can be downloaded from the NIH website: http://grants.nih.gov/grants/forms.htm. Application kits can also be obtained from your institution's Office of Sponsored Research.

The specific aims of an application introduce and define the research questions, hypotheses, or overall theory that the research is seeking to address or test. In this section, the applicant describes the long-term goal or ultimate purpose as well as the aims to be accomplished during the proposed research.

Qualitative studies may ask broad, open-ended, and interconnected questions that are not always specifiable as conventional hypotheses. The applicant expects that key insights may emerge during the course of the research that may steer the project in unforeseeable directions. It is necessary to strike a balance among well-defined areas of inquiry, achievable aims, and openness to unanticipated findings. As the term "specific aims" implies, reviewers expect clearly delineated, precisely defined research aims. Broad or vague aims weaken the argument that the study is well grounded in the existing research and capable of producing important findings.

It is generally best to state a limited number of clearly focused aims. The applicant should consider carefully whether to frame the aims as questions or as hypotheses. A succinct description that introduces the empirical and intellectual merits of the study will underscore the project's significance. It is important not to overstate or understate the anticipated outcomes. It is also important that the aims are feasible for the given time, methods, and stated goals. A clearly and precisely worded narrative about the investigation of understudied issues or uncertain relationships that is achievable within the timeframe and resources available is a mark of a strong application.

Once the specific aims are formulated, the applicant needs to address exactly how these aims relate to each of the remaining application sections and clearly link them to the research methods, procedures, and analytical processes. This is an excellent opportunity to support the need for qualitative data and methods to achieve expected outcomes. The statements and restatements of the goals and aims should be consistent throughout the various sections.

Background and Significance

> *Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in the application by relating the specific aims to the broad, long-term objectives. (Two to three pages are recommended.) PHS 398 Instructions*

In this section of the application, the applicant has the opportunity to display knowledge of the relevant field or fields and an ability to analyze critically the existing research, and to show how the proposed work will extend a research area, fill a gap, or cover new terrain and, most importantly, address public health concerns. The background and significance section provides a well-reasoned and compelling argument for the importance of the research aims described in the Specific Aims section, and for the appropriateness of the methodological approach proposed in the Research Design and Methods section.

The literature review focuses on empirical research and conceptual/theoretical background that are highly relevant to the planned study in such a way as to communicate gaps in existing understanding, to suggest the importance of the planned study, to address the gaps, and to expand the frontiers of scientific knowledge. The section consists of a thoughtful, balanced, and critical evaluation of the research literature, and not just a summary of what has been reported in other studies. The literature review also includes an argument for the

choice of concepts being investigated, the conceptual and theoretical framework underlying the research, and the methodological approaches proposed. It may be helpful to provide information on previous contributions of qualitative methods to the field or topic under investigation, and to provide evidence that the approaches have worked well for studies with similar characteristics to the planned study. It may also be useful to include a brief primer on methods and their results in this section. An applicant may wish to provide specific examples of how results of the previous methodically similar research have made a significant contribution (e.g., to develop or implement interventions, to identify needs of a particular group, or to promote particular health practices).

A commonly identified weakness in applications is that applicants spend too much effort citing an overly broad range of material written on the general topic and pay insufficient attention to organizing the review in light of the specific area they want to investigate. An effective review is complete but concise and includes all important studies or areas. An applicant proposing to use qualitative methods will include the appropriate and relevant range of research studies, both qualitative and quantitative. The applicant should strive for a balanced tone in the review, identifying and discussing the strengths and limitations of existing studies. Finally, although the Background and Significance section should be substantive and demonstrate insight, breadth, and mastery, the applicant is advised to stay within the recommended page limit guidelines.

In short, this section of the application defines or frames the issues or topics of study (that is, its most general and broadest implications and relevance to various public constituencies) and the significance of the study's aims for particular public health issues, concepts, data, and/or current practices, as appropriate. Competitive applications:

- Clearly describe gaps in current knowledge or new areas for inquiry;
- Explicitly link specific aims to identified gaps and innovative topics for investigation; and
- Demonstrate the appropriateness of using qualitative methods for expanding knowledge in the area and addressing unasked or insufficiently answered questions.

"Significance" is one of the five review criteria by which the application will be evaluated; therefore, the following questions are important to answer in conceptualizing and describing the project:

- Does this study address an important problem?
- How will scientific knowledge be advanced?
- What will be the effect of these studies on the concepts or methods that drive this field?

Supportive evidence for the significance of the proposed research is provided through the critical analysis of the literature review and discussion of the applicant's relevant prior research, briefly mentioned here and expanded upon in the next section.

Preliminary Studies/Progress Report

For new applications, use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application and/or any other

information that will help to establish the experience and competence of the investigator to pursue the proposed project. (Six to eight pages are recommended.) PHS 398 Instructions

The Preliminary Studies section provides evidence of the applicant's ability to successfully carry out the proposed research, and also provides the basis for the argument to conduct the study in the manner proposed. In this section, the applicant has the opportunity to demonstrate competence with the methods and issues of concern to the proposed study, and to describe related work and data that led to the application. It can document the applicant's mastery of competencies at concept development, data collection and analyses, and successful project completion and publication.

Brief but detailed statements about prior studies, including aims, size of study group, design, kinds of data, analytic techniques, and key findings are particularly helpful. How the prior work contributed to the proposed design and methods should be described. Strengths and limitations in the previous work should be discussed, but not over- or understated. Reasoning through the limitations of previous work is useful, especially if one can propose substantial improvements.

This section is the place to show precisely how the applicant's past qualitative work has led to useful findings and supports the applicant's ability to undertake the proposed research. Demonstrated expertise in writing qualitative results is important as well. Establishing the applicant's record of publications pertaining to the specific population or methodology is essential. Relevant accomplishments of investigators that may not be apparent in the biographical sketch can also be introduced.

Qualitative methods are often employed in unstudied or understudied areas. When this is the case, writing about preliminary studies can present a challenge. In this situation, showcase the staff's specific experience and expertise that make them uniquely suited to conduct the proposed research. If they have used similar methods and techniques in a different substantive area, a short description of such studies focused on the methodological similarities would be appropriate. Pilot work could strengthen the application. A preliminary analysis of even a few visits to the field or a small number of interviews allows the applicant to demonstrate the feasibility of the proposed data collection and analysis process.

Research Design and Methods

Describe the research design and procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and of alternative approaches to achieve the aims. As a part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. (No specific number of pages is recommended for this section of the application, but the total for Items a–d may not exceed 25 pages, including all tables and figures.) PHS 398 Instructions

Each of the components comprising this section of the Research Plan is discussed below; however, two critical characteristics of a good application apply equally across all components:

- Consistency in the way in which concepts are described and used throughout the Research Plan; and
- Integration of the specific aims and research questions across all elements of the plan.

An important part of the justification for the overall Research Plan is a discussion of the strengths and limitations of the methods that will be used as compared to alternatives not selected and a well-balanced, critical analysis of the information the study can and cannot provide.

The research questions or overall theory that will be addressed are described in the Specific Aims and Background and Significance sections of the Research Plan. The Research Design and Methods section describes how the specific aims will be accomplished. Each element of the section (e.g., the conceptual/theoretical framework guiding the study, sampling methods and sample characteristics, the data collection approaches and procedures, and the analysis and interpretation of the data) is equally important in the overall plan for how the study will be conducted. A key consideration in laying out this section of the application is which research design, sampling strategy, data collection methods and procedures, or data analysis and interpretation approaches are the most appropriate for accomplishing the specific aims of the study. A well-organized Research Plan that flows logically from the specific aims and demonstrates the integration of each specific aim throughout the description of the plan is a crucial component of a successful application. In addition, a successful application also provides a detailed description of each step in the research process.

> *If I had to sum up my experiences as an NIH grant applicant, I would say to potential grantees, "Watch your language." (Workshop Participant)*

Many concepts (e.g., sampling, measurement, reliability, and validity) may have different meanings and may be applied differently in qualitative and quantitative contexts. The definition of key concepts and how they will be applied in the study are, therefore, important parts of the description of the research design and methods. The need for clear definitions applies to other elements of the Research Design and Methods section as well. It is not enough, for example, to say that a theoretical, or purposive, sampling method will be employed or that data will be collected using semi-structured interviews and participant observation. Definitions of these terms and specific descriptions of how they will be applied in the study are needed. The idea is not to present generic, textbook information but to describe, without unnecessary jargon, the application of a particular research design and its related methods and procedures to the current study.

> *It is my sense that the keys to the successful inclusion of qualitative approaches in NIH grant applications lies in: (1) systematic description of the nature of the data collection methods to be used; (2) presentation of a clear and convincing rationale why qualitative approaches are not only appropriate for addressing the research questions(s) at hand but why they are the most likely to produce useful findings; (3) focused discussion of the universe studied and the sample recruited for qualitative assessment (including accounting for the relationship between the sample to the universe, by using a clearly described sampling plan); (4) specification of the timeframes that bound data collection (e.g., observations designed to sample variation across hours of the day, days of the week, and weeks of the year); (5) careful presentation of the nature of the data to be collected; and (6) an orderly account of the analytic procedures to be performed, including specification of how findings can be interpreted. (Workshop Participant)*

DESIGN:

The design section specifies the research design and any adaptations or unique features of the proposed study. Simply naming a design type is not adequate. A brief introductory statement of the research strategy and its defining features provides an overview of how the research will actually be conducted without going into the details of the specific design elements that belong in subsequent sections. The overview may also include a brief synopsis of the links between the theoretical and methodological perspectives reflected in the study. For example, the design overview could convey:

- Whether the aims of the study are descriptive, hypothesis testing, or some combination;
- Whether the design is comparative, and if so, what the unit of comparison will be;
- Whether one approach or an integrated approach will be used;
- Whether data will be collected at one or multiple points in time; and
- How the population will be defined.

The chosen design is reflected in the specific aims, and its influence over ensuing plan components should be obvious in each section.

Sampling Plan:

The sampling plan, and the rationale or justification for the decisions about this element of the design, are linked to the specific aims and research questions to be addressed by the study. The sampling plan specifies the characteristics of the population (e.g., research characteristics of interest, gender, age, ethnicity) from which the sample will be selected; the size of the sample; the inclusion/exclusion criteria; the representativeness of the sample to its population; the specific procedures that will be used for recruiting the sample (and for retaining the sample if data will be collected at more than one point); and the procedures that will be used to determine the sample size. Other issues that need to be addressed include the data collection site, how participants will be identified and contacted, and who will recruit the participants and collect the data.

There are many approaches used by investigators in determining sample size. Previous pilot studies or similar studies in the literature are two sources of information. Regardless of the approach used to determine sample size, the rationale and procedures need to be clearly described. It may be useful to think in parallel to power analysis in quantitative research. What is it about the nature of the questions, the data, and their analyses that helps determine the sample size? What previous studies inform the sample size? How specifically will the investigator know when the necessary sample size is reached?

There are several other approaches to estimating sample size requirements a priori or in situations in which it is difficult to estimate the sample size. One approach is based on the concept of *range*, that is, the number of interviews, observations, and so forth that are needed to capture a representative view of the phenomenon under study. Another approach is based on the concept of *redundancy* or *saturation*, that is, the number of people who need to be interviewed, or observed, before no new data emerge, indicating that the boundaries of

the phenomenon have been tapped. A third approach is based on the concept of stratification, that is, the number of categories along a single dimension (e.g., socioeconomic status) that need to be represented in the people interviewed. Implementation of any of these approaches requires that the criterion or principle for determining when an adequate sample has been achieved be specified in advance (e.g., the quality of the data, whether new information continues to be discovered). Whether, or when, the criterion has been met is often determined through concurrent, ongoing data collection and data analysis in which the substance and types of responses being obtained are monitored. One must also be aware of whether new codes continue to emerge.

Another important aspect of the sampling plan is the specification of the criteria for determining who will, or will not, be included in the sample. For example, will only a certain age range, gender, ethnic, or diagnostic group be included? What are the inclusion/exclusion criteria and their rationale? Sample criteria should always be tied directly to the questions posed or areas of inquiry. Related to the selection criteria is the issue of the representativeness of the sample. The specific strategy for selecting and/or recruiting participants determines what part of the larger population of potential participants is represented in the data and the larger group to which the data will generalize. There is a balance to be struck between breadth versus depth of the sample, for example, how many levels of acculturation or socioeconomic status versus how many participants at one or few levels of acculturation or socioeconomic status will be represented in the sample.

Sampling specification issues also apply to when, where, and how often observations or similar data collection approaches will be done to ensure that the data represent a snapshot across all reasonable possibilities that are related to the research aims.

Differences in levels of acculturation of the proposed participants and differences in primary spoken language among them, and between them and the investigators, often raise methodological (e.g., access, consent, recruitment, and retention) as well as scientific (e.g., instrument validity and translation) problems to be addressed in research on ethnic populations. There are also special sampling issues that are involved in sampling for hidden populations (e.g., access) that may require specific strategies.

Data Collection:

This component of the research design and methods section addresses data collection instruments, methods, and procedures. It also includes explanations of each of these areas and how the methods used will address the research questions. An important issue to consider in this section is the level of detail to include about instruments, data collection, and data management. Clear descriptions of these important components of the research design and methods are critical to communicating what will actually be done in the study. For example, a general statement that “qualitative techniques will be used to discuss and probe information about emergent ideas” does not convey the rationale for the specific methods chosen, or why a particular qualitative data collection method is the most appropriate one to answer the specific questions. Generalities will not build the case for why the qualitative methods to be used are the ones most likely to produce useful findings and advance the state of knowledge.

The methods of data collection, whether participant observation, structured observations, indepth interviews, or some other approach, again will arise from the aims and research questions. Why is the method selected the best one for addressing the questions? What

alternative methods were considered, and why were they rejected? Examples from the literature or from the investigator's own previous work can be useful in demonstrating the yield and interpretation of data collected with the chosen qualitative methods.

Data collection instruments, or at least a preliminary list of questions (or examples) and techniques that will be used to operationalize each topic to be explored or examined, will indicate the kinds of data to be collected. If a questionnaire or structured interview will be used, include sample questions in the narrative rather than in an appendix. A discussion of reliability and validity of the instruments and data collection procedures will provide assurance that the data will be as accurate and robust as possible. If untested instruments or procedures will be used, indicate what procedures will be used to assure reliability and validity. Also, indicate which members of the research team will be involved in the procedures.

The strategy for implementing data collection includes specification of who will conduct interviews or carry out observations, sites and times of data collection, and what and how information will be recorded. It may also describe who will recruit, if different from the data collector(s).

Data collection strategies also include procedures for monitoring the quality of the data, including, for example, how data collectors will be trained and supervised and how information will be cross-checked and triangulated with information from other data sources. Elements of quality monitoring of the data collection process might also include periodic checking of interviews, checking of log books, site visits, practice work followed by discussion of that work, and periodic checking during the course of the work. Other aspects of the data collection strategy may include translation and revalidation, and pilot testing of new as well as standardized instruments.

The overall data collection strategy describes the process through which decisions will be made about how and when the questions or the observational foci will be modified. In addition, consideration of participant burden, that is, people's tolerance and stamina for being observed or interviewed (an issue both of data quality and of protection of research participants) is important to discuss. Applications that include non-English speakers will need to address the language of the interviews, translation procedures, and the use of translators.

Once again, a clear explanation of how each instrument or data collection method relates to and answers a specific aim is useful in demonstrating continued integration and consistency in the Research Plan. Research plans that include a variety of data collection strategies and analyses for different aims may be summarized in a table to provide a clearer picture of the parts of the plan.

Data Analysis:

The data analysis strategy lays out the specific procedures for addressing each of the research questions and/or hypotheses, and the nature and form of the expected results. For example, the first step in analysis may be to identify analytic domains, major thematic areas, and minor thematic areas and to begin to build a theoretical framework. Similarly, the steps in the process of narrative analysis or the concurrent interweaving of analysis and writing in ethnography can be described. In studies where both qualitative and quantitative data are generated, describe the relationship of the data collected through various methods in the analysis.

If a software program will be used to facilitate data analysis, indicate how it will be used, as well as its limitations and how they will be handled. In addition, a description of computer data management, data entry, and data transformation is necessary.

Pilot data can be helpful in constructing a preliminary or hypothetical coding scheme or can provide the yardstick for explaining and clarifying domain analyses. Similarly, tables can be used to demonstrate the hypothetical kinds of data that will be obtained and how they will be analyzed. There is also an extensive literature on specific qualitative methods and data analysis that can be referenced.

Data Interpretation:

It is useful to describe the process by which the investigator will arrive at data integration and conclusions. The potential significance of the findings for both the immediate questions and broader issues can be addressed here. The process and procedures to be used for integration and interpretation of data from various sources are particularly important when using more than one data source and type.

Combining Qualitative and Quantitative Approaches

> *Combining qualitative and quantitative methods has gained broad appeal in public health research. The key question has become not whether it is acceptable or legitimate to combine methods, but rather how they will be combined to be mutually supportive and how findings achieved through different methods will be integrated. Clear and detailed specification of methodological and analytic integration, consequently, is critical. Unfortunately, methods for the triangulation of diverse types of data collected through various methods have not been adequately established. (Workshop Participant)*

The combination of qualitative and quantitative approaches, in which the two approaches inform one another to fulfill the specific aims of the study, has broad appeal in public health research. At the same time, the combination design raises a number of challenging issues. The description of the Research Plan combining qualitative and quantitative components includes how the two methods will address the research questions and/or hypotheses, how the data will be integrated, and how the results will be interpreted taking into account data from two different research paradigms. Each study aim should be easily tracked through the Research Plan in terms of method, data collection instruments and procedures, data analysis, and data interpretations.

Combined approaches require that expertise in both approaches be reflected in the make-up of the team and that this expertise be evident in the specifics of the Research Plan. A major weakness in many applications proposing a combined approach is that one method is well described and the other method is only superficially addressed. In addition, the applicant often fails to describe the contribution of each method to the study problem.

Models for Linking Qualitative and Quantitative Approaches:

The use of multiple methods and concepts within one study can be differentiated from a program of research involving a sequence of studies over time, each using a different

method. Many descriptions of combined approaches exist. Four forms that have been used successfully within a single study are:

- **Sequential.** Qualitative methods serve for the first stage of knowledge building to discover key issues and elements for subsequent study using formal structured methods. For example, focus groups and preliminary pilot studies are conducted to refine a standardized instrument or clinical assessment for use in a new population or ethnic group.
- **Parallel.** Some models effectively conduct qualitative methods such as case studies, focused ethnographic observation, or multiple linked indepth interviews (or a combination of these) in tandem with other methods.
- **Coordinated sub-studies.** Qualitative studies contribute under the umbrella of a larger program project or long-term study.
- **Integrated.** Methodologically diverse concepts and data are integrated at each stage within the study design to develop a robust evaluation of each emerging finding and set of data.

Describing a sequential Research Plan is fairly straightforward; that is, the question/ hypothesis, sample, design, methods, instrumentation, and analysis for each approach are described separately. Describing an integrated design and indicating an iterative process is much more difficult. The potential payoff of the integrated approach is high but a number of difficult analytic obstacles challenge efforts to satisfy the multiple standards for design and analyses. The standards of scientific rigor apply equally to sequential and integrated designs, but in the integrated form, parallel data collection and triangulation in analysis require more extensive explanation.

A more common design involves a chronological integration of qualitative and quantitative methods. For example, qualitative procedure A will be used to assist in the grounding of quantitative procedure B, the findings from which will be clarified through the subsequent use of qualitative method C.

In sum, both qualitative and quantitative approaches to data collection may be used at various stages in the research process, or the two can be used throughout the investigation.

Relevant Considerations for Deciding on the Most Appropriate Model:

Considerations for deciding on the most appropriate model for combining qualitative and quantitative approaches include asking the following kinds of questions:

- **Research area.** Is the field of study developed to the extent that some dimensions or factors are known that must be controlled for during the sample selection, data collection, and analyses processes?
- **Units of analyses.** Are some of the issues or topics of study sufficiently characterized by prior studies that it is hard to argue for totally open-ended exploratory approaches?
- **Design.** Realistically, how much time may be available to prepare, conduct, and analyze complex multi-method data? How many parameters are proposed to be assessed and what analytic parameters must be met to satisfy the requirements of each analytic technique?

- **Expertise.** Is there sufficient expertise on the investigative team in both methods and in the combined approach selected?

A sequential or chronological model often is used to ground quantitative research through the use of formative qualitative approaches. For example, to ensure that a survey instrument includes questions about significant topics using words that will be meaningful to study participants, focus groups or open-ended individual interviews may be used prior to the finalization of the survey instrument. The strength of this approach is that it increases the appropriateness of research instruments for the local research setting (i.e., addresses issues of validity) while allowing for the inclusion of a representative sample (i.e., addresses issues of reliability).

An integrated model tends to involve simultaneous data collection using both qualitative and quantitative procedures. The researcher both records descriptive accounts of behavior and counts the frequency of the behavior in question. While qualitative approaches can be used in formative research, they can also constitute the framework for the primary research design. The strength of this approach is that it allows a fuller, longer use of highly contextualized research for ongoing discovery and identification of emergent phenomena.

When the goal is to understand the lived experience from the social actor's perspective within a specific context, qualitative methods are appropriate. When the data collected are of a numerical nature and the goal is to understand the strength of relationships and to make prediction or generalize to larger populations, quantitative approaches seem appropriate. When the goal is a combination of all of the above, a sequential or integrative model may be the most appropriate means of conducting the research.

Human Subjects

All applicants for NIH funding need to be thoroughly familiar with the latest guidelines and Federal research regulations for the protection of human subjects (research participants). The document, *Protection of Participants in Behavioral and Social Sciences Research*, available at http://obssr.od.nih.gov/IRB/protect.htm, addresses basic questions about Federal regulations protecting research participants and covers such topics as:

- The definition of human subjects
- What investigators need to do to comply with Federal requirements if their research involves human subjects
- The role of the Institutional Review Board (IRB) and the types of review it conducts
- How to decide if the proposed research falls into an exemption category and does not require IRB approval
- Informed consent requirements
- Privacy and confidentiality including applying for a certificate of confidentiality
- Key points when applying for Federal funding
- Additional resources

The Office for Human Research Protections (OHRP), Department of Health and Human Services, is one of the additional resources listed in the document above. The OHRP website, http://ohrp.osophs.dhhs.gov/, has links to educational and training resources as well as to the most current Federal policies and guidelines.

The NIH policy and guidelines on the inclusion of women and minorities in research involving human subjects, and related documents, can be found at http://grants.nih.gov/grants/funding/women_min/women_min.htm. The guidelines require that all applications include a plan for ensuring the appropriate representation of minorities and both genders or provide a justification for why representation will be limited or absent. The NIH policy and guidelines for the inclusion of children as participants in research involving human subjects can be found at http://grants.nih.gov/grants/guide/notice-files/not98-024.html. The guidelines require that all applications describe a plan for including children (i.e., persons under age 21) in the research unless there are clear and compelling reasons not to do so. The information that must be included in the application to address the requirements for gender and minority inclusion and the inclusion of children is described in the instructions of PHS 398.[3]

Although the guidelines for the protection of research participants cover every type of research, qualitative research may involve populations, settings, or methods that evoke special considerations, which may be different from that of quantitative research. Some populations that participate in qualitative research may well hold beliefs and values that challenge such human subject procedures and principles. Obtaining informed consent may also be difficult when there are literacy and language differences within the population. This situation and other special cases may require special informed consent procedures.

Qualitative research evokes consideration about confidentiality and the protection of participant identity. Ethical questions arise due to the special closeness that may develop between qualitative researchers and study participants. Since participant observation is a key methodology, the researcher will need to explain how they plan to address the issue of nonconsenting members of a group. It is not unusual for qualitative researchers to investigate “hidden” populations who engage in behavior defined as deviant. Applicants studying individuals who may be subject to legal sanctions if their identities are revealed will need to specify procedures to ensure confidentiality. There are as well a number of logistical concerns which include the common difficulties involved with hidden populations, such as locating the participants for followup, the nomadic nature of many of the individuals, and overcoming distrust and fear of the outsider. If the research takes place in a setting where laws are being broken, the researcher needs to take special care to identify ethical means of conducting the research in that setting. Similarly, some research participants may want confidentiality protection for financial reasons. In such a case, researchers need to be clear about reimbursement reporting procedures and confidentiality in the application’s Human Subjects section and in the recruiting and consent procedures discussion. Applicants may wish to consult with their own IRB during application development and to consider applying for a Certificate of Confidentiality from the NIH prior to beginning the study, should NIH funding be obtained.

As qualitative researchers often have indepth interactions with participants over a long period of time, the nature of the researcher–participant relationship needs special consideration. Specifically, a close researcher–participant relationship evokes concerns about perceived coercion, experiences of undue burden or distress, and privacy issues. For example, the use

[3]The information about gender and minority inclusion and the inclusion of children is considered part of the Research Plan and is included in the 25 pages allowed for this part of the application. The Human Subjects section, and the six points that must be covered in the application, form a separate part of the application for which no page limitation applies.

of native translators or interviewers in the field may challenge confidentiality. As in any application, qualitative applications must explicitly describe all participant confidentiality concerns and present reasonable steps to address these concerns. This includes maintaining confidentiality in the contexts of electronic data protection, analysis, and dissemination.

In sum, competitive applications involving human research participants must demonstrate an awareness of the most current ethical guidelines and address, to the best of their abilities, all of the possible ethical concerns of the planned study. The application should address potential ethical problem areas; it should describe proactive measures to prevent them and remedies that will be put in place to deal with them should they occur.

Budget

All general principles of developing and describing a research budget apply to qualitative methods as they would to any research methodology. The most significant budgeting problem faced in qualitative research is the relatively costly, labor-intensive nature of the work. Applicants encounter problems in review when the budget does not adequately reflect the effort required. Applicants frequently make the mistake of underestimating or trying to "downplay" the cost of qualitative research methods. The budget must be adequate to support necessary data collection, especially interviews and transcription. The budget and timeline must reflect the effort needed to conduct a sound data analysis, again, quite time consuming and resource intensive for qualitative research. An unrealistically low budget or short timeline for a project may be seen by reviewers as reflecting a lack of experience or judgment on the part of the researcher. On the other hand, an inflated budget is not useful to the application.

Applications for which the direct costs do not exceed $250,000 per year in any year of the project must be submitted as a modular grant application. Full information on NIH modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm. Any questions about this are appropriately directed to the NIH program staff listed on each Institute's home page.[4]

Summary

Applications to NIH featuring qualitative methods must meet all general criteria required of any application. Follow NIH instructions carefully! Contact program staff for questions and assistance during early development of the application. Consult program announcements and descriptions for guidance on content. The Research Plan described in the application must communicate a systematic plan of research and clearly specified data collection and analytic procedures. All sections of the plan must be clearly related to each other. Be certain that the plan flows directly from the specific aims, with direct discussion of how each aim will be achieved through particular data collection and specific analyses. If possible, it is strongly recommended that the Research Plan be distributed to experienced reviewers (successful NIH grantees and content experts) for comment and revision prior to grant submission. Revise and rewrite as many times as necessary to remove all identifiable ambiguities and to be certain that all procedures are clearly and precisely laid out. Finally, be certain that the entire product presents a coherent, clear, and well-documented argument for the importance of conducting this particular research in the particular method specified.

[4]Institute home pages can be accessed through the NIH website at: http://www.nih.gov/icd/.

The checklist attached (page 16) includes areas that have been problematic in some applications using qualitative methods. The applicant may wish to add to or revise the checklist in other ways to personalize it or for use by colleagues who are asked to review the application prior to submission. This checklist is specific to the Research Plan and not to the application as a whole. As a reminder, applicants will want to carefully review and use the official checklist in the PHS 398 application.

Overview of the NIH Grant Review Process

The Center for Scientific Review (CSR) at NIH is responsible for the receipt and initial review of grant applications, and processes some 10,000 grant applications each review cycle. Referral Officers review the contents of the applications using written guidelines, and decide which Integrated Review Group (IRG) would be most appropriate for assessing the scientific merit of the application. Once the IRG is identified, applications are assigned to one of the study sections that comprise the IRG. IRGs, study sections, and their descriptions are listed on the Web at: http://www.csr.nih.gov/review/irgdesc.htm. In addition to IRG assignment, Referral Officers also assign the application to the most appropriate Institute or Center of the NIH. Also consult www.csr.nih.gov/review/peerrev.htm for additional details.

The CSR considers written requests from applicants for both IRG and Institute assignments. The assignment process is a collegial one, and applicants are encouraged to submit a cover letter indicating assignment preferences with their application. Within several weeks following assignment of the application, the CSR will send the applicant a notice indicating the study section and Institute assignments. Applicants with questions or concerns regarding assignment may contact the study section administrator (Scientific Review Administrator [SRA]) or the CSR Referral Officer. Applications in response to a specific request for applications (RFA) may be reviewed by a special emphasis panel convened on a one-time basis.

Official NIH guidelines define the scientific content and boundaries of each study section. A CSR study section is typically composed of 18–20 members, nominated by the SRA, from active and productive researchers in the extramural community. The goal is to have the study section's combined knowledge span the breadth of the subject matter designated for that study section. If an application requires expertise not represented on a study section, the membership of the study section can be supplemented by temporary members and written outside reviews.

Following assignment of an application to a section, the SRA for each study section reviews the application to determine which study section members are best qualified to review it or to act as discussants. Usually, two or three members are assigned to provide written reviews of each application, and one or two other members serve as discussants. Approximately one week prior to completion of the review, the SRA will ask all members of the study section to provide a list of applications thought to rank in the lower half of those submitted based on scientific merit. These applications are streamlined or, in other words, not discussed or scored at the review meeting unless there is a difference of opinion from a study section member during the review meeting. Reviewers' written comments are provided to all applicants, including those with unscored applications. All applications may be revised and resubmitted two times within a 24-month period, except those in response to an RFA, which is a one-time submission.

During a study section meeting, the assigned reviewers and discussants provide their evaluations, and any outside opinions are read. Reviewers discuss the substantive content of the application, as well as review human subjects protection issues and the inclusion of women, minorities, and children in the study.[5] All members are then asked to mark their priority scores privately for the application. Each application that is not streamlined is given a single score reflecting the overall impact the project could have on the field based on consideration of five criteria: significance, approach, innovation, investigator, and environment. (A full description of the review criteria can be found at http://www.csr.nih.gov/archives/review criteria.htm.)

Priority scores, percentiles, and summary statements are then mailed to the applicants and forwarded to the appropriate NIH Institute for consideration. At this point, the CSR's oversight of the application ends and an Institute program representative is responsible for overseeing the disposition of the application. Although there are many types of grant applications at NIH, most reviews within CSR are similar to the process just described. Specific guidelines for review of different grant applications are available on the CSR website at http://www.csr.nih.gov/guidelines/guidelines.htm. The CSR review responsibility and the Institute program responsibility are intentionally kept separate.

A second level of review is provided by each Institute's Advisory Council (comprised of extramural scientists and public representatives who also provide advice to the Institute on Scientific Program and Policy areas). Oversight of the applications at the Institute level is the responsibility of extramural program staff, who may advise applicants in the development of the initial application or any resubmission and who serve as the liaison to the NIH if the research study is funded.

For current and detailed information, applicants are encouraged to visit websites identified in this document.

[5]NIH policy requires the appropriate representation of genders, minorities, and children under age 21 in study populations for all research involving human subjects, so that research may benefit all individuals at risk for the illness or disease. As of October 1, 2000, NIH requires that all investigators be educated on the protection of human subjects if the research involves human participants (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html for a complete description of the policy and the availability of on-line training).

Checklist for Research Plan

Narrative Includes	Yes	Needs Work
The research paradigm and approach are clearly described.		
The scientific rationale for the research design and its strengths and weaknesses relative to alternative designs are discussed.		
Qualitative and quantitative methods, when both apply, are addressed with equal care and specificity.		
In studies combining qualitative and quantitative methods, the linkages between the two types of methods and the integration of the data and findings to answer the research questions are explicitly described.		
Expertise needed for the study is available on the team. This includes expertise for: all methodologies used, data analysis techniques, software for data management, and other areas requiring particular expertise.		
The research problem, aims, methods, and data analysis are linked in a consistent manner, and the terms are consistently defined and used.		
The limitations and potential pitfalls of the proposed methods and procedures and how they will be minimized or handled are addressed.		
The rationale for sampling decisions and the theoretical and scientific basis of the sampling technique are discussed.		
The Federal guidelines for inclusion of women, minorities, and children are followed. Explanations include scientific reasons for why participants in each of these categories will or will not be included. The explanation includes population demographics both nationally and within the data collection site.		
Data collection procedures are fully explained.		
Data analysis procedures are fully described for each aim or research question.		
The potential future applications of the study findings are discussed. For example, what is the purpose of the study for the population or for health care providers? Is there another step in the research before application to practice can occur? What are the next steps? What can be expected as the immediate or ultimate outcomes of the research? In other words, the “so what?” question is addressed.		

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