

Best Practices for Mixed Methods Research in the Health Sciences

Commissioned by the

Office of Behavioral and Social Sciences Research (OBSSR)
Helen I. Meissner, Ph.D., Office of Behavioral and Social Sciences Research

By

John W. Creswell, Ph.D., University of Nebraska-Lincoln
Ann Carroll Klassen, Ph.D., Drexel University
Vicki L. Plano Clark, Ph.D., University of Nebraska-Lincoln
Katherine Clegg Smith, Ph.D., Johns Hopkins University

With the Assistance of a Specially Appointed Working Group



TABLE OF CONTENTS

Introduction and Background	1
The Need for Best Practices	2
The Nature and Design of Mixed Methods Research	4
Teamwork, Infrastructure, Resources, and Training for Mixed Methods Research	11
Developing an R Series Plan that Incorporates Mixed Methods Research.....	16
Beyond the R Series – High-Quality Mixed Methods Activities in Successful Fellowship, Career, Training, and Center Grant Applications	27
Reviewing Mixed Methods Applications	31
Overall Recommendations	35
Appendix A. NIH Working Group on Developing Best Practices for Mixed Methods Research	36



Introduction and Background

In November 2010, The Office of Behavioral and Social Sciences Research (OBSSR) of the National Institutes of Health (NIH) commissioned the leadership team of John W. Creswell, Ann Klassen, Vicki L. Plano Clark, and Katherine Clegg Smith to develop a resource that would provide guidance to NIH investigators on how to rigorously develop and evaluate mixed methods research applications. Pursuant to this, the team developed this report of “best practices” following three major objectives.

To develop practices that:

- ❖ assist investigators using mixed methods as they develop competitive applications for support from NIH;
- ❖ assist reviewers and staff for review panels at NIH who evaluate applications that include mixed methods research;
- ❖ provide the Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Institutes and Centers, with “best practices” to use as they consider potential contributions of mixed methods research, select reviewers, plan new initiatives, and set priority areas for their science.

OBSSR convened a Working Group of 18 individuals (see Appendix A. NIH Working Group on Developing Best Practices for Mixed Methods Research) to review a preliminary draft of “best practices.” This Group was composed of experienced scientists, research methodologists, and NIH health scientists. These individuals were selected because of their expertise in NIH investigations, their specific knowledge of mixed methods research, and their experience in the scientific review process. The composition of the Working Group was diverse with members representing fields such as public health, medicine, mental health professions, psychology, sociology, anthropology, social work, education, and nursing. This Working Group met in late April 2011, and reviewed and made recommendations for the final document presented in this report.

This report consists of seven sections:

- ❖ **The Need for Best Practices**
- ❖ **The Nature and Design of Mixed Methods Research**
- ❖ **Teamwork, Infrastructure, Resources, and Training for Mixed Methods Research**
- ❖ **Developing an R Series Plan that Incorporates Mixed Methods Research**
- ❖ **Beyond the R Series – High-Quality Mixed Methods Activities in Successful Fellowship, Career, Training, and Center Grant Applications**
- ❖ **Reviewing Mixed Methods Applications**
- ❖ **Overall Recommendations**



The Need for Best Practices

- ❖ **Mixed methods research in the health sciences:** A priority exists in health science research to develop new methodologies to improve the quality and scientific power of data that is leading to an extraordinary surge in methodological diversity. This diversity reflects the nature of the problems facing public health, such as disparities among populations, age groups, ethnicities, and cultures; poor adherence to treatment thought to be effective; behavioral factors contributing to disability and health; and translational needs for health research. The diversity also signals a growing acceptance of qualitative and social science research, the formation of interdisciplinary research teams, and use of multi-level approaches to investigate complicated health problems, such as the patient's point of view and cultural and social models of illness and health.

Contributing to this interest has been the increased methodological sophistication of mixed methods research in the social and behavioral sciences. NIH-funded investigators are using research approaches, such as in-depth interviews, field observations, and patient records to understand individual experiences, participant involvement in interventions, and barriers to and facilitators of treatment. These approaches often are combined with clinical trials, surveys of attitudes and beliefs, and the epidemiological measures to better understand health problems (Plano Clark, 2010).

- ❖ **Recent evidence:** Evidence in the published literature attests to the current use of mixed methods approaches in health-related research, such as in cardiology (Curry, Nembhard, & Bradley, 2009), pharmacy (Almarsdottir & Traulsen, 2009), family medicine (Stange, Crabtree, & Miller, 2006), pediatric oncology nursing (Wilkins & Woodgate, 2008), mental health services (Creswell & Zhang, 2010; Palinkas, Horwitz, Chamberlain, Hurlburt, & Landsverk, 2011), disabilities (Mertens, 2009), and public health nutrition (Klassen, Smith, Black, & Caulfield, 2009). The settings vary from the clinic (McVea et al., 1996) to the social context of daily activities and relationships (Pasick et al., 2009). The growing interest in mixed methods research recently has been documented in a study of funded NIH investigations that incorporated “mixed methods” or “multimethods” in their abstracts. This study demonstrated a dramatic increase in the use of these words in funded projects since 1996 (Plano Clark, 2010). The federally funded mixed methods investigations spanned 23 different NIH institutes, with many supported by the National Institute of Mental Health, the National Institute of Nursing Research, and the National Cancer Institute.
- ❖ **New guidelines needed:** Despite the expanding interest in mixed methods research in health fields and at NIH, no recent guidelines for “best practices” exist to assist scientists developing applications for funding or to aid reviewers assessing the quality of mixed methods investigations. The 2001 NIH OBSSR report, “Qualitative Methods in Health Research: Opportunities and Considerations in Application and Review” (NIH, 2001) was created to assist investigators using qualitative methods in submitting competitive applications for support from NIH. One section of this report addressed “combined” quantitative and qualitative research, recognizing that combined approaches had gained “broad appeal” in public health research. In a brief section, this “combined” research discussion advanced four general models for mixed methods research and suggested considerations for deciding on the most appropriate models. As we revisit this report, we see that the recommendations for “combined” research are out of date and not in step with current knowledge in the field of mixed methods research or real-world health problems calling for diverse methodologies.
- ❖ **Models for guidelines:** As our Working Group moved forward, we became aware of other existing reports that could assist us in our task. For example, in 1995, as an outgrowth of the NIH Conference on Complementary and Alternative Medicine Research Methodology, a report was issued providing a “methodological manifesto” for quantitative research in alternative medicine (Levin et al., 1997). This report was helpful as we considered a core set of recommendations for mixed methods research. In 2002, the National Science Foundation (NSF) issued a “User-Friendly Handbook for Project Evaluations” (Frechtling, 2002). This report included a chapter providing an overview of quantitative and qualitative data collection methods, thus suggesting to us the importance of clarifying the nature of mixed methods research. We also reviewed the website for the Robert Wood Johnson project on qualitative research (Cohen & Crabtree, 2008), “The Qualitative Research Guidelines Project.” From reviewing this website we learned that a Web-based delivery mode for our “best practices” would be feasible, and that such a delivery system would be helpful in providing material that could be easily understood and used. Finally, we examined criteria for evaluating mixed methods research that recently have been presented in the health science and mixed methods literature (O’Cathain, 2010; Schifferdecker & Reed, 2009). We found this material useful to help us design a checklist that might be used by individuals reviewing mixed methods applications.



KEY REFERENCES AND RESOURCES

- ❖ Almarsdottir, A. B., & Traulsen, N. M. (2009). Multimethod research into policy changes in the pharmacy sector – the Nordic case. *Research Social Administrative Pharmacy*, 5(1), 82-90.
- ❖ Castro, F. G., Kellison, J. G., Boyd, S. J., & Kopak, A. (2010). A methodology for conducting integrative mixed methods research and data analysis. *Journal of Mixed Methods Research*, 4(4), 342-360.
- ❖ Cohen, D., & Crabtree, B. (2008). Robert Wood Johnson, Qualitative research guidelines project. Retrieved from <http://www.qualres.org/>.
- ❖ Creswell, J. W., & Zhang, W. (2009). The application of mixed methods designs to trauma research. *Journal of Traumatic Stress*, November, 1-10.
- ❖ Curry, L. A., Nembhard, I. M., & Bradley, E. H. (2009). Qualitative and mixed methods provide unique contributions to outcomes research. *Circulation*, 119, 1442-1452.
- ❖ Curry, L. A., Shield, R. R., & Wetle, T. T. (2006). *Improving aging and public health research: Qualitative and mixed methods*. Washington D. C.: American Public Health Association.
- ❖ Frechtling, J. (January, 2002). *The 2002 user friendly handbook for project evaluation*. Washington D.C.: National Science Foundation. Retrieved from <http://www.nsf.gov/pubs/2002/nsf02057/start.htm>.
- ❖ Klassen, A. C., Smith, K. C., Black, M. M., & Caulfield, L. E. (2009). Mixed method approaches to understanding cancer-related dietary risk reduction among public housing residents. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*, 86(4), 624-640.
- ❖ Levin J. S., Glass, T. A., Kushi, L. H., Schuck, J. R., Steele, L., & Jonas, W. B. (1997). Quantitative methods in research on complementary and alternative medicine. *Medical Care*, 35, 1079-1094.
- ❖ McVea, K., Crabtree, B. F., Medder, J. D., Susman, J. L., Lukas, L., McIlvain, H. E., et al. (1996). An ounce of prevention? Evaluation of the 'Put Prevention into Practice' program. *Journal of Family Practice*, 43, 4, 73-81.
- ❖ Mertens, D. M. (2009). *Research and Evaluation in Education and Psychology: Integrating Diversity with Quantitative, Qualitative, and Mixed Methods*. Thousand Oaks, CA: Sage.
- ❖ National Institutes of Health, Office of Behavioral and Social Sciences Research. (2001). *Qualitative methods in health research: Opportunities and considerations in application and review*. Washington D.C.: Author. Retrieved from obssr.od.nih.gov/pdf/qualitative.pdf.
- ❖ O’Cathain, A. (2010). Assessing the quality of mixed methods research: Toward a comprehensive framework. In A. Tashakkori & C. Teddlie (Eds.), *SAGE handbook on mixed methods research in the behavioral & social sciences* (2nd ed.) (pp.531-555). Thousand Oaks, CA: Sage.
- ❖ Palinkas, L. A., Horwitz, S. M., Chamberlain, P., Hurlburt, M. S., & Landsverk, J. (2011). Mixed-methods designs in mental health services research: A review. *Psychiatric Services*, 62(3), 255-263.
- ❖ Pasick, R. J., Burke, N. J., Barker, J. C., Galen, J., Bird, J. A., Otero-Sabogal, R., et al. (2009). Behavioral theory in a diverse society: Like a compass on Mars. *Health Education Behavior*, 36(5), 11S-35S.
- ❖ Plano Clark, V. L. (2010). The adoption and practice of mixed methods: U.S. trends in federally funded health-related research. *Qualitative Inquiry*, 16(6), 428-440.
- ❖ Schifferdecker, K. E., & Reed, V. A. (2009). Using mixed methods research in medical education: Basic guidelines for researchers. *Medical Education*, 43, 637-644.
- ❖ Stange, K. C., Crabtree, B. F., & Miller, W. L. (2006). Publishing multimethod research. *Annals of Family Medicine*, 4, 292-294.
- ❖ Wilkins, K, & Woodgate, R. (2008). Designing a mixed methods study in pediatric oncology nursing research. *Journal of Pediatric Oncology Nursing*, 25, 242-33.



The Nature and Design of Mixed Methods Research

This section discusses key information about mixed methods research:

- ❖ **What is Mixed Methods Research?**
- ❖ **When Should Mixed Methods be Used?**
- ❖ **How Should a Mixed Methods Study be Designed?**
- ❖ **What are the Methodological Challenges in Conducting Mixed Methods Investigations?**

What is Mixed Methods Research?

- ❖ **A definition:** Many definitions of mixed methods are available in the literature (e.g., see Johnson, Onwuegbuzie, & Turner, 2007). For purposes of this discussion, mixed methods research will be defined as a research approach or methodology:
 - focusing on research questions that call for real-life contextual understandings, multi-level perspectives, and cultural influences;
 - employing rigorous quantitative research assessing magnitude and frequency of constructs and rigorous qualitative research exploring the meaning and understanding of constructs;
 - utilizing multiple methods (e.g., intervention trials and in-depth interviews);
 - intentionally integrating or combining these methods to draw on the strengths of each; and
 - framing the investigation within philosophical and theoretical positions.
- ❖ **Philosophy in mixed methods research:** Mixed methods researchers use and often make explicit diverse philosophical positions. These positions often are referred to as dialectal stances that bridge postpositivist and social constructivist worldviews, pragmatic perspectives, and transformative perspectives (Greene, 2007). For example, researchers who hold different philosophical positions may find mixed methods research to be challenging because of the tensions created by their different beliefs (Greene, 2007). However, mixed methods research also represents an opportunity to transform these tensions into new knowledge through a dialectical discovery. A pragmatic perspective draws on employing “what works,” using diverse approaches, giving primacy to the importance of the research problem and question, and valuing both objective and subjective knowledge (see Morgan, 2007). A transformative perspective suggests an orienting framework for a mixed methods study based on creating a more just and democratic society that permeates the entire research process, from the problem to the conclusions, and the use of results (Mertens, 2009).
- ❖ **Theories and mixed methods research:** Optimally, all studies draw upon one or more theoretical frameworks from the social, behavioral, or biological sciences to inform all phases of the study. Mixed methods studies provide opportunities for the integration of a variety of theoretical perspectives (e.g., ecological theories, complexity theory, stress theory, critical theories, or others).
- ❖ **The nature of qualitative research and its evidence:** A salient strength of qualitative research is its focus on the contexts and meaning of human lives and experiences for the purpose of inductive or theory-development driven research. It is a systematic and rigorous form of inquiry that uses methods of data collection such as in-depth interviews, ethnographic observation, and review of documents. Qualitative data help researchers understand processes, especially those that emerge over time, provide detailed information about setting or context, and emphasize the voices of participants through quotes. Qualitative methods facilitate the collection of data when measures do not exist and provide a depth of understanding of concepts. Typical qualitative approaches used in health research are case studies, grounded theory, ethnography, and phenomenology.
- ❖ **The nature of quantitative research and its evidence:** Quantitative research is a mode of inquiry used often for deductive research, when the goal is to test theories or hypotheses, gather descriptive information, or examine relationships among variables. These variables are measured and yield numeric data that can be analyzed statistically. Quantitative data have the potential to provide measurable evidence, to help to establish (probable) cause and effect,



to yield efficient data collection procedures, to create the possibility of replication and generalization to a population, to facilitate the comparison of groups, and to provide insight into a breadth of experiences. Typical quantitative approaches used in the health sciences are descriptive surveys, observational studies, case-control studies, randomized controlled trials, and time-series designs.

- ❖ **The combination of quantitative and qualitative data:** Mixed methods research begins with the assumption that investigators, in understanding the social and health worlds, gather evidence based on the nature of the question and theoretical orientation. Social inquiry is targeted toward various sources and many levels that influence a given problem (e.g., policies, organizations, family, individual). Quantitative (mainly deductive) methods are ideal for measuring pervasiveness of “known” phenomena and central patterns of association, including inferences of causality. Qualitative (mainly inductive) methods allow for identification of previously unknown processes, explanations of why and how phenomena occur, and the range of their effects (Pasick et al., 2009). Mixed methods research, then, is more than simply collecting qualitative data from interviews, or collecting multiple forms of qualitative evidence (e.g., observations and interviews) or multiple types of quantitative evidence (e.g., surveys and diagnostic tests). It involves the intentional collection of *both* quantitative and qualitative data and the combination of the strengths of each to answer research questions.
- ❖ **The integration of multiple forms of data:** In mixed methods studies, investigators intentionally integrate or combine quantitative and qualitative data rather than keeping them separate. The basic concept is that integration of quantitative and qualitative data maximizes the strengths and minimizes the weaknesses of each type of data. This idea of integration separates current views of mixed methods from older perspectives in which investigators collected both forms of data, but kept them separate or casually combined them rather than using systematic integrative procedures. One of the most difficult challenges is how to integrate different forms of data. Three approaches have been discussed in the literature (Creswell & Plano Clark, 2011): merging data, connecting data, and embedding data.
 - **Merging data.** This integration consists of combining the qualitative data in the form of texts or images with the quantitative data in the form of numeric information. This integration can be achieved by reporting results together in a discussion section of a study, such as reporting first the quantitative statistical results followed by qualitative quotes or themes that support or refute the quantitative results. It also can be achieved by transforming one dataset (e.g., counting the occurrence of themes in a qualitative dataset) so that the transformed qualitative results can be compared with the quantitative dataset (Sandelowski, Voils, & Knaf, 2009). This integration also can occur through the use of tables or figures that display both the quantitative and the qualitative results (i.e., data displays).
 - Wittink, Barg, and Gallo (2006) studied the concordance and discordance between physicians and patients about depression status. The parent study for this research was the Spectrum Study (2001-2004), supported by grants from the NIMH (MH62210-01, MH62210-01S1, MH67077). Data were collected from patients aged 65 and older. Quantitative data consisted of ratings of depression from physicians as well as self-reported patient ratings of depression and anxiety. Qualitative data consisted of semi-structured interviews with patients. On the rating scales, the standard measures did not differentiate patients whose physicians rated them as depressed from those whose physicians did not rate them as depressed. Qualitative themes, however, identified a typology of differing emotions and feelings by patients toward physicians. Differences among the qualitative categories in terms of demographics and quantitative ratings were examined in a table.
 - **Connecting data.** This integration involves analyzing one dataset (e.g., a quantitative survey), and then using the information to inform the subsequent data collection (e.g., interview questions, identification of participants to interview). In this way the integration occurs by connecting the analysis of results from the initial phase with the data collection from the second phase of research.
 - Dawson et al. (2002-2009) studied non-abusing drinkers diagnosed with hepatitis C in a NIAAA R01 project funded in 2002-2007 and reported by Stoller et al. (2009). An initial qualitative component based on interviews and Internet postings described new decision factors related to curtailing the consumption of alcohol. These findings were used to develop new items for a quantitative instrument, which was administered in the second phase to assess the prevalence of the new factors and their association with current drinking.



- **Embedding data.** In this form of integration, a dataset of secondary priority is embedded within a larger, primary design. An example is the collection of supplemental qualitative data about how participants are experiencing an intervention during an experimental trial. Alternatively, a qualitative data collection may precede an experimental trial to inform development of procedures or follow an experimental trial to help explain the results of the trial.
 - Miaskowski et al. (2006-2012) compared two doses (high and low) of a nurse-led psycho-educational intervention to assist oncology outpatients to effectively manage their pain in an R01 project funded by NCI and NINR. They implemented an RCT study to compare the two treatments in terms of various repeated measure patient outcomes, including pain levels. Embedded within the RCT study, they also gathered qualitative data in the form of audiotapes of the intervention sessions, along with nurse and patient notes, to describe the issues, strategies, and interactions experienced during the intervention. The results provide evaluation of both the outcomes and process of the intervention.

When Should Mixed Methods Be Used?

- ❖ **Research problems suitable for mixed methods:** The research methods in an investigation must fit the research problem or question. Problems most suitable for mixed methods are those in which the quantitative approach or the qualitative approach, by itself, is inadequate to develop multiple perspectives and a complete understanding about a research problem or question. For example, quantitative outcome measures may be comprehensible using qualitative data. Alternatively, qualitative exploration may usefully occur prior to development of an adequate instrument for measurement. By including qualitative research in mixed methods, health science investigators can study new questions and initiatives, complex phenomena, hard-to-measure constructs, and interactions in specific, everyday settings, in addition to experimental settings.
- ❖ **Typical reasons for using mixed methods:** There are several reasons for using mixed methods in health science research. Researchers may seek to view problems from multiple perspectives to enhance and enrich the meaning of a singular perspective. They also may want to contextualize information, to take a macro picture of a system (e.g., a hospital) and add in information about individuals (e.g., working at different levels in the hospital). Other reasons include to merge quantitative and qualitative data to develop a more complete understanding of a problem; to develop a complementary picture; to compare, validate, or triangulate results; to provide illustrations of context for trends; or to examine processes/experiences along with outcomes (Plano Clark, 2010). Another reason is to have one database build on another. When a quantitative phase follows a qualitative phase, the intent of the investigator may be to develop a survey instrument, an intervention, or a program informed by qualitative findings. When the quantitative phase is followed by the qualitative phase, the intent may be to help determine the best participants with which to follow up or to explain the mechanism behind the quantitative results (Plano Clark, 2010). These are a few of the reasons that might be cited for undertaking mixed methods research; a more expansive list is available in Bryman's (2006) study of investigators' reasons for integration.

How Should a Mixed Methods Study be Designed?

- ❖ **Consider several general steps in designing a mixed methods study:** There is no rigid formula for designing a mixed methods study, but the following general steps should provide some guidance, especially for an investigator new to mixed methods.
 - Preliminary considerations:
 - Consider your philosophy and theory
 - Consider if you have resources (e.g., time, financial resources, skills)
 - Consider the research problem and your reasons for using mixed methods
 - State study aims and research questions that call for qualitative, quantitative, and mixed methods, and that incorporate your reasons for conducting a mixed methods study.
 - Determine your methods of quantitative and qualitative data collection and analysis (when it will be collected, what emphasis will be given to each, and how they will be integrated or mixed).



- Select a mixed methods design that helps address your research questions and the data collection/analysis/integration procedures.
 - Collect and analyze the data.
 - Interpret how the combined quantitative and qualitative approaches contribute to addressing the research problem and questions.
 - Write the final report making explicit the contribution of the mixed methods approach.
- ❖ **Consider several basic considerations within these steps:**
- **Theoretical and conceptual orientation:** The choice of a mixed methods design should be informed by a theoretical and conceptual orientation that supports the overarching science and needs of the study. In some cases, there may be one or more frameworks informing the study. For example, the orientation might be a transformational model in which the intent is to assist the community and to bring about change. Complexity theory may be used in primary care projects seeking to change clinical practice.
 - **Fixed and emergent mixed methods designs:** Mixed methods studies may be either fixed or emergent. In a fixed design, the methods are predetermined at the start of the research process. In this design the investigators have a specific intent to mix qualitative and quantitative approaches at the start of the study. In an emergent (or cyclical) design, the methods emerge during the process of the research rather than being predetermined at the outset of the study. For example, a community-based design might include results about the needs of communities that subsequently inform the design of further phases of the project.
- ❖ **Recognize that mixed methods designs differ in several important ways:**
- **Analytic logic.** Discussions about the types of mixed methods designs available to the NIH investigator still are emerging and being debated in the literature with several typologies available (see Creswell & Plano Clark, 2011, for an overview of available typologies). However, the design possibilities follow the reasons for mixed methods, and they can be differentiated analytically in terms of whether the quantitative and qualitative datasets are merged into one analysis or interpretation to address the research questions, or whether one dataset builds on the results of an initial dataset.
 - **Timing.** The qualitative and quantitative data may be timed so that they are collected concurrently or roughly at the same time. This concurrent data collection is attractive to a health investigator who must maximize the amount of data collected in the field for the time spent. Alternatively, an investigator may collect the data in a sequence with one phase of collection followed by another. This approach is useful for single investigators who have ample time to stretch data collection over a lengthened period, and when the investigator needs results from an initial phase to inform a subsequent phase.
 - **Priority.** In some mixed methods studies, the quantitative and qualitative research is equally emphasized. In other studies, priority is given to either the quantitative or the qualitative research. An unequal priority occurs when the investigator embeds a secondary dataset within a larger, primary design or reports unequal quantitative or qualitative components in the study.
 - **Point of interface.** The “point of interface” (Morse & Niehaus, 2009), or the point where mixing occurs, differs depending on the mixed methods design. This “point” may occur during data collection (e.g., when both quantitative items and qualitative open-ended questions are collected on the same survey), during data analysis (e.g., when qualitative data are converted or transformed into quantitative scores or constructs to be compared with a quantitative dataset), and/or during data interpretation (e.g., when results of quantitative analyses are compared with themes that emerge from the qualitative data).
 - **Single study or multiphase program of inquiry.** Some mixed methods projects employ a design that is a “stand-alone” design, a single study conducted by an investigator or a team of investigators. Other mixed methods projects (i.e., those typically advanced in large NIH applications) consist of multiple studies, some quantitative and some qualitative, that build on each other and contribute to an overall program objective or purpose.



- ❖ **Consider examples of specific designs:** The following possibilities for design are not meant to be exhaustive and are intended to be illustrative of several possible approaches that have been used in health science research (see Creswell & Plano Clark, 2011; Morse & Niehaus, 2009). More complex designs are commonplace and are driven by the specific questions and aims in the particular investigations.
 - **Convergent (or parallel or concurrent) designs:** When the intent is to merge concurrent quantitative and qualitative data to address study aims, the investigator combines both quantitative and qualitative research. This design is known as a convergent design. For example, an investigator might collect both quantitative correlational data as well as qualitative individual or group interview data and combine the two to best understand participants' experiences with a health promotion plan. The data analysis consists of merging data and comparing the two sets of data and results.
 - **Sequential (or explanatory sequential or exploratory sequential) designs:** Another design possibility is to have one dataset build on the results from the other. These are known as sequential designs, and they may begin by a qualitative exploration followed by a quantitative follow up or by a quantitative analysis explained through a qualitative follow up. A popular approach in the health sciences is the latter in which qualitative data help to explain in more depth the mechanisms underlying the quantitative results. The quantitative results from a quality-of-life scale may be explained by collecting qualitative follow-up data to better understand the responses on the scale. Another popular approach is to first explore with qualitative data collection followed by using the resulting qualitative findings to design a quantitative instrument, and then to administer the instrument to a sample from a population. For example, the use of group interview data themes to design a questionnaire about the risks involved in a treatment for diabetes might be followed by an administration of the instrument to a large sample to determine whether the scales can be generalized.
 - **Embedded (or nested) designs:** A popular design in the health sciences is to use quantitative and qualitative approaches in tandem and to embed one in the other to provide new insights or more refined thinking. These designs are called embedded or nested designs. They may be a variation of a convergent or sequential design. A prototype would be to conduct an intervention study and to embed qualitative data within the intervention procedures to understand how experimental participants experience the treatment. Qualitative data may be used prior to the intervention to inform strategies to best recruit individuals or to develop the intervention, during the experiment to examine the process being experienced by participants, or after the experiment to follow up and better understand the quantitative outcomes. For example, an experimental study of outcomes from an alcohol prevention program might be followed by individual interviews with participants from the experimental group to help determine why the program worked.
 - **Multiphase designs:** A multiphase design emerges from multiple projects conducted over time linked together by a common purpose. These are called multiphase projects, and they are used frequently in the health sciences. They commonly involve convergent and sequential elements. For example, the overall purpose might be to develop, test, implement, and evaluate a health prevention program for adolescents. This type of design calls for multiple projects – one quantitative, one qualitative, one mixed and so forth – conducted over time with links in place so that one phase builds on another with the common overall objective of designing and testing a health prevention program.

What are the Methodological Challenges in Conducting Mixed Methods Investigations?

- ❖ **Methodological issues:** In mixed methods research, methodological issues arise that need to be anticipated. These methodological issues have been detailed in several books (see Creswell & Plano Clark, 2011; Teddlie & Tashakkori, 2009).
 - **Resources.** Because multiple forms of data are being collected and analyzed, mixed methods research requires extensive time and resources to carry out the multiple steps involved in mixed methods research, including the time required for data collection and analysis. [See section on Building Infrastructure and Resources.]
 - **Teamwork.** In multidisciplinary, interdisciplinary, and transdisciplinary teamwork, different approaches might emerge to an investigation as well as different writing styles. Team leaders need to anticipate the challenges and benefits of a team approach to mixed methods research [See section on Forming the Mixed Methods Research Team.]



- **Page and word limitations.** Despite current NIH page limitations, investigators still need to justify their procedures in a high-quality mixed methods study. Organizing information into a table or presenting a figure of the mixed methods procedures can aid in conserving space. Page and word limitations also affect publication of mixed methods studies in scholarly journals in which word limitations call for creative ways to present material (see Stange, Crabtree, & Miller, 2006). [See section on Developing an R Series Plan.]
- **Sampling issues.** Detailed discussions about the sampling issues involved in mixed methods research and in specific designs is beyond the scope of this document. Adequate discussions are available elsewhere (Creswell & Plano Clark, 2011; Teddlie & Yu, 2007). However, some challenges specific to concurrent designs (i.e., merging quantitative and qualitative research) include having adequate sample sizes for analyses, using comparable samples, and employing a consistent unit of analysis across the databases. For sequential designs (i.e., one phase of qualitative research builds on the quantitative phase or vice versa), the issues relate to deciding what results from the first phase to use in the follow-up phase, choosing samples and estimating reasonable sample sizes for both phases, and interpreting results from both phases.
- **Analytic and interpretive issues.** Issues arise during data analysis and interpretation when using specific designs. When the investigator merges the data during a concurrent design, the findings may conflict or be contradictory. A strategy of resolving differences needs to be considered, such as gathering more data or revisiting the databases. For designs involving a sequential design with one phase following the other, the key issues surround the “point of interface” in which the investigator needs to decide what results from the first phase will be the focus of attention for the follow-up data collection. Making an interpretation based on integrated results may be challenging because of the unequal emphasis placed on each dataset by the investigator or team, the accuracy or validity of each dataset, and whether philosophies related to quantitative or qualitative research can or should be combined.

Key References and Resources

- ❖ Bryman, A. (2006). Integrating quantitative and qualitative research: How is it done? *Qualitative Research*, 6, 97-113.
- ❖ Creswell, J. W., & Plano Clark, V. L. (2011). *Designing and conducting mixed methods research*. (2nd ed.). Thousand Oaks, CA: Sage.
- ❖ Dawson, N. V. (2002-2007). Alcohol reduction in medical illnesses: HCV as prototype. NIH Grant #1R01AA013302-01A1.
- ❖ Greene, J. C. (2007). *Mixed methods in social inquiry*. San Francisco: John Wiley & Sons.
- ❖ Hesse-Biber, S. N. (2010). *Mixed methods research: merging theory with practice*. New York: Guilford.
- ❖ Johnson, R. B., Onwuegbuzie, A. J., & Turner, L. A. (2007). Toward a definition of mixed methods research. *Journal of Mixed Methods Research*, 1(2), 112-133.
- ❖ Miaskowski, C. (2006-2012). Improving cancer pain management through self-care. Research grant funded by the National Cancer Institute and the National Institute of Nursing Research (5R01CA116423).
- ❖ Mertens, D. M. (2009). *Transformative research and evaluation*. New York: Guilford.
- ❖ Morgan, D. L. (2007). Paradigms lost and pragmatism regained: Methodological implications of combining qualitative and quantitative methods. *Journal of Mixed Methods Research*, 1(1), 48-76.
- ❖ Morse, J., & Niehaus, L. (2009). *Mixed method design: Principles and procedures*. Walnut Creek, CA: Left Coast Press.
- ❖ O’Cathain, A. O., Murphy, E., & Nicholl, J. (2010). Three techniques for integrating data in mixed methods studies. *BMJ*, 341, c4587.
- ❖ Pasick, R. J., Burke, N. J., Barker, J. C., Galen, J., Bird, J. A., Otero-Sabogal, R., et al. (2009). Behavioral theory in a diverse society: Like a compass on Mars. *Health Education Behavior*, 36(5), 11S-35S.



- ❖ Plano Clark, V. L. (2010). The adoption and practice of mixed methods: U.S. trends in federally funded health-related research. *Qualitative Inquiry*, 6(6), 428-440.
- ❖ Sandelowski, M., Voils, C. I., & Knafl, G. (2009). On quantitizing. *Journal of Mixed Methods Research*, 3(3), 208-222.
- ❖ Song, M., Sandelowski, M., & Happ, M. B. (2010). Current practices and emerging trends in conducting mixed methods intervention studies in the health sciences. In: A. Tashakkori & C. Teddlie (Eds.), *Handbook of mixed methods in social & behavioral research* (2nd ed., pp. 725-747). Thousand Oaks, CA: Sage.
- ❖ Stange, K. C., Crabtree, B. F., & Miller, W. L. (2006). Publishing multimethod research. *Annals of Family Medicine*, 4, 292-294.
- ❖ Stoller, E. P., Webster, N. J., Blixen, C. E., McCormick, R. A., Hund, A. J., Perzynski, A. T., Kanuch, S. W., Thomas, C. L., Kercher, K., & Dawson, N. V. (2009). Alcohol consumption decisions among nonabusing drinkers diagnosed with hepatitis C: An exploratory sequential mixed methods study. *Journal of Mixed Methods Research*, 3(1), 65-86.
- ❖ Teddlie, C., & Tashakkori, A. (2009). *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences*. Thousand Oaks, CA: Sage.
- ❖ Teddlie, C., & Yu, F. (2007). Mixed methods sampling: A typology with examples. *Journal of Mixed Methods Research*, 1(1), 77-100.
- ❖ Wittink, M. N., Barg, F. K., & Gallo, J. J. (2006). Unwritten rules of talking to doctors about depression. *Annals of Family Medicine*, 4(4), 302-309.



Teamwork, Infrastructure, Resources, and Training for Mixed Methods Research

This section discusses the following key considerations related to the process of engaging in mixed methods research:

- ❖ **Forming the Mixed Methods Research Team**
- ❖ **Leading and Guiding a Mixed Methods Research Team**
- ❖ **Building Infrastructure and Resources**
- ❖ **Training of the Mixed Methods Research Team**

Forming the Mixed Methods Research Team

- ❖ **The nature and structure of the mixed methods research team is significant:** Successful applications for NIH grants are highly likely to call upon the skills and insight of a team of researchers, and may well include investigators at various stages of their career trajectories.
- ❖ **The nature of the research question shapes the nature of the research team compiled to address them:** The questions that are driving the research initiative determine the expertise required to address them. The design follows from the questions: multidisciplinary, interdisciplinary, or transdisciplinary. There are different kinds of teams and ways of working together that are better suited to different kinds of questions.

Distinguishing among multidisciplinary, interdisciplinary, and transdisciplinary team research:

- Rosenfield (1992) created a taxonomy of three levels of collaborative research between social and health scientists: multidisciplinary, interdisciplinary, and transdisciplinary research. The basic definitions of each are outlined below in Box 1.

Box 1. Rosenfield's (1992) Taxonomy of Three Levels of Collaboration

Multidisciplinary (Level One): Researchers work in parallel or sequentially from a disciplinary-specific base to address common problems.

Interdisciplinary (Level Two): Researchers work jointly but from disciplinary-specific basis to address a common problem.

Transdisciplinary (Level Three): Researchers work jointly using a shared conceptual framework drawing together disciplinary-specific theories, concepts, and approaches to address common problems (p. 1351).

- ❖ Crabtree et al. (1994) provided a diagrammatic interpretation of the different ways in which disciplines contribute to each level of collaborative research (Crabtree, Miller, Addison, Gilchrist, & Kuzel, 1994).
- ❖ The boundaries between the different levels of collaboration are often somewhat blurry (Adler & Stewart, 2010). However, the idea of thoughtful and purposeful collaboration that goes beyond any one discipline has been central to the development of team science. It is hoped that such collaboration will make an important contribution to solving important health problems (e.g., Stokols, Hall, Taylor, & Moser, 2008; Adler & Stewart, 2010)



- ❖ **Successful mixed methods teams include breadth and depth of expertise:** The prioritization of breadth versus depth of expertise of team members is an early issue to be addressed in the formation of a team. The construction of a successful mixed methods team requires planning the integration of both varied methodological and disciplinary expertise. It is important for the team to include the breadth of disciplines relevant to the key questions and with the conceptual and analytic depth to answer them. Mixed methods research teams need to incorporate individual researchers who are collectively capable of conducting each aspect of the research (breadth). In addition, it is important that the team has sufficient capacity for researchers to support and challenge one another in each aspect of the research so as to produce the highest quality research (depth).
- ❖ **A mixed methods team is not simply a team of individual researchers with distinct methodological traditions and skills:** Successful mixed methods research requires that the team transcend distinct methodological and epistemological differences at least to some extent, so as to create processes for data collection and analysis that can integrate both qualitative and quantitative approaches. The point and processes of integration are important issues for careful deliberation. Ideally, multiple members of the research team should be engaged in the integration processes, rather than having integration fall to a single investigator.
- ❖ **The relationship of each member of the research team to mixed methods research:** One question likely to surface in forming a mixed methods team is whether all of the team members need to be mixed methods researchers. While all team members need to be open to a mixed methods perspective, it is not necessary or even possible for everyone to hold expertise in all methods employed in any research project. A successful leader of a mixed methods application will integrate team members who hold distinct methodological positions and expertise and those who cross methodological and disciplinary boundaries. The nature of these teams may be multidisciplinary, interdisciplinary, or transdisciplinary.
- ❖ **The capacity of a mixed methods research team takes time to develop:** A mixed methods perspective cannot simply be added at the end of the research development process by including a “mixed methods expert” on the team. Rather, in order for mixed methods research to be successful, this perspective and approach should be adopted by core team members, and evolve over time. The research development process should be organic and should start as soon as it becomes clear that mixed methods research is appropriate for addressing the proposed research questions.
- ❖ **A team that has a history of successful collaboration is in a strong position to demonstrate capacity for mixed methods research:** As in all research, but perhaps particularly so for mixed methods teams, a record of successful collaboration among the key personnel is critical to establishing the credibility of any proposed effort. The team will need to demonstrate indicators of competency and experience along methodological lines. The team will need to consider what products (such as publications) can demonstrate a collective history. Research products (such as publications) should represent the array of methods being used within the team (qualitative, quantitative, and mixed methods).
- ❖ **Mixed methods research is not ideal for every problem or person:** There are significant benefits to taking a mixed methods approach to addressing a research question in terms of innovation, creativity, and synergy, and, subsequently, the data generated. There are, however, also necessary tradeoffs in terms of complexity of process, time investment, and comfort with uncertainty. Not all research questions will benefit from such a tradeoff. Similarly, not all researchers are well suited to it.

Leading and Guiding a Mixed Methods Research Team

- ❖ **The skills and outlook of the principal investigator or research leader are critical:** As in all successful research projects, the skills and perspective of the principal investigator or research leader is paramount in mixed methods research. However, constructing successful mixed methods research raises particular leadership issues. The leader of a mixed methods research team should espouse a broad perspective on the utility of different methodologies, an ability to support and acknowledge different team member contributions, an effort to maintain continual dialogue about issues in working together, a sensitivity to workloads of team members that may pose challenges to working on the project, and support for educating team members in different methodologies, when needed.
- ❖ **An effective leader for a mixed methods project should be experienced and interested in qualitative, quantitative, and mixed methods research:** Beyond the need for the research leader to be knowledgeable about the array of methods employed in the study, the training needs for any single individual in a mixed methods team



are dependent on the specific roles of each member, as well as the capacity of other team members. This is especially true for the leader of the mixed methods team. People in positions of team leadership will benefit from having a broad level of experience across qualitative, quantitative, and mixed methods methodologies. When the leader does not have such experience, there is a need to demonstrate a commitment to and an appreciation for the breadth of methodologies and disciplinary approaches integrated in the proposed work. The most effective mixed methods team leader may not be the greatest expert in any one approach, but rather the person who is able to bridge differences and create synergy.

- ❖ **A shared vision and defined roles within the mixed methods team is critical:** In the formation of a successful mixed methods team, it is essential to construct a shared vision of the purpose of a mixed methods approach as it relates to the research problem or question. It will be important to clearly demonstrate how the team will work together, how each individual's role is defined, and how these roles are interrelated, conceptually, spatially, and temporally. Defined roles will be important for effective data collection, analysis, integration, and interpretation. Achieving and maintaining a shared vision within the team requires a significant investment of time and energy on the part of the leader as well as other team members.
- ❖ **A mixed methods team can be structured as a linear relationship or as a spoked wheel:** In a linear structure, quantitative and qualitative perspectives and expertise will sit at either end of the research team and processes, with key individuals bridging these distinct perspectives. In a spoked-wheel structure, each individual member of the research team will be tied into some core component of the research initiative, possibly via the principal investigator and/or a common data source.
- ❖ **Different team perspectives need to be recognized and honored:** The priority given to different perspectives (both methodological and philosophical) in the overall design will likely be a function of team member characteristics, such as the seniority of team members and the leader of the team. These different perspectives, manifest in team/personality dynamics, should be recognized and honored throughout the application development process. Ideally, mixed methods teams will include experienced members from each of the methods/disciplines included in the design. Team leaders need to recognize that the most persuasive products result from significant engagement by each of the team members in the majority of tasks related to the project. Such engagement has the potential to significantly increase the time and efforts involved in the application writing process.

Building Infrastructure and Resources

- ❖ **All research initiatives benefit from being conducted in a well-resourced and dynamic research environment:** It is necessary to have access to resources that benefit the specific needs and requirements of a particular initiative. In most ways, mixed methods proposals will have considerable overlap with complex single-method studies in terms of resource and infrastructure needs. An adequate library service, for example, is important for all studies. However, there are aspects of mixed methods research that warrant explicit consideration in terms of necessary resources and support.
- ❖ **Mixed methods research is likely to require a wider array of computer software needs than a single method study:** Both statistical and qualitative analysis software are likely to be integral tools for successful mixed methods projects. This raises issues in relation to establishing necessary analytic expertise for both qualitative and quantitative methods.
- ❖ **Mixed methods teams will benefit from being able to call upon other experienced and informed colleagues at their own institutions:** Institutional capacity in terms of training opportunities, research capabilities, and institutional knowledge related to the various methods are all important factors that may need to be incorporated into a mixed methods study. Departments, centers, and individuals beyond those who are actively engaged in the proposed research can serve as useful support for the ongoing work.
- ❖ **Effective mixed methods research teams require collective as well as individualized workspace:** Research space for mixed methods research will need to accommodate various data collection approaches, including possible primary data collection. It is also especially valuable to prioritize the need for the research team to have the ability to come together on a regular basis (either physically or virtually). Frequent and ongoing interaction will benefit the productivity of the group and the quality of the research. For some teams (particularly those working long distance and even globally), the creation of virtual space in which to collaborate may be most effective.



- ❖ **Flexibility for staffing support:** The various data collection and analytic approaches incorporated into mixed methods research require specific types and levels of staffing support, and careful management throughout the research process.
- ❖ **Team members can profit from mixed methods training and workshops:** Mixed methods research raises many distinct challenges in terms of the education and management of the research team. Identifying and making available formal coursework, short in-person workshops, and online courses on mixed methods are likely to improve collaboration, research products, and future capacity.
- ❖ **Mixed methods teams may benefit from the ability to work together virtually:** Establishing virtual spaces and tools that facilitate brainstorming, instrument development, data sharing, and analytic collaboration will be increasingly important for effective mixed methods teams.

Training of the Mixed Methods Research Team

- ❖ **Engaging in mixed methods research can serve as a learning opportunity for team members:** It is possible to prioritize collaborative educational opportunities for all members of a mixed methods team in the research design in order to build methodological capacity throughout the team. Effective prioritization is most likely to occur when research leaders understand and appreciate each team member's desire to expand their methodological perspective. Productivity and effective collaborations on a mixed methods team largely will be defined by explicit and shared understanding of each member's expectations and goals.
- ❖ **Mixed methods research is likely to require additional training some or all of the research team:** Until recently, it has been almost inevitable that all researchers will have a stronger foundation in and comfort with either quantitative or qualitative methods of inquiry, and the philosophical traditions that underpin each. The increasing acceptance of mixed methods approaches may be changing this reality – but only slowly. It is still the case that most researchers are formally trained in one tradition, potentially with supplemental training in the other. It is also the case that many researchers have only formal training in one tradition, and only an interest in or experience with the other. The issue of how to adequately demonstrate competence across methods within the team is worth careful consideration.
- ❖ **Appropriate and effective training for mixed methods research need not necessarily occur in a traditional classroom setting:** Embracing an explicit mixed methods approach to conducting health research is still relatively new, and thus many researchers come to mixed methods long after their formal training is complete. Similarly, while the numbers of programs that provide courses in mixed methods continues to grow, this type of training is not available to all. It is both appropriate and necessary for those interested in and/or engaging in mixed methods research to be self-directed in their learning – including taking part in mixed methods conferences and immersing oneself in the growing mixed methods literature both within health and from other areas of scientific inquiry.
- ❖ **Mixed methods analysis benefits from team members' comfort with multiple types of data and analysis methods and approaches:** Mixed methods research involves integration of data such that the analytic process benefits from multiple perspectives and data sources. In order for team members to fully engage with the analytic process, it is necessary to establish familiarity and comfort with the various data sources generated and analytic approaches undertaken.
- ❖ **Mixed methods research can benefit from adopting training and materials from other scholarly disciplines:** To the extent that additional formal training is either desirable or needed for members of a research team, training from other research areas (such as education, or more broadly the social, behavioral, or cognitive sciences) may be modified for a health application.
- ❖ **Building mixed methods expertise should explicitly prioritize collective capacity:** When additional training is necessary for some team members in either qualitative, quantitative, or mixed methods research, it may be most effective to create collective training that the team (or parts of it) can engage in together. Such collective training can identify areas of capacity strengths and possible shortfalls.



Key References and Resources

- ❖ Adler, N.E., & Steward J. (2010). Using team science to address health disparities: MacArthur Network as case example. *Annals of the New York Academy of Sciences*, 1186, 252-260.
- ❖ Committee on Facilitating Interdisciplinary Research (2004). *Facilitating interdisciplinary research*. Washington, D.C., National Academies Press.
- ❖ Crabtree, B.F., Miller, W.L., Addison, R.B., Gilchrist, V.J., & Kuzel, A.J. (1994). *Exploring collaborative research in primary care*. New York, New York: Sage Publications.
- ❖ Curry, L. A., O’Cathain, A., Plano Clark, V. L., Aroni, R., Fetters, M., & Berg, D. (in press). The role of group dynamics in mixed methods health sciences research teams. *Journal of Mixed Methods Research*.
- ❖ Kessel, F., Rosenfeld, P. L., & Anderson, N. B. (Eds.). (2008). *Interdisciplinary research: Case studies from health and social science*. New York, Oxford University Press.
- ❖ Mabry, P. L., Olster, D. H., Morgan, G. D., & Abrams, D. B. (2008) Interdisciplinarity and systems science to improve population health: A view from the NIH Office of Behavioral and Social Science Research. *American Journal of Preventive Medicine*, 35(2S), S211-S224.
- ❖ O’Cathain, A., Murphy, E., & Nicholl, J. P. (2008) Dysfunctional, multidisciplinary or interdisciplinary? Team working in mixed methods research. *Qualitative Health Research*, 18, 1574-85.
- ❖ Rosenfield, P. (1992) The potential of transdisciplinary research for sustaining and extending linkages between the health and social sciences. *Social Science and Medicine*, 35(11), 1343-1357.
- ❖ Shulha, L. M., & Wilson, R. J. (2003). Collaborative mixed methods research. In A. Tashakkori & C. Teddlie (Eds.), *Handbook of mixed methods in social and behavioral research* (pp. 639-669). Thousand Oaks: Sage Publications.
- ❖ Stokols, D., Hall, K. L., Taylor, B., K., & Moser, R. P. (2008) The science of team science: Overview of the field and introduction to the supplement. *American Journal of Preventive Medicine*, 35(2S), S77-S89.



Developing an R Series Plan that Incorporates Mixed Methods Research

A primary mechanism for obtaining NIH grants to conduct mixed methods research is through research grants (R series) offered by the NIH Institutes and Centers. These grants include R01 research projects, R03 small grants, and R21 exploratory/developmental research grants. As researchers plan their mixed methods research projects and develop their R series applications, they need to follow the NIH instructions as well as incorporate key elements of mixed methods research. This section is organized in the following topics and offers suggestions for how to bring these two sets of criteria together:

- ❖ **General Comments about Preparing Mixed Methods Research Applications**
- ❖ **The Research Plan**
- ❖ **Additional Application Elements**

General Comments about Preparing Mixed Methods Research Applications

- ❖ **Follow the basic instructions for the NIH R Series Applications.** Guidelines for the process of developing and submitting research applications to NIH can be found on the NIH website. R series applications need to follow the PHS SF424 standard forms as described in the “PHS SF424 (R&R) Application and Electronic Submission Information.” The PHS SF424 instructions discuss requirements for the major sections of a research plan, including the study aims, the significance, innovation, and approach sections of the research strategy, and several additional categories of supporting information. In addition, there are several online resources to assist investigators with preparing research applications to NIH.
- ❖ **Match the narrative page length to the appropriate funding mechanism.** The PHS SF424 forms require that the project investigators include a 1-page statement of specific aims. In addition, the length of the research strategy narrative is limited to 12 pages for R01 applications and to 6 pages for R03 and R21 applications. These limits require investigators to carefully think through and articulate their mixed methods approach so that the application provides both the essential details and is concise.
- ❖ **Embed mixed methods throughout the application elements.** The use of a mixed methods approach has implications for each part of the development of the research plan. Investigators need to have basic knowledge about mixed methods research and embed important mixed methods components into the aims and research strategy of the application. These components target the application as a mixed methods investigation and relate to the quality of the overall mixed methods approach.
- ❖ **Start the development process early to prepare a high quality mixed methods application.** Preparing a successful mixed methods research plan within the narrative page limits is a challenge. It is important to think through the mixed methods components of a research plan in advance and to view the mixed methods approach as an integral aspect of the project as opposed to a minor add-on feature. Investigators need to allow sufficient time to develop and refine the overall mixed methods plan into a coherent and logical application.
- ❖ **Reflect on the Research Project Evaluation Criteria while developing the application.** The PHS SF424 instructions include “Research Project Evaluation Criteria” for evaluating the overall impact of a project as well as the quality of a project’s significance, investigator(s), innovation, approach, and environment. These criteria are considered in the context of a mixed methods application in the Reviewing Mixed Methods Applications section of this document. Investigators should keep these criteria in mind to evaluate their own research plans and applications during the development and writing process.



The Research Plan

The PHS SF424 (R&R) instructions call for several key sections within the overall research plan. Some sections (e.g., Introduction, Enrollment Report, and Progress Report) apply only to applications that are renewals or revisions, but all applications need to include a section on Specific Aims and sections on Significance, Innovation, and Approach within the Research Strategy narrative. A key to a successful mixed methods application is demonstrating that there is congruence among all the elements of the plan, including the study aims, the overall design, the specific procedures, the investigation team members, the available resources, and the budget parameters.

Here we consider how mixed methods research can be embedded within the following application elements:

- ❖ Specific Aims
- ❖ Research Strategy
 - Significance
 - Innovation
 - Approach
- ❖ Additional Application Elements
 - The Project Summary/Abstract
 - The Protection of Human Subjects
 - Facilities & Other Resources
 - Biographical Sketches
 - Budget

Specific Aims

The PHS SF424 instructions for Specific Aims state:

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Writing Specific Aims for a Mixed Methods Application

- ❖ **State an overall goal that addresses the overarching research problem or question.** Provide a statement of the overall goal (or purpose or intent) of the application. The types of goals that lend themselves to mixed methods inquiry are those that address multiple levels of influence, such as theory development and testing, process and outcomes, and context and meanings. Ensure that the goal informs the specific aims and research questions, leading naturally to a mixed methods approach.
- ❖ **State study aims that identify discrete components of the goal to be achieved in the investigation.** Aims should be driven by the substantive research question, not by the methodology. The methodology should flow naturally from the aims and question.
- ❖ **For each aim, identify the methodological approach to be used to accomplish it (which may be quantitative, qualitative, or mixed methods) to tie together the goals of the study with the methods.**
 - Aims that call for a qualitative approach may be inductive in nature; emphasize exploration; contextualize



individual behavior, group behavior, organizational dynamics, and cultural influences; and convey the researchers' openness for learning from participants and data sources.

- Aims that call for a quantitative approach may be deductive in nature; emphasize measurable constructs; test theorized associations; and demonstrate probable causality or generalizability.
 - Aims that call for a mixed methods approach require the integration of qualitative and quantitative data and results to yield multi-dimensional, synergistic understandings of the phenomena of interest; the use of qualitative methods to explain and elaborate quantitative findings; or the use of quantitative methods to generalize, test, or confirm qualitative findings.
- ❖ **Order the aims so that they are congruent with the overall approach as discussed in the Research Strategy section of the application.**
- **Aims that will be addressed concurrently:** If two or more aims will be addressed concurrently within the investigation, then consider the relative importance of the aims for addressing the overall goal. List the study aims in the order of their priority. Include at least one aim that explicitly calls for the integration of qualitative and quantitative data and results. For example, investigators studying the efficacy and process of a treatment may choose to state three aims. First, they state a primary aim related to assessing treatment outcomes that will be addressed with an experimental approach. Second, they state a secondary aim to describe the process that will be addressed with a qualitative approach embedded within the experiment. Third, they state an aim that specifically calls for understanding the treatment outcomes within the context of the treatment process, which requires an integrated, mixed methods approach.
 - **Aims that will be addressed sequentially:** If two or more aims will be addressed sequentially within the investigation, then list the aims in the chronological order in which they will be addressed. This is particularly important when subsequent aims depend on the results of initial aims. If stating aims that separately lead to the use of qualitative and quantitative approaches, then provide an aim that explicitly calls for the investigators to connect from the results of an initial phase to the design and implementation of a subsequent phase. For example, investigators wanting to develop and test a culturally sensitive instrument may choose to state three aims. First, they state an aim to understand the cultural context of the phenomenon of interest that will be addressed with a qualitative approach. Second, they state an aim to develop the instrument based on the initial qualitative results that will be addressed with a connected mixed methods approach. Third, they state an aim to assess the construct of interest in the population that will be addressed with a quantitative approach utilizing the new instrument.

Research Strategy: Significance

The PHS SF424 instructions for the Significance section of the Research Strategy state:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Writing the Significance Section for a Mixed Methods Application

- ❖ Review literature on the topic that includes prior quantitative, qualitative, and mixed methods research. Consider adding critiques related to the methods that have and have not been used to study the topic.
- ❖ Identify a gap in the extant knowledge that suggests the need for gathering both quantitative and qualitative data to address the research problem.
- ❖ Identify the rationale for using mixed methods research, that is, the reasons for collecting both quantitative and qualitative data, in order to establish the importance of the problem and how the investigation will enhance scientific knowledge.



Research Strategy: Innovation

The PHS SF424 instructions for the Innovation section of the Research Strategy state:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Writing the Innovation Section for a Mixed Methods Application

- ❖ Provide arguments suggesting in what ways knowledge gained from the combination of quantitative and qualitative approaches will bring needed insights and improved practices that go beyond what could be learned from using one method alone.
- ❖ The use of mixed methods research may be an innovation in and of itself. If this is the case, investigators need to explain why the planned use of mixed methods can be considered an innovation. Examples of the use of mixed methods adding an innovative component to the investigation might be when the investigation includes novel approaches for integrating the quantitative and qualitative components of the project or when no prior research in the area of interest has used a mixed methods approach. Identify and highlight any innovative mixed methods approaches that are planned.
- ❖ Highlight any new tools or products that will be part of the mixed methods research approach, such as a new instrument or intervention that is developed and quantitatively tested based on qualitative findings.

Research Strategy: Approach

The PHS SF424 instructions for the Approach section of the Research Strategy state:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application.

Writing the Approach Section for a Mixed Methods Application

- ❖ **Introduce mixed methods research and the specific mixed methods design.** Since many reviewers may not be experienced with mixed methods research, investigators need to provide important background information about their choice to use mixed methods. To do this, investigators should:
 - Identify the use of mixed methods research and provide a definition of this approach. Cite studies that used a mixed methods approach from the health/disease area of interest (if available). Studies that used a mixed methods approach can often be located in databases using search terms such as “mixed methods” or “quantitative AND qualitative” in combination with terms representing the content area of interest.
 - Name the specific mixed methods design being used and cite studies illustrating its use. Locating examples can be a challenge, but searching databases using the relevant mixed methods design name [See the Section: Consider examples of specific designs] may identify several examples. A good strategy is to search NIH's



RePORTER database to locate successful applications that used a specific approach.

- State the reason(s) or rationale for the use of mixed methods and the selected design. Consider the variety of possible reasons for using mixed methods [See the Section: Typical reason for using mixed methods], such as seeking a more comprehensive account of a phenomenon, examining structure and process, or generating and testing hypotheses. The stated reason(s) should match the overall problem and research question and be congruent with the selected mixed methods design.
- Provide a diagram of the overall quantitative and qualitative procedures to assist reviewers in following the sequence of activities within the design. Since mixed methods approaches are necessarily complex, such a diagram will serve as an overview of the implementation of the quantitative and qualitative components of the study plan. Ivankova et al. (2006) provide guidelines for developing mixed methods diagrams.
- In addition to a diagram, many researchers find it useful to provide a table outlining the specific project sampling, procedures, and analytic strategies utilized to address each of the study aims. This helps to overview the research design in a concise format. See the provided examples: Box 2 and Box 3.

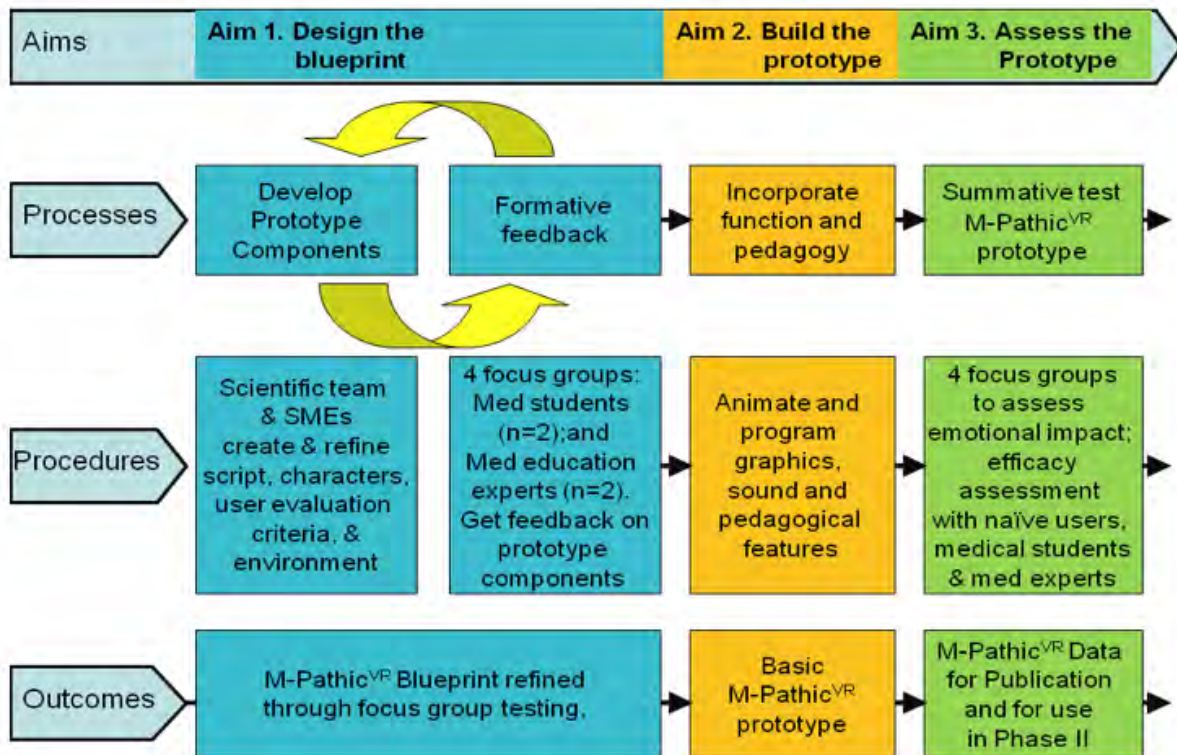
Box 2. Table of Strategy, Sample, Goals, and Analysis

Strategy	Sample	Goal	Analysis
Structured, standardized interviews	Stratified random sample (based on depressive symptoms) of older adult patients from non-academic primary care settings	Assess depressive symptom patterns and correlates	Multivariate regression models
Semi-structured interviews	Purposive: 50 African American and 50 white adults from Spectrum sample (who may or may not be depressed)	Identify an explanatory model for depression	Grounded theory
Free listing and pile sorts	First 25 African American and 25 white adults selected above for semi-structured interviews for free listing. Second 25 African American and 25 white adults selected above for pile sorts	Identify the domain of depression and its characteristics	Cultural consensus analysis
Ethnographic discourse-centered analysis	Purposive: Another 15 African American and 15 white adults who are depressed based on survey responses from the Spectrum sample	Identify social meaning of depression	Discourse analysis

Gallo, J.J. (2003-2007). The sociocultural context of depression in late life. Research grants funded by the National Institute of Mental Health (R01MH67077, R01MH62210, and R01MH62210-01S1).



Box 3. Table of Aims, Processes, Procedures, and Outcomes



NIH 3R03LM010052-0151, *Modeling Professional Attitudes and Teaching Humanistic Communication in VR (M-PathicVR™)*. Fetters MD and Kron FW(lead), Co-PIs

- ❖ **Provide detailed information describing and justifying the rigor of the qualitative data collection and analysis plans.** Qualitative data collection topics should include the qualitative design/approach, purposeful sampling strategy, sample size considerations, participant recruitment, data sources, data collection protocols, how data will be recorded, procedures, and relevant ethical issues. Qualitative data analysis topics should include data preparation procedures such as transcription, coding and theme development strategies, and qualitative data analysis software tools. In addition, detail specific strategies that relate to the rigor of the qualitative approach to ensure a high level of trustworthiness, credibility, transferability, and accuracy of the qualitative findings and conclusions. Examples of strategies include: triangulating multiple data sources or investigators when applicable, member checking results when participants are available to provide feedback, inter-coder agreement checks when reliability of codes is important, and prolonged engagement when data are collected in the field.
- ❖ **Provide detailed information describing and justifying the rigor of the quantitative data collection and analysis plans.** Quantitative data collection topics should include the quantitative design/approach, the population, sampling strategy, target sample size, participant recruitment, instruments (including reliability and validity evidence), intervention conditions (if relevant), procedures, data handling, and relevant ethical issues. Quantitative data analysis topics should include the tools and procedures for appropriate descriptive and inferential statistical analyses. In addition, detail specific strategies that relate to the rigor of the quantitative approach and address threats to internal and external validity.
- ❖ **Balance the information provided about the qualitative and quantitative data collection and analysis plans.** Although investigators should provide sufficient details about both types of data they plan to collect, many tend to write more about one method than the other because they know more about it. This can lead to a strong qualitative

or quantitative section and a weak quantitative or qualitative section. The presentation of the information, however, should be in proportion to the goals of the investigation. Therefore, an imbalance may be particularly problematic in convergent approaches where the results of each method are to be compared. Investigators need to be cognizant of any potential imbalance and ensure that they are providing an adequate level of detail about each approach. If an imbalance in the presentation occurs that does not match the balance suggested by the aims, investigators may consider adjusting their team to augment the expertise in the weaker area.

- ❖ **Explicitly state how the quantitative and qualitative components of the study will be combined.** Mixed methods research requires the integration of the quantitative and qualitative approaches within an overall design. Investigators need to describe this essential step in their applications.
 - In mixed methods approaches that involve the concurrent implementation of quantitative and qualitative methods, discuss the planned merging analytic and interpretation procedures for comparing, relating, or synthesizing the quantitative and qualitative data and results after discussing their separate analysis procedures. Include a discussion of how potential divergent or inconsistent findings will be managed and interpreted.
 - In mixed methods approaches that involve the sequential implementation of the quantitative and qualitative methods, discuss the planned procedures for connecting from the results of one phase to the collection of data in a subsequent phase (e.g., how the qualitative findings will be used to develop a quantitative instrument or treatment or how the quantitative results will be used to inform or design a qualitative follow-up). Investigators also should state how they will interpret the two sets of connected results.
- ❖ **Order the data collection and analysis topics to match the overall mixed methods designs and study aims.** The order of these topics needs to facilitate a concise description by the application authors. The order also needs to be logical and easy to follow for the reviewers.
 - In mixed methods approaches that involve the concurrent implementation of quantitative and qualitative methods, investigators often discuss the collection of both types of data (quantitative and qualitative) before discussing the analysis of both types of data (quantitative and qualitative). That is, a typical approach section for a concurrent implementation would be ordered:
 - Data Collection
 - * Quantitative
 - * Qualitative
 - Data Analysis and Interpretation
 - * Quantitative
 - * Qualitative
 - * Integration/Merging Procedures
 - In mixed methods approaches that involve the sequential implementation of the quantitative and qualitative methods, investigators often discuss the collection and analysis of the first type of data (quantitative or qualitative) and then discuss the collection and analysis of the subsequent type of data (qualitative or quantitative). That is, a typical approach section for a sequential implementation would be ordered:
 - First Phase (quantitative or qualitative)
 - * Data Collection
 - * Data Analysis and Interpretation
 - Connecting Procedures (e.g., development of sampling procedures or materials based on the results from the first phase)
 - Second Phase (qualitative or quantitative)
 - * Data Collection
 - * Data Analysis and Interpretation



- ❖ **Describe potential methodological issues and challenges that may arise in using a particular mixed methods design.** This description should identify specific challenges and include suggestions of how the investigators plan to address or overcome the challenges, citing examples from methodological references and past research using the design when possible.
- ❖ **Include a timetable of the quantitative, qualitative, and mixed methods procedures involved in the design.** Researchers unfamiliar with qualitative research and/or mixed methods research often underestimate the time required for completing qualitative data collection and analysis and for integrating the two research approaches. Be sure to plan on sufficient time to allow for transcribing qualitative data, meaningful qualitative data analysis, and the integration of the quantitative and qualitative data and results.
- ❖ **In discussing Preliminary Studies for New Applications, highlight prior quantitative, qualitative, and mixed methods research experiences.** Each of these approaches requires researchers to understand different sets of assumptions and procedures and to have skills for their implementation. Foundations for conducting quantitative, qualitative, and mixed methods research should be adequately documented through prior experiences and/or supplemented through the inclusion of individuals with expertise in these three areas.

Additional Application Elements

The use of mixed methods research can have implications for the research plan development that go beyond the Specific Aims and Research Strategy. Here are additional considerations relevant to other elements of an R series application.

- ❖ The Project Summary/Abstract
- ❖ The Protection of Human Subjects
- ❖ Facilities & Other Resources
- ❖ Biographical Sketches
- ❖ Budget

The Project Summary/Abstract

Include key information about the mixed methods approach of the project in the Project Summary. A good mixed methods project summary highlights the use of mixed methods by including:

- ❖ terms that identify the use of mixed methods research;
- ❖ an indication of the mixed methods design;
- ❖ the general approach (quantitative, qualitative, or mixed methods) planned for accomplishing each study aim; and
- ❖ the primary means by which the quantitative and qualitative approaches will be merged, connected, or integrated.

The Protection of Human Subjects

- ❖ **Identify and describe issues related to the protection of human subjects as required with all forms of research involving human participants.**
- ❖ **Understand the ethical issues associated with quantitative and qualitative research procedures.** Researchers using mixed methods need to be cognizant of the ethical issues typically associated with quantitative research approaches (e.g., implications of manipulating conditions experienced by participants) and qualitative research procedures (e.g., implications of gathering personal information through audio-recordings that could identify a participant).
- ❖ **Anticipate ethical issues specifically related to the use of mixed methods research.** The use of mixed methods research may introduce ethical issues that are in addition to those typically faced in research that uses a single quantitative or qualitative research approach. Here are three examples of ethical issues that may relate to the use of a mixed methods approach.



- **Mixed methods research may require the collection of identifying information from participants.** Quantitative survey research often is conducted in such a way as to maintain the anonymity of the participants. If this same procedure is part of a sequential mixed methods approach, however, the investigator may need to gather information that can identify participants so that they may be contacted for a qualitative follow-up phase. This requires that the researcher justify the need for gathering identifying information and put safeguards in place for protecting that information.
 - **Mixed methods research may require contacting participants at a later time for more information.** A strength of many mixed methods approaches is that investigators return to participants at a later time to follow-up on initial results. Although this may help provide greater insights on a topic, it also requests more time from participants. If such follow-up activities are planned, investigators should inform participants about the possibility of a follow-up contact so they understand the full nature of their participation at the time of initial consent.
 - **Mixed methods research may place a higher burden on participants than single-method approaches, but may also provide greater benefit.** Mixed methods research allows researchers to study a topic using different approaches. These different approaches, however, may place an additional burden on participants, particularly those who are experiencing health difficulties or who have a high level of constraint on their available time. Investigators should carefully consider and articulate the need for multiple forms of data and select means of data collection that will not overly burden participants. Likewise, investigators should carefully consider and identify any unique benefits that arise from the use of mixed methods, such as the potential for individual or community impact.
- ❖ **Be prepared to educate IRB reviewers at your institution about mixed methods research.** Just as many researchers are new to mixed methods research, many individuals serving on Institutional Review Boards may not have expertise in mixed methods research. Investigators need to be prepared to provide additional explanation and justification for the use of mixed methods procedures and the ethical considerations that go along with its use. As mixed methods studies are complex, some researchers have found a table or matrix can provide an effective overview of the project procedures and sampling. Explanation of sample size may be particularly challenging for the qualitative component for studies that use saturation (i.e., sampling to a point where no new information is obtained from participants) as a criterion for determining sample size. It may be prudent to estimate the upper limit of expected need for participants as IRBs may not be accustomed to exceeding projected levels of recruitment.

Facilities & Other Resources

Investigators need to describe the scientific environment that will contribute to the probability of success of the proposed mixed methods project. High-quality mixed methods applications should:

- ❖ **Specify the equipment and expertise available to support sophisticated quantitative research.** These resources might include computers, online survey software, statistical software packages (e.g., SPSS, SAS, etc.), resources to support intervention procedures, and expertise in statistics.
- ❖ **Specify the equipment and expertise available to support sophisticated qualitative research.** These resources might include computers, digital recording equipment, space for interviewing, transcription services, qualitative data analysis software packages (e.g., MAXQDA, NVivo, Atlas.ti, HyperResearch, etc.), resources to support entry into a site, and expertise in the procedures of the chosen qualitative approach.
- ❖ **Specify the equipment and expertise available to support sophisticated mixed methods research.** Examples of these resources might include software packages that facilitate the relating of quantitative and qualitative data, expertise in developing quantitative instruments from qualitative findings, and expertise in mixed methods research designs and approaches.

Biographical Sketches

Investigators need to use the NIH format for providing biographical sketches related to each key personnel. This presents a good opportunity to highlight the backgrounds, contribution, and synergy of the mixed methods team members.



- ❖ Highlight prior quantitative, qualitative, and mixed methods experiences in the biographical sketches as appropriate to demonstrate investigators' expertise. This includes tying each person's experience and qualifications to their roles in the overall mixed methods study.
- ❖ Provide clear delineation of responsibility relative to the roles for integration as this typically requires collaboration between qualitative and quantitative researchers on the team.
- ❖ Synthesize across bio-sketches so that each person's unique role is clear, and the roles are seen as distinct yet complementary. When done well, this should demonstrate the synergy of the mixed methods team that has been assembled. In addition, clearly identify if a given person is going to serve as leader on all, or certain specific elements of the mixed methods activities.

Budget

- ❖ Include adequate personnel time and resources to complete the quantitative, qualitative, and mixed methods aspects of the project. Recognize that there are costs associated with the implementation of each component of a mixed methods project, including the integration, and that investigators need to budget accordingly. Examples of costs specifically associated with a mixed methods project include:
 - providing training in quantitative, qualitative, and mixed methods procedures for personnel unfamiliar with one or more of these approaches;
 - purchasing software that facilitates the linking of quantitative data to qualitative data;
 - incorporating team aspects that support meaningful integration of study components; and
 - covering the effort required to address the mixed methods aim(s), such as supporting additional analyses required to integrate two sets of results.

KEY REFERENCES AND RESOURCES

References for Writing about Mixed Methods Research:

- ❖ Creswell, J. W., & Plano Clark, V. L. (2011). *Designing and conducting mixed methods research* (2nd ed.). Thousand Oaks, CA: Sage.
- ❖ Sandelowski, M. (2003). Tables or tableaux? The challenges of writing and reading mixed methods studies. In A. Tashakkori & C. Teddlie (Eds.), *Handbook of mixed methods in social & behavioral research* (pp. 321–350). Thousand Oaks, CA: Sage.
- ❖ Stange, K. C., Crabtree, B. F., & Miller, W. L. (2006). Publishing multimethod research. *Annals of Family Medicine*, 4, 292–294.

References for Developing Diagrams for Mixed Methods Research Studies:

- ❖ Ivankova, N. V., Creswell, J. W., & Stick, S. (2006). Using mixed methods sequential explanatory design: From theory to practice. *Field Methods*, 18(1), 3–20.
- ❖ Plano Clark, V. L., & Creswell, J. W. (2008). *The mixed methods reader*. Thousand Oaks, CA: Sage.

References for Reasons to Mix Methods:

- ❖ Bryman, A. (2006). Integrating quantitative and qualitative research: How is it done? *Qualitative Research*, 6(1), 97–113.
- ❖ Greene, J. C., Caracelli, V. J., & Graham, W. F. (1989). Toward a conceptual framework for mixed-method evaluation designs. *Educational Evaluation and Policy Analysis*, 11(3), 255–274.



References for Writing Mixed Methods Study Aims:

- ❖ Plano Clark, V. L., & Badiee, M. (2010). Research questions in mixed methods research. In A. Tashakkori & C. Teddlie, *Handbook of mixed methods research* (2nd ed., pp. 275-304). Thousand Oaks, CA: Sage
- ❖ Tashakkori, A., & Creswell, J. W. (2007). Exploring the nature of research questions in mixed methods research [Editorial]. *Journal of Mixed Methods Research*, 1(3), 207–211.

References for Developing High Quality, Rigorous, and Ethical Quantitative and Qualitative Research:

- ❖ National Institutes of Health (NIH). (1999). *Qualitative methods in health research: Opportunities and considerations in application and review*. Washington, DC: Author. Retrieved from: obsr.od.nih.gov/pdf/qualitative.pdf
- ❖ National Institutes of Health (NIH). (2010). *Bioethics resources on the web*. Retrieved from: <http://bioethics.od.nih.gov/>
- ❖ Cohen D., & Crabtree, B. (2006). *Qualitative research guidelines project*. <http://www.qualres.org/>
- ❖ Padgett, D. K. (2008). *Qualitative methods in social work research* (2nd ed.), Thousand Oaks, CA: Sage.
- ❖ Shadish, W. R., Cook, T. D., Campbell, D. T. (2002). *Experimental and quasi-experimental designs for generalized causal inference*. Boston: Houghton Mifflin.

Resources to Assist with the NIH Grant Application Process:

- ❖ Everything You Wanted to Know About the NCI Grants Process: <http://www3.cancer.gov/admin/gab/2005GPB/GPB05-LowRes.pdf>
- ❖ NIAID's All About Grants tutorials page (multiple tutorials that apply regardless of research area): <http://funding.niaid.nih.gov/researchfunding/grant/pages/aag.aspx>
- ❖ NIH-OER on planning your application: http://grants.nih.gov/grants/planning_application.htm
- ❖ NIH-CSR review process videos: <http://cms.csr.nih.gov/ResourcesforApplicants/InsidetheNIHGrantReviewProcessVideo.htm>
- ❖ NIH-OER on writing your application: http://grants.nih.gov/grants/writing_application.htm



Beyond the R Series – High-Quality Mixed Methods Activities in Successful Fellowship, Career, Training, and Center Grant Applications

The National Institutes of Health, as well as many other supporters of biomedical, social and behavioral science research, fund a wide range of scientific activities beyond the traditional research (R series) grants. The foundation of all successful requests for funding is their persuasive presentation of a plan of research. However, applications for other types of support also must convey to reviewers and funders a capacity in other key domains as well, such as mentorship and environment for career and training awards, and leadership, administrative structure, and integration across research activities for center grants and multi-project initiatives.

This section addresses how a mixed methods approach to research influences the presentation of the key elements in each of these unique types of funding applications. Not all Institutes offer funding in all of these categories, and often a specific mechanism may require unique capacity or activities. Nevertheless, across each type of special funding, there are common elements to consider when writing or evaluating an application that includes mixed methods research. These types of applications and activities have not historically included specific descriptions of mixed methods research; however, as the field continues to develop, there will be more funded examples of such training programs. A search of the NIH RePORTER database will identify specific examples of successful applications in specific fields, to serve as models.

- ❖ Building Capacity in Individual Scholars – Fellowship and Career Awards
- ❖ Providing Institutional Training – The T Series
- ❖ Creating Collaborative Research Centers and Programs – The P Series

Building Capacity in Individual Scholars – Fellowship and Career Awards

Fellowship Awards – The F Series

- ❖ Fellowship series awards, as the name indicates, are training, not research awards. They are awarded to applicant fellows who demonstrate “potential for a productive career, ... the need for the proposed training, and ... a research training proposal, sponsor, and environment which will satisfy those needs.” Criteria for evaluating these awards include assessment of the applicant, the sponsors, collaborators and consultants, the research training plan, the training potential, and the institutional environment and commitment to training.

Career Awards – The K Series

- ❖ Although commonly thought of as exclusively for early-career stage investigators, there are categories of career awards that support early postdoctoral training, mid-career, or established investigators, and categories specifically for clinician-researchers, and quantitative researchers. Career awards offer single candidates protected time to carry out a series of training and research activities in a focused, interconnected way, in order to enable the candidate to enhance their capacity for scholarship more fully, than in their existing circumstances. Criteria for evaluating K awards are similar to those for fellowships. They specifically assess the likelihood “for the candidate to maintain a strong research program, taking into consideration” the candidate, career development plan, research plan, mentors, collaborators, or (for established investigators) the plan to provide mentoring, and the environment and institutional commitment.

F and K Series Awards – Issues Specific to Mixed Methods Research

For career awards and fellowships in which some portion of the supported activities will utilize, and build, the trainee’s capacity in mixed methods, the following criteria may be relevant.

- ❖ **Candidate:** The candidate him or herself should present a compelling rationale for investing in mixed methods training. If the applicant is already a competent quantitative and/or qualitative researcher, there should be a strong argument presented as to how enhanced mixed methods skills will move their scholarship capacity forward. If they
-

are trained in only one area (e.g., quantitative research), then there should be a clear plan for developing skills in both qualitative and quantitative research, as well as in mixed methods. If there are letters of support, these should provide evidence that mixed methods is an important component of the candidate's future contributions to the relevant field of science.

- ❖ **Mentors:** The plan for mentorship is especially critical for mixed methods research. If there is a single mentor, then the capacity for guidance and skill development in mixed methods must be clearly demonstrated. However, given that most environments do not have mixed methods researchers in all areas of science, it is important to critically assess the plan for shared guidance, and the likelihood of success. If the candidate proposes a collaborative mentorship model, there must be evidence that the mentors involved have planned this carefully, and that the mentors have each previously co-mentored similar candidates (ideally, together). A split mentorship model, in which one person will provide qualitative and one quantitative research guidance, is less likely to successfully improve the candidate's capacity in mixed methods research. Split arrangements can be difficult for trainees to navigate, and can result in little attention to the trainees building skills they will need to integrate their training experiences, goals, and research findings.

One indicator of the feasibility is the mentor(s)'s demonstrated prior accomplishments in this regard, such as a list of previous trainees and their foci, skill sets gained, and career paths post-training. For more established candidates, the criteria are evidence of their own mentorship accomplishments and their prior contributions to mixed methods training of others.

Letters of support from people in related fields also can be used persuasively to demonstrate that mixed methods training will enable the trainee to make innovative and needed research contributions to the relevant fields or areas of research. To the extent that these experts can specifically state how the field or problem could benefit from expertise in mixed methods, and that the trainee will fill a needed gap in expertise, then this further reinforces the case that the trainee and mentor will make in the training and research plan.

- ❖ **Training Environment:** As with mentorship, the most compelling evidence of an adequate training environment for mixed methods research capacity building is the existence of other trainees in the same areas, promising a supportive collective intellectual atmosphere for the trainee. As well, some review of the types and diversity of funding and scholarship produced is important to include. In addition, an institution or group's previous track record of training scholars in this area, and the current achievement of those former trainees, is also persuasive in regard to future capacity. For mixed methods scientists, the issues of separate mentorship also can carry over into the training environment. Thus, capacity should be documented by specific structural indicators of a mixed methods environment, such as journal clubs, classes, and seminars, rather than a list of separate qualitative and quantitative events and opportunities. If these do not yet exist in the home institution or environment, the application should include specific experiences, such as meetings, short courses, or other activities, that will supplement the home institution's resources.
- ❖ **Research and Training Plan:** In addition to the elements discussed in the section on the R Series research plan, career and fellowship awards must carefully explain how the research to be undertaken will be consistent with the candidate's goals to develop as a mixed methods researcher. Thus, mapping specific experiences and activities within the research plan to opportunities for training and skill development is important. For mixed methods researchers, capacity-building must involve continued contact with the larger mixed methods community of scholars, and ongoing assessment of the degree to which full integration of methodologies is occurring in the candidate's ongoing and emerging work. Structured opportunities, such as short courses and scientific meetings, as well as ongoing informal training should be described.

Products from the training should include the types of professional meetings where the trainee will present his or her work and how those audiences will enhance the trainee's professional development. Similarly, journals open to mixed methods work in the relevant field should be discussed.

Providing Institutional Training – The T Series

- ❖ For proposals that seek funding for the training of multiple pre- or postdoctoral students, the value added of mixed methods capacity for training is substantial. One important criterion for the overall impact evaluation of institutional



training grants is the “likelihood that a program will exert a sustained powerful influence on the research field(s) involved.” Therefore, if a training program can offer mixed methods training as one component of its contributions, there is a great likelihood its impact will be substantial, given the scarcity of mixed methods training opportunities.

- ❖ The criteria for mentorship, as well as the institutional environment and capacity (see discussion in the F & K Series section), are even more important in an application for institutional training grants. When students from different backgrounds and perspectives interact, the mixed methods trainees will benefit from multiple perspectives and epistemologies of science. These are fundamental skills for emerging mixed methods scientists. However, it is even more important in this case for faculty mentors to avoid creating disciplinary “camps,” and subgroups of students and skill sets within the program. If not all students are trained in mixed methods, there nevertheless should be specific resources identified for the proportion of trainees who will become skilled in mixed methods. Furthermore, the culture of the program should reflect the respectful inclusion of mixed methods as an equal partner area, so that all trainees are socialized into this view.

Creating Collaborative Research Centers and Programs – The P Series

For larger collaborative efforts, including center grants, the fundamental quality of the individual research projects proposed creates the foundation for the overall center. However, center grants are evaluated as a whole, and therefore must create synergies across individual research and educational activities. These mechanisms therefore also are ideally suited for building or enhancing mixed methods research capacity at an institution, if the scientific area of focus can demonstrably benefit from such capacity.

- ❖ **Research Projects:** In program project grants, where there are multiple independent research projects proposed, one overarching criterion is whether or not there will be value added to the impact of the individual investigations, because they are taking place within a center and concurrently with the other proposed projects and activities. If one research activity uses only a qualitative approach and another a strictly quantitative approach, it could be tempting to describe the overall research as taking a mixed methods approach; however, without explicit mixed methods strategies throughout, this is not likely to be persuasive to knowledgeable reviewers. A specific project focusing on mixing data, analytical strategies, inference, and interpretation from separate studies could be feasible. However, the value of this would depend both on the objectives desired and the feasibility of the mixed research process. It may be more feasible to design at least one of the projects as a separate stand-alone activity, which nevertheless contributes to the overall scientific goals of the center or program.
- ❖ **Cores:** In program projects, cores are organizational units that consolidate activities, resources, and multiple projects, and thus create synergies and economies of scale for resource use. As well, they often can serve to enhance the scientific impact of activities and to disseminate results. In program projects and centers that include mixed methods research, the benefits of methodology and analysis cores are substantial. Cores allow staff and investigators who may be tasked with different individual contributions to communicate effectively and to ensure that equivalent methodologies, measures, and procedures are undertaken. For mixed methods, a well-designed core, containing both the appropriate personnel and resources, will ensure high-quality products from both individual research projects and the center as a whole.

Beyond methodology cores, other types of cores focus on training and education, or dissemination and community participation activities. Administrative cores often are charged with tasks such as facilitating input and feedback from external experts or managing IRB issues. Again, centers that include mixed methods research must use core resources to support the unique needs of this field. Therefore, IRB applications for mixed methods work must be able to draw on expertise about the unique mixed methods issues in regard to use of participants, data collection, and dissemination. Community-based advisory boards, composed of persons with differing levels of sophistication toward research in general, and mixed methods in particular, will provide both a challenge and an opportunity for creating support for these elements of the research. The dissemination core may create content for web and other media activities, help select venues such as journals and conferences where mixed methods work is accepted, and broadly bring capacity to the center to maximize impact of the research.

- ❖ **Resources and Environment:** Institutional capacity for mixed methods research in centers includes many of the considerations discussed for individual projects. However, given the prominence of a center in most institutions, the commitments from the institution to serve as an adequate home for the venture should be clear. Review of



institutional capacity should include looking for evidence that activities of similar scope and purpose have been successful previously, as well as evidence of an existing niche for the work of the center within the scientific culture of the organization. If the center will bring mixed methods research and training capacity to an organization where it has not existed previously, this should be presented as a logical next step in the growth and mission of the organization.

- ❖ **Program Leadership:** Scientific leaders direct individual projects within centers, and the center director plays less of a direct role in the scientific management of each project. However, the overall leadership of a center requires an individual who can create opportunities for balance and synergy within and across research teams and projects. Presenting the center to external stakeholder audiences requires the ability to communicate persuasively about the value of a mixed methods approach to the given scientific questions and issues addressed by the center.
- ❖ **Program as an Integrated Effort:** One of the most important evaluative elements of a center grant review is the assessment of the program as an integrated effort. Successful program projects create systems of research activities and projects, all working toward a well-defined scientific goal. As discussed previously, many of the fundamental epistemological and methodological foundations of mixed methods research are based on integration, making a program project that includes mixed methods a compelling activity, if designed and presented carefully.
- ❖ **Impact:** Impact scores are assigned to program projects and centers by reviewers to assess the “scientific merit, impact, and coherence of the overall application as a synergistic and interactive enterprise.” Given the substantial resources used by such centers and program projects, the return on investment must be seen as moving a field forward in ways that are significantly different than those of individual projects. Further, reviewers must specify which audiences and communities of scholarship benefit from the resources given to this center activity, and in what ways, and to what extent.



Reviewing Mixed Methods Applications

- ❖ **NIH Review Criteria:** Applications submitted to the NIH for awards or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system. Reviewers consider criteria as summarized across Center grants, R, F, K, T, P grants (see the NIH website for details). As discussed in the section on Beyond the R Series – High Quality Mixed Methods Activities in Successful Fellowship, Career, Training, and Center Grant Applications, the criteria for evaluating grants in each of these categories varies. However, several general comments about reviewing applications that include mixed methods research can be made.
- ❖ **Use both quantitative and qualitative criteria:** In all mixed methods investigations, the criteria for a rigorous quantitative investigation and a qualitative investigation should be met in evaluating a mixed methods investigation (see The nature of qualitative research and its evidence and The nature of quantitative research and its evidence). Further, specific criteria about mixed methods need to be employed.
- ❖ **Use mixed methods criteria:** A body of literature is emerging about how to assess the quality of a mixed methods investigation. This literature addresses criteria that might be used, what components might go into a mixed methods study, where to examine a project for mixed methods components, and checklists for assessing the value of such an investigation. For example, the NSF evaluation guidelines advance quality criteria for quantitative and qualitative data and methods (Frechtling, 2002), the Robert Wood Johnson website suggests specific guidelines for qualitative research (Cohen & Crabtree, 2008), and the article by Levin et al. (1997) state guidelines for quantitative research. *The Journal of Mixed Methods Research* (Tashakkori & Creswell, 2007) advances criteria for evaluating mixed methods submissions to the journal.
- ❖ **Consult existing mixed methods research quality criteria:** Several standards for reviewing the quality of mixed methods research have been advanced in the literature (see O’Cathain, 2010). Three recent discussions (Creswell & Plano Clark, 2011; O’Cathain, Murphy, & Nicholl, 2008; Schifferdecker & Reed, 2008) use different criteria: a methods orientation, a research process orientation, and the timing of phases of the investigation orientation.
 - Creswell and Plano Clark (2011) suggest that to evaluate a mixed methods study, the researcher needs to:
 - collect both quantitative and qualitative data;
 - employ rigorous procedures in the methods of data collection and analysis;
 - integrate or mix (merge, embed, or connect) the two sources of data so that their combined use provides a better understanding of the research problem than one source or the other;
 - use a mixed methods research design and integrate all features of the study with the design; and
 - convey research terms consistent with those being used in the mixed method field.
 - O’Cathain, Murphy, and Nicholl (2008) offer guidance for Good Reporting of a Mixed Methods Study (GRAMMS):
 - describe the justification for using a mixed methods approach to the research question;
 - describe the design in terms of the purpose, priority, and sequence of methods;
 - describe each method in terms of sampling, data collection and analysis;
 - describe where integration has occurred, how it has occurred, and who has participated in it;
 - describe any limitation of one method associated with the presence of the other method; and
 - describe any insights gained from mixing or integrating methods.
 - Schifferdecker and Reed (2008) made seven recommendations for steps to be taken in designing, analyzing, and publishing mixed methods studies:
 - Identify the study design as mixed methods.
 - Decide on the prominence of each data type in data collection, analysis, and results.



- Develop sampling strategies that provide adequate data and adhere to guidelines within the methods chosen.
- Decide how and when data are collected, analyzed, and integrated.
- Set realistic time requirements for each project phase.
- Explore software programming tools or methods to integrate the quantitative and qualitative data.
- Review mixed methods research articles to generate ideas for reporting results and displaying data.

A Checklist for Reviewing NIH Mixed Methods Applications: In view of these alternative sets of criteria, we suggest a checklist for an R Series application that reviewers might use to review the research plan for NIH applications that incorporate mixed methods research. These sections may be weighted differently and given different emphases depending on the type of R Series application. Different criteria will apply to other types of applications (e.g., K Series applications, Center applications) as well as the announced grant mechanism and funding opportunity [see Table 1. Sample review criteria and strategies for reviewing an R-series application].

Table 1. Sample review criteria and strategies for reviewing an R Series application

Criterion	Strategies for Meeting the Criterion	NIH Scoring
Significance	<ul style="list-style-type: none"> • Does the application make a convincing case that the problem is relevant (e.g., if aims are achieved, the work will improve knowledge or practice)? • Can the problem be best studied through the multiple perspectives of mixed methods research? 	1-9
Investigator(s)	<ul style="list-style-type: none"> • Do the investigator(s) have the required skills to conduct all proposed methods (e.g., investigator(s) have prior publications and/or grants related to proposed qualitative, quantitative, and mixed methods; co-investigators with appropriate expertise are identified to lead each method as needed)? • Is there evidence that the project leadership is committed to mixed methods research (e.g., each component of the study is addressed sufficiently and consistently throughout the application; there are references to current relevant literature on mixed methods; investigators have experiences in professional development in mixed methods)? • Has the approach to collaboration been described (e.g., frequency of meetings between leaders of different components, management of differences between co-investigators)? 	1-9
Innovation	<ul style="list-style-type: none"> • Does the use of mixed methods provide a platform for innovative investigation of the research problem(s) (e.g., provides insights into mechanisms of organizational change not possible with a single method)? • Is the combination of methods used innovative, or the way in which they are integrated innovative? 	1-9



Table 1. Sample review criteria and strategies for reviewing an R Series application

Criterion	Strategies for Meeting the Criterion	NIH Scoring
Approach	<ul style="list-style-type: none"> • Is there a description of the philosophy or theory informing the research and the ways this philosophy or theory shapes the investigation? • Have the applicants offered a convincing explanation of why mixed methods research is needed to address the study aims and the value added by using this approach (e.g., explained how alternative designs would be inappropriate or inadequate)? • Is there a clear description of the full study design, including where integration occurs (e.g., using a comprehensive figure or matrix)? • Is the integration of the methods well described, including the timing, techniques, and responsibilities for integration? • Is the design appropriate for the study aims? • Are the methods consistent with established standards of rigor for quantitative and qualitative data collection and analysis (e.g., sampling, sample size and analysis plans are specified for each method, with appropriate citations)? • Will appropriate computer software be used for each analytic component, and if not, is a convincing rationale provided? • Is the study feasible within its proposed time frame and resources (e.g., a timetable is provided that allocates time for data integration)? 	1-9
Environment	<ul style="list-style-type: none"> • Is there evidence that the institution supports mixed methods research (e.g., forums for multidisciplinary collaborations, faculty with funding for mixed methods research)? 	1-9

Rating Scale: See the general NIH guidelines for scoring for more information about the evaluation categories and scoring.

Key References and Resources

- ❖ Cohen, D., & Crabtree, B. (2008). *Robert Wood Johnson, qualitative research guidelines project*. Retrieved from <http://www.qualres.org/>.
- ❖ Creswell, J. W., & Plano Clark, V. L. (2011). *Designing and conducting mixed methods research* (2nd ed.). Thousand Oaks, CA: Sage.
- ❖ Frechtling, J. (January, 2002). *The 2002 user friendly handbook for project evaluation*. Washington D.C.: National Science Foundation. Retrieved from <http://www.nsf.gov/pubs/2002/nsf02057/start.htm>.
- ❖ Levin J. S., Glass, T. A., Kushi, L. H., Schuck, J. R., Steele, L., & Jonas, W. B. (1997). Quantitative methods in research on complementary and alternative medicine, *Medical Care*, 35, 1079-1094.



- ❖ O’Cathain, A. (2010). Assessing the quality of mixed methods research: Toward a comprehensive framework. In A. Tashakkori & C. Teddlie (Eds.), *SAGE handbook of mixed methods in social & behavioral research* (2nd ed.) (pp. 531-555) Thousand Oaks, CA: Sage.
- ❖ O’Cathain, A., Murphy, E., & Nicholl, J. (2008). The quality of mixed methods studies in health services research. *Journal of Health Services Research Policy*, 13(2), 92-98.
- ❖ Plano Clark, V. L., & Creswell, J. W. (2010). *Understanding research: a consumer’s guide*. Upper Saddle River, N.J.: Prentice Hall – Merrill.
- ❖ Schifferdecker, K. D. & Reed, V.A. (2009). Using mixed methods research in medical education: Basic guidelines for researchers. *Medical Education*, 43, 637-644.
- ❖ Tashakkori, A., & Creswell, J. W. (2007). The new era of mixed methods. [Editorial]. *Journal of Mixed Methods Research*, 1(1), 3-7.



Overall Recommendations

❖ For applicants

- Make sure that all parts of the application from the broader philosophical perspectives to the methods of data collection are consistent.
- Use the Review Criteria Checklist to be responsive to the needs of the reviewers.
- Provide a clear rationale for the use of mixed methods based on the study goals, questions, and aims.
- Take mixed methods seriously in the planning of research to improve the quality and utility of the research.
- Understand the benefit/choice of explicitly choosing to identify the research as mixed methods.
- Make clear the innovative nature of the work being proposed, such as the way mixed methods is used and addressed.
- Participate in formal training opportunities (e.g., courses, conferences, workshops, journals, special issues, article and book readings) to learn about mixed methods.
- Integrate an awareness of formal mixed methods research considerations within the application.
- Take time to assemble a successful mixed methods team, not simply add people to fill methodological gaps. The group needs to meet regularly during the design phase and throughout the process.
- Describe the individuals on projects that hold qualitative expertise in addition to quantitative and mixed methods expertise.

❖ For reviewers

- Look for evidence of ongoing collaboration and team process building in the biographical statements or publication records of applicants.
- Use the Review Criteria Checklist as a guide for assessing the quality of the planned use of mixed methods research in applications.
- Look for evidence of awareness/knowledge of mixed methods.
- Refer to the mixed methods quality checklists beyond these “best practices” for further information.
- Look for applications that fail to use mixed methods when they should have to best address the identified research problem.
- Be fair and constructive in comments, recognizing that mixed methods is a new, innovative methodology.
- Add information into background profiles about mixed methods expertise.
- Recognize that the application cannot educate everyone and be careful to use criteria that are appropriate for the content and methodological aspects of the application.

❖ For NIH stakeholders

- Consider developing/updating the NIH guidelines for qualitative research for applicants and reviewers.
- Hold a meeting at NIH with presentations by mixed methods experts and funded researchers to reach those less familiar with mixed methods.
- Widely disseminate these “best practices” through journals, conferences, and other outlets.
- Work for developing criteria for the quality and the presentation of mixed methods research along the example of the CONSORT guidelines.
- Where appropriate, explicitly specify the needs for mixed methods approaches in FOAs.
- Ensure that study section membership includes a combination of qualitative, quantitative, and mixed methods expertise.
- Seek volunteers to review mixed methods applications for NIH.



Appendix A. NIH Working Group on Developing Best Practices for Mixed Methods Research

NIH

Helen I. Meissner, Ph.D.
Senior Advisor
Office of Behavioral and Social Sciences Research
(OBSSR)
National Institutes of Health

Shobha Srinivasan, Ph.D.
Health Disparities Research Coordinator
National Cancer Institute
National Institutes of Health

William Elwood, Ph.D.
Health Scientist Administrator
Office of Behavioral and Social Sciences Research
(OBSSR)
National Institutes of Health

FACILITATORS

John W. Creswell, Ph.D.
Professor of Educational Psychology
University of Nebraska-Lincoln

Ann Klassen, Ph.D.
Professor, Associate Dean for Research
Drexel University School of Public Health

Vicki L. Plano Clark, Ph.D.
Director, Office of Qualitative and Mixed Methods
Research
University of Nebraska-Lincoln

Katherine Clegg Smith, Ph.D.
Associate Professor
Department of Health, Behavior, and Society,
Department of Sociology, and Department of Oncology
Johns Hopkins University

MEMBERS OF THE WORKING GROUP

Lisa Bowleg, Ph.D.
Associate Professor
Department of Community Health and Prevention
Drexel University School of Public Health

Benjamin Crabtree, Ph.D.
Professor and Director, Research Division, Department
of Family Medicine
Robert Wood Johnson Medical School

Lesley Curry, Ph.D., M.P.H.
Research Scientist
Yale School of Public Health and
Core Faculty Robert Wood Johnson Clinical Scholars
Program
Yale School of Medicine

Michael Fetters, M.D. M.P.H., M.A.
Associate Professor
Department of Family Medicine
University of Michigan Medical Center
Director, Japanese Family Health Program
Director, Family Medicine Ethics Curriculum

Joseph J. Gallo, M.D., M.P.H.
Professor, Department of Mental Health,
Bloomberg School of Public Health
Johns Hopkins University

Nancy Gerber, Ph.D., ATR-BC, LPC
Director, PhD Program in Creative Arts Therapies and
Associate Clinical Professor
Creative Arts Therapies Department
Drexel University

Donna Mertens, Ph.D.
Professor, Department of Education Foundations and
Research
and Editor, Journal of Mixed Methods Research
Gallaudet University



Alicia O’Cathain, Ph.D.
Professor of Health Services Research
School of Health and Related Research
University of Sheffield
United Kingdom

Deborah Padgett, Ph.D., M.P.H.
Interim Director, Global Health Leadership
Concentration, Masters in Public Health Program
Professor
Silver School of Social Work
New York University

Rena Pasick, Dr.P.H.
Adjunct Professor of Medicine, Division of General
Internal Medicine
Department of Medicine
Associate Director, Community Education and Outreach
UCSF Comprehensive Cancer Center
University of California San Francisco

Margaret Sandelowski, Ph.D., R.N.,F.A.A.N.
Cary C. Boshamer Professor, School of Nursing
University of North Carolina at Chapel Hill

