

Best Practices for Mixed Methods Research in the Health Sciences

NIH Office of Behavioral and Social Sciences Research

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Executive summary

Mixed methods research appears increasingly in peer-reviewed health sciences literature, reflecting the growing integration of qualitative and quantitative data. Multi-level approaches to investigate complex health problems--such as patient-provider interactions, and cultural and social models of illness, health, and wellbeing--portend an increase in the formation of interdisciplinary research teams and training needs so investigators with different yet complementary expertise can collaborate effectively.

Definitions and names for *mixed methods research* have evolved as the field has developed. For this report, we posit *mixed methods research* as a methodological approach that:

- Focuses on research questions that call for real-life contextual understandings, multi-level perspectives, and socio-cultural influences,
- Employs rigorous quantitative research that assesses the magnitude and frequency of constructs and rigorous qualitative research that explores the meaning and understanding of constructs,
- Involves multiple sources and types of data (e.g., geospatial types, in-depth informant interviews, survey questionnaire responses, text messages, and visual content including emoji, photos, video, and other graphics),
- Systematically integrates and triangulates different types of data to maximize the strengths and counterbalance the weaknesses of each data type, and,
- Develops and integrates conceptual and theoretical frameworks into the development of research questions.

Mixed methods involve *both* quantitative and qualitative data throughout research endeavors. Deliberate collection and analyses of both forms facilitate a more comprehensive understanding of health issues and potential resolutions; moreover, integration of quantitative and qualitative approaches maximizes strengths and minimizes weaknesses of each type of data.

Research issues most suitable for mixed methods are those in which a quantitative approach or the qualitative approach alone is inadequate to provide a comprehensive understanding about a research problem or question. By using mixed methods, health science investigators can answer new questions and more comprehensively capture complex phenomena, hard-to-measure constructs, and interactions in specific settings and contexts as well as in experimental settings. Mixed methods also can speed translation from a tested intervention to evidence-based interventions in real-life settings that often have more complexities than the environments in which funded intervention research occurs.

Research team members should be open to a mixed methods perspective, though it is not necessary or possible for all investigators to hold expertise in all methods in any research project. The principal investigator of a mixed methods team need not hold consummate expertise in any one approach, but must have sufficient expertise across approaches to be able to cultivate synergy, resolve differences among team members with more distinct expertise, and support team members' education in different methodologies when needed.

All research initiatives benefit from a well-resourced and dynamic research environment. In most ways, mixed methods applications have considerable overlap with complex single-method studies in terms of resource and infrastructure needs. That said, mixed methods research:

- Likely requires a wider array of statistical and qualitative computer software and staff than a single-method study.
- Benefits from being able to call upon other experienced and informed colleagues at their respective institutions.

Mixed methods approaches have implications for each part of a NIH application. Investigators need to embed important mixed methods components into the application's aims and research strategy and to demonstrate 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. Nevertheless, the methodology the research team chooses should flow naturally from the scientific aims and questions rather than from a desire to use a specific approach. Implications for career, institutional training, and program project/center projects are included, as are recommendations reviewers may use to review research plans for NIH applications that incorporate mixed methods research. Active projects using mixed methods from the current 2018 NIH portfolio appear in the final chapter.

Introduction and background

In November 2010, the National Institutes of Health (NIH) Office of Behavioral and Social Sciences Research (OBSSR) commissioned a team to develop a NIH resource for investigators on how to develop and evaluate rigorous mixed methods projects for health research. This resource meets three main objectives:

1. Assist investigators to use mixed methods as they develop competitive applications for NIH support;
2. Support reviewers and staff for NIH peer review panels who evaluate applications that include mixed methods research; and,
3. Provide OBSSR and the NIH Institutes and Centers (ICs) with best practices to use as they consider potential contributions of mixed methods research, plan new initiatives, select reviewers, and set priority areas for their respective areas of health science.

To complement the original lead authors, John W. Creswell, Ann C. Klassen, Vicki L. Plano Clark, and Katherine Clegg Smith, OBSSR convened an expert panel (Appendix A) to review a preliminary draft of “best practices.” This panel included experienced scientists, research methodologists, and NIH health scientists. OBSSR selected these individuals because of their expertise in NIH investigations, their specific knowledge of mixed methods research, and their experience in the scientific review process. Panel members had expertise in fields including anthropology, education, medicine, mental health professions, nursing, psychology, public health, social work, and sociology. This panel reviewed the document and met in late April 2011 to discuss their recommendations for the final report.

This best practice report has been the most frequently visited page on OBSSR’s website since its release in 2011. In 2018, OBSSR updated this report to reflect advances in the field as they relate to NIH’s mission to support research that enhances health, lengthens life, and reduces illness and disability over the life course.

This report consists of eight sections:

1. The need for best practices
2. The nature and design of mixed methods research
3. Teamwork, infrastructure, resources, and training for mixed methods research
4. Developing R series plans that incorporate mixed methods research
5. Beyond the R series: High-quality mixed methods activities in successful fellowship, career, training, and center grant applications
6. Reviewing mixed methods applications
7. Overall recommendations
8. Sample mixed methods projects from the 2018 NIH portfolio

The need for best practices

Mixed methods research in the health sciences

There is a continuous need to develop and refine methodologies that improve researchers' abilities to collect, combine, analyze, and report on increasingly diverse data made available through increasing platforms and technologies. This diversity reflects the nature of public health problems including behavioral factors that contribute to health, wellbeing, illness, and disability; disparities among populations, age groups, ethnicities, and cultures; poor adherence to treatments; and translational needs across the basic-through-applied research continuum.

This diversity in data requires increased integration 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-provider interactions, and cultural and social models of illness, health, and wellbeing. Accordingly, mixed methods approaches appear increasingly in peer-reviewed literature.

Models for guidelines

Multiple reports informed the original version of this report including a "methodological manifesto" for quantitative research in alternative medicine based on the NIH Conference on Complementary and Alternative Medicine Research Methodology (Levin et al., 1997). This report was helpful as we considered an original 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) that included an overview of quantitative and qualitative data collection methods, thus suggesting to us the importance to clarify the nature of mixed methods research. We reviewed the Robert Wood Johnson Qualitative Research Guidelines Project (Cohen & Crabtree, 2008). For this update, we also considered NIH-funded projects and peer reviewed literature since this report's original edition.

Finally, we examined criteria for the design and evaluation of mixed methods research projects (Schifferdecker & Reed, 2009; O'Cathain, 2010; Feters et al., 2013; Gallo & Lee, 2015). These resources informed the design of a checklist individuals may use to review mixed methods applications.

The nature and design of mixed methods research

This section addresses three issues:

1. Background of mixed methods
2. Qualities of mixed methods projects
3. Methodological challenges in mixed methods investigations

Background of mixed methods

Definitions and names for *mixed methods research* have evolved with the field over 20-30 years (e.g., [Johnson, Onwuegbuzie, & Turner, 2007](#); [Pluye & Hong, 2014](#); Creswell, 2015; Gallo & Lee, 2015). For this report, we posit *mixed methods research* as a methodological approach that:

- Focuses on research questions that call for real-life contextual understanding, multi-level perspectives, and cultural influences;
- Employs rigorous quantitative research that assesses the magnitude and frequency of constructs and rigorous qualitative research that explores the meaning and understanding of constructs;
- Involves multiple types of data (e.g., geospatial points, in-depth oral interviews, survey questionnaire responses, text messages, and visuals including emoji, photos, and other graphics);
- Intentionally integrates these data and analyzes them systemically to maximize the strengths and counterbalance the weaknesses of each data type; and,
- Frames the investigation within philosophical and theoretical frameworks.

Philosophy in mixed methods research. Those new to mixed methods research might wonder how this or any approach can bridge the constructivist and empiricist worldviews inherent in qualitative and quantitative designs, respectively (DePoy & Gitlin, 2015). Indeed, much qualitative research draws upon the constructivist perspective to understand human perceptions associated with health, wellness, disease, recovery, and other health related issues. Randomized controlled trials are the ultimate reflection of objective empiricism, to test hypotheses. Researchers rooted in discrete philosophical positions may find that initial ventures into mixed methods research may challenge their respective beliefs (Greene, 2007; Curry et al., 2012).

Rather than challenge beliefs, this report suggests that the mixed methods approach draws upon the philosophical approach *pragmatism*. An oversimplified explanation of pragmatism is that humans use scientific knowledge to explain changing natural and human conditions (Peirce, 1878; James, 1907, 1909; see also, Greene, 2007; [Pluye & Hong, 2014](#)).

In other words, mixed methods research provides an opportunity for multiple methods and their philosophical traditions to generate new knowledge through dialectical discovery and practice. Like pragmatism, mixed methods research focuses first on research problems and questions, values objective and subjective knowledge, and draws upon diverse design and methods (Morgan, 2007; [Pluye & Hong, 2014](#)). Mertens (2009) posits that mixed methods research is a transformative perspective that permeates the entire research process, from the problem to the conclusions, and the use of results.

Theories and mixed methods research. Optimally, all studies draw upon one or more theoretical frameworks from social, behavioral, or biological sciences to inform all study phases. Mixed methods studies inherently provide opportunities to integrate a variety of theoretical perspectives (e.g., complexity theory, critical theories, ecological theories, stress theory).

The nature of qualitative research and its evidence. A salient strength of qualitative research is its focus on contexts and meanings of human lives and experiences for inductive or theory-development driven research. It is a systematic and rigorous form of inquiry that uses data collection methods including 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 data collection when measures do not exist and provide a depth of understanding of concepts. Qualitative approaches in health research include case studies, discourse analysis, ethnography, grounded theory, and phenomenology.

The nature of quantitative research and its evidence. Quantitative research tests theories or hypotheses, gathers descriptive information, or examines 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 in the health sciences are case-control studies, descriptive surveys, observational studies, pragmatic clinical trials, randomized controlled trials, and time-series designs.

The combination of quantitative and qualitative data. Mixed methods research begins with the assumption that investigators gather evidence based on the nature of the health-related question as well as the social, behavioral, and biomedical theoretical orientations associated with the project. Social inquiry considers an individual's behavior in relation to a group, a population, or social institutions including families and organizations (e.g., hospitals, schools). Quantitative methods are mainly deductive and ideal to measure pervasiveness of "known" phenomena and central patterns of association, including inferences of causality. Qualitative methods are mainly inductive and allow for identification of previously unknown processes, explanations of why and

how phenomena occur, and the range of their effects (Pasick et al., 2009; Pollock, 2012; Peter, 2015).

Mixed methods research involves the intentional collection of *both* quantitative and qualitative data to combine the strengths of each to answer research questions. This approach is more than simply collecting qualitative data from interviews, or collecting multiple forms of qualitative evidence (e.g., interviews, observations, photos) or multiple types of quantitative evidence (e.g., diagnostic tests, surveys) could provide. Rather, analyses of these multiple forms of data facilitate a more comprehensive understanding of health problems and means to ameliorate them than a sole data type or concurrent collection and analyses of multiple forms of data (e.g., O’Cathain, Murphy, & Nichol, 2008; Lewin, Glenton, & Oxman, 2009; Fetters, Curry, & Creswell, 2013).

The integration of multiple forms of data. In mixed methods studies, investigators intentionally integrate quantitative and qualitative data. 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. Four approaches have been discussed in the literature: connecting, building, merging, and embedding data (Creswell & Plano Clark, 2017; Fetters, Curry, & Creswell, 2013; Sandelowski, Voils, & Knaf, 2009; Scammon et al., 2013; Tomoia-Cortisel et al., 2013).

- **Connecting data** occurs through the sampling frame. It involves analyzing one dataset (e.g., a quantitative survey), and then using the analytical results to inform 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 research phase.
 - For example, a NIAAA-funded project with [non-abusing drinkers diagnosed with hepatitis C](#) had an initial qualitative component based on interviews and Internet postings to describe new decision factors related to curtailing alcohol consumption. Investigators used these findings to develop new items for a quantitative instrument, administered in the second phase to assess the prevalence of the new factors and their association with current drinking (cf. Stoller et al., 2009).
- **Building data** occurs when the results from one dataset informs a subsequent approach to collect data. For example, a research team might create survey research questions based on the argot or cultural constructs of specific target populations. This subsequent survey instrument would collect data to answer hypotheses that emanated from the initial data collection. The NIAAA-funded project also serves as a building-data example given that the first set of findings also led to the development of a quantitative instrument.

- In addition, the first stage of a four-site [NIDA-funded project](#) with illegal drug users conducted extended interviews on sociodemographics, life history; terms for and personal meanings of sexual activities, knowledge on sexually transmitted infections including HIV, attitudes toward risk reduction practices including and risk-reduction behaviors during types sexual encounters. Data analysis found participants to attribute unique meanings to standard sexual terminology used in previous questionnaires. Also apparent was a social hierarchy that informed participants' risk and risk-reduction behavior, based on where a participant perceived a partner's status in the social hierarchy. The research team used these data to create intervention curriculum, survey questionnaires, and qualitative publications (e.g., Elwood & Greene, 2003; Elwood & Vega, 2005).
- **Merging data** combines qualitative data (e.g., images or texts) with quantitative data to compare and analyze. 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. One also can use tables or figures that display both quantitative and qualitative results.
 - For example, 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 multiple NIMH grants (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. (cf. Gallo et al., 2005; Wittink, Barg, & Gallo, 2006)
- **Embedding data** involves systematically linking the collection of qualitative to quantitative data at multiple points. One secondary dataset can be embedded within a larger, primary design. Embedding is frequently used in intervention design. For example, supplemental qualitative data on participants' intervention experience can help researchers adapt an ongoing adaptive intervention. 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.

- For example, a [NCI-NINR-funded R01 project](#) compared high and low doses of a nurse-led intervention to assist oncology outpatients to manage their pain more effectively. This RCT compared 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.

Qualities of mixed methods design

The research methods in any investigation must fit the research problem or question. Research issues most suitable for mixed methods are those in which a quantitative approach or the qualitative approach alone is inadequate to develop multiple perspectives or to provide a comprehensive understanding about a research problem or question. For example, quantitative outcome measures may be better understood if combined with qualitative data. By using mixed methods, health science investigators can answer new questions and more thoroughly capture complex phenomena, hard-to-measure constructs, and interactions in specific settings and contexts as well as in experimental settings.

Another reason is for one database build on another. A qualitative phase may help investigators develop a survey instrument or an intervention. After analyzing followup quantitative data, a qualitative phase may help researchers determine additional qualities or mechanisms suggested by the quantitative results (Plano Clark, 2010). Gallo and Lee (2015) posit that mixed methods can speed translation from a tested randomized controlled trial to evidence-based interventions in real-life settings that often have more complexities than the environments in which funded intervention research occurs. Randomized trials target specific groups of people and, therefore, inherently exclude others.

To adapt an evidence-based intervention for a broad patient group, one might need to account for patients with multiple chronic conditions, multiple perceptions of healthcare systems, unequal health insurance coverage, and healthcare providers who may lack the extensive training a funded research project would have provided interventionists. Qualitative research that follows a proven intervention can provide crucial information for more thorough implementation in community and healthcare settings.

Researchers increasingly use mixed methods within intervention trials to understand participants' experience with intervention curricula and reasons for drop out or loss to follow-up. Mixed methods may provide clues to how an intervention works by identifying potential mediators from participants' viewpoints. In implementation research, mixed methods may be central to illuminate how medical practices or providers adapt interventions to specific settings or circumstances. Regardless of purpose, mixed methods studies share some unique considerations:

Analytic logic. Discussions about mixed-methods design types available to investigators continue to develop (e.g., Creswell & Plano Clark, 2011, 2017; Fetters, Curry, & Creswell, 2013). Regardless, design possibilities should follow the reasons to involve mixed methods in a research project. They can be differentiated analytically by whether the quantitative and qualitative datasets are integrated for analysis or interpretation to address the research questions, or whether one dataset builds on the results of an initial dataset.

Timing. Collection of qualitative and quantitative data may be timed to be collected concurrently or sequentially. Concurrent data collection is attractive to investigators who must maximize the amount of data collected in the field for the time spent. Alternatively, an investigator may collect data in sequence, with one phase of collection followed by another. This approach is useful for investigators who need results from an initial phase to inform a subsequent phase.

Priority. In some mixed methods studies, quantitative and qualitative research have equal emphasis. 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; Klassen et al., 2012), 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), during data interpretation (e.g., when results of quantitative analyses are compared with themes that emerge from the qualitative data), or even as the unit of reference (Guest, 2012). This last perspective emphasizes the *timing* and *purpose* of data integration.

Single study or multiphase program of inquiry. Some mixed methods projects employ a design that is “stand-alone,” a single study conducted by an investigator or a team. Other mixed methods projects (typically proposed in larger NIH-funded projects) consist of multiple studies, some quantitative and some qualitative, that build on each other and contribute to an overall program objective or purpose—for example, to prevent a specific disease or to promote adherence to manage a chronic condition.

Methodological challenges in mixed methods investigations

In mixed methods research, there are multiple many methodological issues to anticipate (see Teddlie & Tashakkori, 2009; Gallo & Lee, 2015; Creswell & Plano Clark, 2011, 2015;) including,

- **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, 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 towards investigating and writing might emerge. 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](#).].
- **Sampling issues.** Detailed discussions about the sampling issues involved in mixed methods research and in specific designs appear elsewhere (e.g., Teddlie & Yu, 2007; Gallo & Lee, 2015; Creswell & Plano Clark, 2011, 2017). Nevertheless, 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 often can arise during data analysis and interpretation. When the investigator merges the data during a concurrent design, the findings may conflict or be contradictory. Strategies to resolve them include gathering more data and revisiting the databases. For designs involving sequential data collection, 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. Interpreting 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 the philosophies related to quantitative or qualitative research can or should be combined.

Teamwork, infrastructure, resources, and training for mixed methods research

This section discusses four key considerations related to the mixed methods research process:

1. Forming the Mixed Methods Research Team
2. Leading and Guiding a Mixed Methods Research Team
3. Building Infrastructure and Resources
4. Training the Mixed Methods Research Team

Forming the Mixed Methods Research Team

The nature and structure of a mixed methods research team arises from the research questions and the expertise required to address them. Rather than including a single “mixed methods expert” on a grant application, successful mixed methods research projects transcend distinct methodological and epistemological differences at least to some extent, to create processes for data collection and analysis that integrate both qualitative and quantitative approaches. The point and processes of integration are important issues for careful deliberation. Ideally, multiple team members work together to integrate the data, rather than leaving integration to a single investigator. Successful NIH-funded projects generally involve the skills and insights of a team of researchers from multiple disciplines, and often include investigators at various career stages.

Regardless of discipline or career stage, all collaborators must identify as members in the research team by learning one another’s argot (e.g., diagnostic terms, learning approaches) and developing a common language that facilitates a mixed methods approach designed to answer the study’s research questions (Curry et al., 2012). The process of sharing one another’s expertise and developing shared terminology concurrently develops reciprocal knowledge and trust as well as recognition of each member’s unique expertise (see Burke, 1966, 1969; Elwood, 1999).

Moreover, 21st-century technologies facilitate optimal expert collaborations across countries and continents so long as there is cyber-infrastructure to support collaborations. Additional possibilities to consider include community-based (i.e., non-academic) collaborators and social-organizational psychologists to facilitate and/or resolve issues impeding working in partnership ([Stokols et al., 2008](#); Bennett, Gadlin, & Levine-Finley, 2010; Börner et al, 2010; Falk-Krzesinski et al., 2011). Team science expressly involves investigators with diverse skills and knowledge to study complex social problems with multiple causes (Börner et al., 2010; Falk-Kresinski et al., 2011; National Research Council, 2015; [Stokols et al., 2008](#); Tebes, Thai, & Matlin, 2014).

Obviously, previous successful collaborations among key personnel enhance the credibility of any proposed project. In such cases, the team should indicate its collective methodological competency and experience, delineate previous team accomplishments

(e.g., publications) and provide complementary examples that reinforce the members' array of methodological expertise (e.g. qualitative, quantitative, mixed).

Successful team qualities include breadth, depth and history. All team members need to be open to a mixed methods perspective; however, it is not necessary or even possible for all investigators to be expert in all methods in any research project. A mixed methods project leader involves colleagues with distinct methodological positions yet disciplinary breadth to pose then answer a research project's key questions. Mixed methods research teams need to incorporate individual researchers who collectively have the breadth to conduct every aspect of a project. Concurrently, teams must have sufficient collective depth to support and challenge its members in each project aspect to produce the highest quality research.

Leading and Guiding a Mixed Methods Research Team

The leader of a mixed methods research team should espouse a broad perspective on the value of different methodologies, support and acknowledge different team member contributions, maintain continual dialogue about issues in working together, be sensitive to workloads of team members that may pose challenges to working on the project, and support team members' education in different methodologies when needed.

An effective mixed methods project leader should have experience and interest in qualitative, quantitative, and mixed methods research. A mixed methods team leader need not be an expert in any one approach, but must have sufficient expertise across methodologies to be able to cultivate synergy and resolve differences among team members with more distinct expertise.

A mixed methods team shares a vision and understands its members roles. A successful mixed methods team constructs a purposeful vision that relates to the research problem or question. Once constructed, the vision can help members delineate everyone's respective role, and how they collaborate conceptually, spatially, and temporally. Structure is another important consideration. In a linear structure, quantitative and qualitative perspectives sit at either end of research team processes, with key individuals bridging these distinct perspectives. In a spoked-wheel structure, each team member will participate in some core component of the research initiative via the principal investigator and/or a common data source. Defined roles facilitate effective data collection, analysis, integration, and interpretation. Achieving and maintaining a shared team vision requires a significant investment of time and energy on everyone involved.

Ideally, mixed methods teams 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 member engagement in most tasks including the application writing process and subsequent publications.

Building Infrastructure and Resources

All research initiatives benefit from a well-resourced and dynamic research environment. In most ways, mixed methods applications have considerable overlap with complex single-method studies in terms of resource and infrastructure needs. That said, there are aspects of mixed methods research that warrant explicit consideration.

Mixed methods research likely requires a wider array of computer software and staff 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. 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.

Mixed methods teams benefit from being able to call upon other experienced and informed colleagues at their respective institutions. Institutional capacity in training opportunities, research capabilities, and institutional knowledge related to the various methods are important factors that may need to be incorporated into a mixed methods study. Departments, centers, and individuals beyond those actively engaged in the proposed research can serve as useful support for the ongoing work.

Effective mixed methods research teams require collaborative workspace. Research space for mixed methods research accommodates various data collection approaches, including possible primary data collection. It is also especially valuable to prioritize the need for the research team to meet regularly, either physically or virtually. Frequent and ongoing interaction will benefit group productivity and research quality. Teams working across an academic campus or the globe should consider creating a virtual space in which to collaborate on instrument development, data sharing, and analytic collaboration among other tasks.

Training the Mixed Methods Research Team

Participation in a mixed methods research team can build methodological capacity for its members when the members prioritize collaborative educational opportunities for all its members. 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 within a mixed methods team will be defined largely by explicit and shared understanding of each member's expectations and goals.

A mixed methods research project may require training some or all the research team. Many researchers have a stronger foundation in either quantitative or qualitative methods of inquiry and the philosophical traditions that underpin each. The increasing

acceptance of mixed methods approaches has changed this reality; however, many researchers remain formally trained in one approach and hold supplemental training in the other. The issue of how to demonstrate competence across methods within the team is worth careful consideration. A publication from a NIH-funded team provides a self-rated mixed methods skills assessment (Guetterman et al., 2017).

Mixed methods analyses benefit from team members' comfort with multiple types of data and analysis methods and approaches. As mixed methods research involves data integration, the analytic process benefits from multiple perspectives to illuminate all the data. Team members need familiarity with multiple data sources to engage fully in analyses and implications.

When additional training is necessary in either qualitative, quantitative, or mixed methods research, it may be most effective to engage in collective training that edifies, strengthens, and builds additional capacity.

Developing R series plans that incorporate mixed methods research

The primary mechanism for NIH research grants is the R series. These include R01 research projects, R03 small grants, and R21 exploratory/developmental research grants. All NIH Institutes and Centers participate in the R01 mechanisms ([clinical trial not allowed](#); [clinical trial required](#)). Participation in other R mechanisms including [R03](#), and [R21](#), is less universal. As researchers plan mixed methods research projects and develop R-series applications, they need to follow the NIH instructions as well as to incorporate key elements of mixed methods research. This section is organized in the following topics and offers suggestions for how to synthesize these criteria:

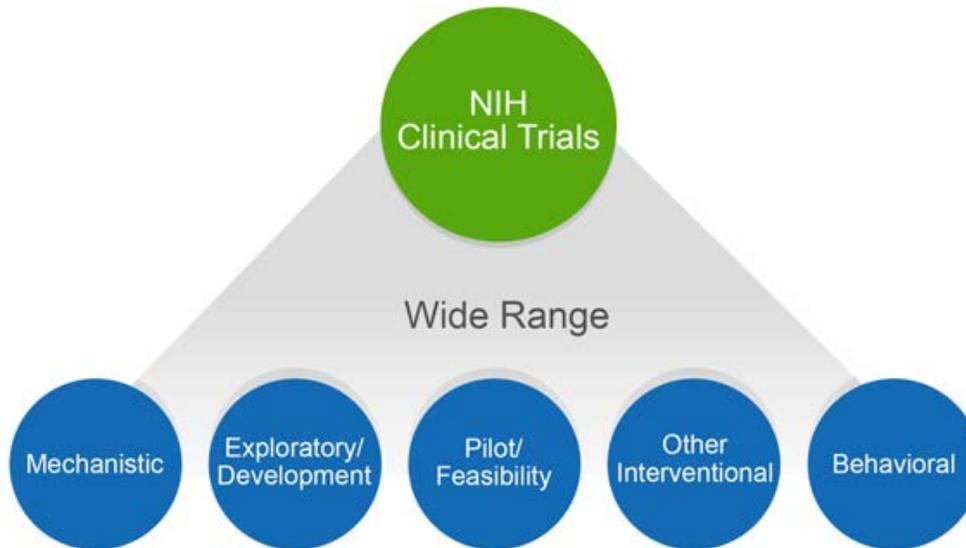
- General Comments on Preparing Mixed Methods Applications
- The Research Plan
- Additional Application Elements

General Comments on Preparing Mixed Methods 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 [General Instructions for NIH and Other PHS Agencies](#). 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, clinical trial materials, and additional categories of supporting information. NIH defines [clinical trial](#) broadly, as “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes” (See Table 1). Online resources on preparing NIH research applications, including clinical trial requirements, appear at the end of this chapter.

Match the narrative page length to the appropriate funding mechanism. The PHS SF424 forms require project investigators to include a 1-page statement of specific aims. In addition, the length of the research strategy is limited to 12 pages for R01 applications and to 6 pages for R03 and R21 applications. These limits require investigators to consider and articulate their mixed methods approach concisely.

Integrate mixed methods throughout the application. A mixed methods approach has implications for each part of the research plan. Investigators need to have basic knowledge about mixed methods research to embed important mixed methods components into the application’s aims and research strategy. These components target the application as a mixed methods investigation and relate to the quality of the overall mixed methods approach.

Table 1: Infographic of studies that qualify as clinical trials per NIH policy

Start 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 consider the mixed methods components in advance and integrate this approach as integral research project component rather than as an added feature. Investigators need commensurate time to develop and refine the overall mixed methods plan into a coherent and logical application.

Reflect on the NIH 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 proposed project’s significance, investigator(s), innovation, approach, and environment. Reviewers consider these criteria in the context of a mixed methods application. Investigators should keep these criteria in mind to evaluate their own research plans and applications during the development and writing process. This document includes suggestions for reviewing mixed methods applications.

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

According to the PHS SF424 instructions, Specific Aims:

- 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).

State an overall goal that addresses the overarching research problem or question. 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 meaning. Ensure that the goal informs the specific aims and research questions, and leads naturally to a mixed methods approach.

Ensure study aims 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 (quantitative, qualitative, or mixed methods). Link the study goals 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 integration of qualitative and quantitative data and results to yield multi-dimensional, synergistic understandings; 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 an investigation will address two or more aims, 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 who want to develop and test a culturally sensitive instrument may state three aims:

1. To understand the cultural context of the phenomenon of interest that will be addressed with a qualitative approach.
2. To develop the instrument based on the initial qualitative results that will be addressed with a connected mixed methods approach.
3. 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 this section 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.
- Ensure the Scientific Premise, serves as the basis for the proposed research question or project.

- This is distinct from the hypothesis or justification, and refers to the quality and strength of the prior research. The Scientific Premise is one criterion NIH uses to ensure rigor and reproducibility among the projects it funds.

Writing the Significance Section

- 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, to establish the importance of the problem and how the investigation will enhance scientific knowledge. Clarify this approach's Scientific Rigor in the tradition of the scientific method that ensures robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results.

Research Strategy: Innovation

According to the PHS SF424 instructions for this section,

- 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, methodologies, instrumentation, or interventions.

Writing the Innovation Section for a Mixed Methods Application

- Articulate how 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 itself may be an innovation. 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 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 state,

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the 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.
- For new applications, describe results from any Preliminary Studies. Discuss the Principal Investigator'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. Some reviewers may not have experience with mixed methods research; consequently, investigators should provide a rationale on their choice to use mixed methods. Toward that end,

- Identify the use of mixed methods research and provide a definition of this approach. Cite any extant studies that used a mixed methods approach from the health/disease area of interest.
- Name the specific mixed methods design proposed. Cite studies that illustrate its use. Use [NIH's RePORTER](#) database to locate successful applications that used a similar approach.
- State the rationale for the use of mixed methods and the selected design. Consider the variety of possible reasons 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.
- 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 reviewers perceive the research design in a concise format.

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 leave the other section weak. 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 augmenting their team with expertise in the weaker area.

Explicitly state how the proposed study will combine qualitative and quantitative components. 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.

- Approaches that involve concurrent use of quantitative and qualitative methods should discuss the planned merging of analytic and interpretation procedures to compare, relate, or synthesize quantitative and qualitative data and results after discussing their separate analysis procedures. Discuss how potential divergent or inconsistent findings will be managed and interpreted.
- Approaches that involve the sequential implementation of quantitative and qualitative methods should discuss the planned procedures to connect 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 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 correspond with the overall mixed methods designs and study aims. The order also needs to be logical and easy to follow for 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 using a mixed methods design. This description should identify specific challenges and suggest 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 mixed methods and/or qualitative research often underestimate the time required to complete qualitative data collection and analysis, and to integrate the two research approaches. Allow sufficient time to transcribe qualitative data, conduct meaningful qualitative data analysis, and integrate quantitative and qualitative data and results.

New applications should highlight prior quantitative, qualitative, and mixed methods research experiences in the Preliminary Studies section. Each approach requires researchers to understand different sets of assumptions and procedures and to have skills for their implementation. Document the PI's and co-investigators' previous experiences in quantitative, qualitative, and mixed methods research.

Additional Application Elements

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

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

Project Summary/Abstract. Include key information about the mixed methods approach in the Project Summary, specifically,

- 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.

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.

Consideration of Sex and Other Biological Variables includes the critical factors affecting health or disease in vertebrate animals or human subjects. Biological variables, such as sex, age, weight, and underlying health conditions, often are critical factors affecting health or disease.

- NIH expects applicants to factor Sex as a Biological Variable (SABV) into research designs, analyses, and reporting in vertebrate animal and human studies.
- Consideration of SABV does not necessarily mean sex differences research. See Figure 1 in "[Studying both sexes: A guiding principle for biomedicine](#)" for further detail.
- A justification is expected if the application proposes to study one sex, for example in the case of a sex-specific condition or phenomenon (e.g., ovarian or prostate cancer), acutely scarce resources, or sex-specific hypotheses when there are known differences between males and females.
- Cost and absence of known sex differences are inadequate justifications for not studying both sexes.
- Reviewers will assess the applicant's plans to address relevant biological variables, such as sex, as part of the Approach (or Research Plan) criterion score and the overall impact score, and comment on the adequacy of those plans in their written critiques and in meeting discussions.
- Reviewers will assess justifications for numbers of animals according to the section where it is included in the application.

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 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.

- 1. Mixed methods research may require the collection of identifying information from participants.** Quantitative survey research often is conducted to maintain participant anonymity or confidentiality. If this same procedure is part of a sequential mixed methods approach, however, the investigator may need to gather identifying information, so researchers can contact participants for a qualitative follow-up

phase. This requires a justification to obtain identifying information and put safeguards in place to protect participant identity and information.

- 2. Mixed methods research may require contacting participants later for more information.** A strength of many mixed methods approaches is that investigators return to participants later 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.
- 3. Mixed methods research may place a higher burden on participants than single-method approaches, but also may 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 limited time to participate. Investigators should 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 consider and articulate 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. Investigators may need to provide additional explanation and justification for the use of mixed methods procedures and corresponding ethical considerations. 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 and Other Resources

Investigators need to describe the scientific environment that will facilitate the success of the proposed mixed methods project. High-quality mixed methods projects often specify available equipment and expertise to support

- **Quantitative research** including computers, online survey software, statistical software packages (e.g., R, SAS, SPSS), resources to support intervention procedures, and expertise in statistics.
- **Qualitative research** including computers, digital recording equipment, interviewing space, transcription services or software, qualitative data analysis software packages (e.g., Atlas.ti, HyperResearch, MAXQDA, NVivo), resources to support

entry into a site, and expertise in the procedures of the chosen qualitative approach.

- **Mixed methods research** including software packages that facilitate the relating of quantitative and qualitative data, expertise in developing quantitative instruments from qualitative findings, geocoding and e-health expertise and software packages, and expertise in mixed methods research designs and approaches.

Biographical Sketches

Investigators must use the NIH format to provide biographical sketches related to each key personnel. The Personal Statement within each investigator's biosketch provides a superb opportunity to describe the background, contribution, and collaborative history of each mixed methods team member. For prime effectiveness, the statements should complement one another to facilitate a reviewer's understanding of the research team's synergistic ability to complete the proposed research project effectively.

- 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 proposed mixed methods study.
- Clearly delineate responsibility for data-integration, as this process typically requires collaboration between qualitative and quantitative researchers.
- Coordinate biosketches so each person's unique role is distinct yet complementary. When done well, this should demonstrate the synergy of the mixed methods team that has been assembled.
- Identify the investigators who will lead all or 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 should budget accordingly.

- Examples of typical mixed methods project costs include:
 - Training in quantitative, qualitative, and mixed methods procedures for personnel unfamiliar with one or more of these approaches,
 - 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.

NIH grantspersonship resources

- CSR. (2010, June 14). NIH tips for applicants: <https://www.youtube.com/watch?v=IAOGtr0pM6Q>
- CSR. (n.d.) CSR insider's view to peer review for applicants: <https://public.csr.nih.gov/aboutcsr/NewsAndPublications/Publications/Pages/InsidersGuide.aspx>
- NCCIH. (2017, August 24). Tips for new NIH research grant applicants: <https://nccih.nih.gov/grants/resources/tips.htm>
- NIAID. (2017, August 7). Apply for a grant: Sample applications and more: <https://www.niaid.nih.gov/grants-contracts/sample-applications>
- NIH. (2017, September 25). *General instructions for NIH and other PHS agencies: SF424 (R&R) application packages*. Bethesda: National Institutes of Health. <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf>
- NIH. (2016, May 23). Plan your application: https://grants.nih.gov/grants/planning_application.htm
- NIH. (2016, January 28). Write your application: <https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm>
- NIH. (2017, July 2017). Clinical trial requirements for grants and contracts: <https://grants.nih.gov/policy/clinical-trials.htm>
- NIH. (2017, August 8). Does your human subjects research study meet the NIH Definition of a clinical trial? (checklist/decision tree): <https://grants.nih.gov/ct-decision/index.htm>

Beyond the R series: High-quality mixed methods activities in Fellowship, Career, Training, and Center grant applications

The National Institutes of Health, and 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 funding requests is a compelling presentation of research issues and the plans to address them.

Applications for other types of support also must convey 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 mixed methods research approaches influence the presentation of the key elements in each of these unique types of funding applications. Not all [NIH Institutes and Centers \(ICs\)](#) offer funding in these categories; often, an IC-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. A search of the [NIH RePORTER](#) database will identify specific examples of funding projects in specific fields, to serve as models.

Building Capacity in Individual Scholars: Fellowship and Career Awards

[Fellowship Awards: F Series.](#) As the name indicates, fellowships are training, not research, awards. They are awarded to applicants with “the potential to become productive, independent investigators in scientific health-related research fields.” A compelling application explains, “the need for the proposed training,” and “a research training proposal, sponsor, and environment which will satisfy those needs.” Evaluation criteria 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: K Series.](#) Career awards provide individuals with protected time for focused activities that enhance a researcher’s capacity beyond her/his current expertise. Though some think of K awards solely for early-career stage investigators, there is an array of awards for postdoctoral, mid-career, and established investigators, and additional categories for clinician and quantitative researchers.

Criteria for evaluating K awards are like 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: Issues Specific to Mixed Methods Research. For career awards and fellowships that involve a mentor's or trainee's capacity in mixed methods, the following criteria may be relevant.

- **Candidates** should present compelling rationales for dedicated time for mixed methods training. For example, a competent quantitative applicant should articulate how mixed methods skills enhance the individual's scholarship and, perhaps, the capacity of a larger research team. If trained in only one area (e.g., quantitative research), then there should be a clear plan to develop skills in both qualitative and quantitative research, as well as in mixed methods. Support letters should provide evidence that mixed methods is an important component to the candidate's future scientific contributions.
- The **mentorship** plan is equally critical. If there is a single mentor, the application must demonstrate this individual's capacity to guide and develop the candidate's mixed methods abilities. Many environments do not have mixed methods researchers in all areas of science, however. Consequently, a candidate might propose mentors at different institutions. If the candidate proposes a collaborative mentorship model, there must be evidence that the proposed mentors have planned this carefully, and that each mentor has 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.

Mentors should demonstrate prior accomplishments including 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 researchers in related fields also can demonstrate that mixed methods training will enable the candidate to make innovative contributions to relevant research areas. Expert opinion that explains how the field could benefit from mixed methods approaches, and that the candidate will be poised to benefit the field once trained will reinforce the case for the career training plan.

- As with mentorship, the most compelling evidence of a supportive adequate **training environment** to build mixed methods research capacity is the existence of other trainees, promising a supportive collective intellectual atmosphere for the candidate. In addition, an institution or group's previous track record of training scholars in this area, and the current achievement of those former trainees, demonstrates environmental capacity.

Types and diversity of funding and scholarship of mentors and trainees constitutes another exemplar. 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.

- Career and fellowship awards must explain how the proposed **research training** 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, including courses, scientific meetings, and other training should be described. Products from the training should include the types of professional meetings where the candidate will present her or his work and how those audiences will enhance the trainee's professional development. Similarly, journals to which the candidate plans to submit mixed methods work also should be discussed.

Providing Institutional Training: T Series

The Ruth L. Kirschstein National Research Service Awards (NRSA) support the training of biomedical, behavioral, and clinical researchers through institutional research training grants. Dr. Kirschstein was the first female director of a major NIH Institute (NIGMS), served extended periods as acting NIH Director, helped develop the Sabin polio vaccine, and strongly advocated for research training (Davis, 2011). Congress renamed the program in Kirschstein's honor in 2002. Though individual fellowships (F30-F33) technically fall within the NRSA rubric, they are discussed above with the individually-focused career awards.

Institutional training awards ([T Series](#)) allow institutions to recruit individuals for predoctoral and postdoctoral research training in specified shortage areas. The goal of this program is to prepare qualified predoctoral and/or postdoctoral trainees for careers that have a significant impact on health-related research needs.

- An 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 it can make a substantial impact given the growth of interest in mixed methods approaches.

- The criteria for mentorship, as well as the institutional environment and capacity (see F & K Series discussions), are even more important in an application for institutional training grants. When students from different backgrounds and perspectives interact, mixed methods trainees can benefit from multiple scientific perspectives and epistemologies. These are fundamental skills for emerging mixed methods scientists. In this case, it is even more important for faculty mentors to avoid creating disciplinary “camps,” and subgroups of students and skill sets within the program. If all students do not receive mixed methods training, there should be specific resources identified for the proportion of mixed methods trainees. 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 accordingly.

Creating Collaborative Research Centers and Programs: 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. As reviewers evaluate center project application packages in relation to one another—not simply in relation to submissions from other institutions. Consequently, a submission must demonstrate synergies across research and educational within any single activity. Center and program-project grants are ideally suited to build or enhance mixed methods research capacity at an institution, particularly if the scientific area of focus can demonstrably benefit from such capacity.

- **Research Projects:** Center/program projects propose multiple independent research projects that together become greater than the sum of their parts. One overarching criterion is whether each individual project increases the impact of the individual investigation, as they occur within a center’s 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, knowledgeable reviewers may disagree with that description. 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 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. They 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. Methodology and analysis cores are crucial for mixed methods program projects/center grants. Cores allow staff and investigators tasked with different individual contributions to communicate effectively; cores 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 entire center.

Beyond methodology cores, other types of cores focus on training and education, or dissemination and community participation activities. Administrative cores can facilitate input and feedback from external experts or manage IRB issues. Again, centers that include mixed methods research must use core resources to support the unique needs of this field. Therefore, IRB applications must be able to draw on mixed methods expertise to explain participant confidentiality, data collection, and dissemination issues to IRB members without such expertise.

Community-based advisory boards consist of people with disparate levels of sophistication toward research, and mixed methods, and provide another opportunity to tailor mixed methods to this audience. 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 includes many of the considerations discussed for individual projects. Given the prominence of a center in most institutions, however, there should be clear institutional commitments to serve as an adequate home for the venture. Review of institutional capacity should consider evidence of previous similar successful activities and a supportive organizational culture for mixed methods. If the center will bring mixed methods research and training capacity to an organization where it has not existed previously, the application should make it apparent that this is a logical next step in the organization's mission and growth.
- **Program Leadership:** Scientific leaders direct individual projects within centers; a center director is less involved in the management of each scientific project. Nevertheless, overall center leadership requires an individual who can create opportunities for balance and synergy within and across individual 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 the center proposes to address.
- **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 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. As discussed in the section *Beyond the R series*, the evaluation criteria vary by application mechanism. 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 mixed methods research](#)). Moreover, reviewers should consider the overall mixed methods approach rather than discretely consider quantitative and qualitative approaches.
- **Use mixed methods criteria:** As the approach has matured, recommendations to assess the quality of a mixed methods investigation have developed accordingly. The following three assessment approaches, in authorial alphabetical order, offer different orientations.

Creswell and Plano Clark (2017) suggest that to evaluate a mixed methods study, one should consider,

- Collection of both quantitative and qualitative data
- Rigor of procedures in the methods of data collection and analysis
- Integration or mix (merge, embed, or connect) of data sources so that their combined use provides a better understanding of the research problem than one source could provide alone
- A research design that integrates all study features with the mixed methods approach, and
- Convey research terms consistent with those being used in the mixed method field.

O’Cathain, Murphy, and Nicholl (2008, 2010) offer GRAMMS, Good Reporting of a Mixed Methods Study:

- Justification to use a mixed methods approach to the research question
- Articulation of the design in terms of purpose, priority, and sequence of methods
- Describe each method in terms of sampling, data collection and analysis
- Delineate where and how integration occurs and who has participated in it
- Describe any limitation of one method associated with the presence of another, and,
- Describe insights gained from mixing or integrating methods.

Schifferdecker and Reed (2008) posit seven steps to design, analyze, and publish 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 review checklist for mixed methods NIH applications. NIH does not recommend private researchers' approaches or publications. Nevertheless, as there are multiple sets of criteria in this burgeoning field, this NIH publication provides a checklist that reviewers may use to review research plans 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 funding opportunity announcement (FOA) and funding mechanism (e.g., K01, R01, U01). Though this NIH publication provides this checklist, NIH cannot require reviewers to use it.

<i>Table 1. Sample review criteria and strategies for reviewing an R Series application</i>		
Criterion	Strategies for Meeting Criterion	NIH Scoring
Significance		1-9
	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?	
Investigator(s)		1-9
	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)?	
Innovation		1-9
	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?	
Approach		1-9
	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)?	
Environment		1-9
	Is there evidence that the institution supports mixed methods research (e.g., forums for multidisciplinary collaborations, faculty with funding for mixed methods research)?	

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



Overall recommendations

Applicants

- Choose the mixed methods approach to improve the quality and utility of your research project.
- Ensure all parts of the application—from broader philosophical perspectives to data collection methods—are consistent.
- Rely on the Review Criteria Checklist to ensure you write your application with its reviewers' needs in mind.
- Provide a clear rationale for the use of mixed methods based on the proposed study's goals, questions, and aims.
- Articulate the benefit that 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.
- Assemble a successful mixed methods team, not simply add people to fill methodological gaps. The group needs to meet regularly during the application design phase and throughout the process.
- Describe the individuals on projects that hold qualitative expertise in addition to quantitative and mixed methods expertise.

Reviewers

- Be aware that the mixed methods approach is appropriate to answer research questions proposed in many applications, even those that missed an opportunity to use them when mixed methods may have been the best approach to an identified research problem.
- Look for evidence of ongoing collaborations and team process-building in the biographical statements and publication records of the principal and co-investigators.
- Use the Review Criteria Checklist to assess 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.
- Recognize that an application cannot provide a complete education on any methodology. Use criteria that are appropriate for the content and methodological aspects of the application.
- Be fair and constructive in comments, recognizing that mixed methods are an innovative approach.

Sample funded projects from the FY2018 NIH portfolio

NIH RePORTER provides public access to NIH-funded intramural and extramural research projects from the past 25 years. It also includes information on projects funded by the Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Administration for Children and Family (ACF), and U.S. Department of Veterans Affairs (VA). Below are sample NIH-funded projects that were active during this revision of this resource. Links to each grant's RePORTER description and publications are embedded in each description.

Research projects

Enhancing pre-hospital outcomes for cardiac arrest

Mashid Abir, MD, MSc

University of Michigan Medical School

1R01HL137964-01 (new R01 project)

Out-of-hospital cardiac arrest (OHCA) is a common, life-threatening event associated with poor patient outcomes. Approximately 30% of patients survive to hospital admission and less than 10% are ultimately discharged alive. Some communities have been consistently more successful than others to respond and treat OHCA. How these successful processes are practiced and the factors that contribute to their successful implementation is largely unknown. Moreover, it is unknown how interaction of EMS agencies with other important stakeholders who provide care before and after EMS arrives such as first-responders (e.g., police, fire) and hospitals has not been undertaken. This project uses sequential mixed methods to accomplish three aims:

1. Identify top-and bottom-performing EMS agencies in survival for OHCA.
2. Define best practices at top-performing EMS agencies.
3. Validate factors associated with high survival at top-performing EMS agencies.

Sample publication

- An emergency medicine-primary care partnership to improve rural population health: Expanding the role of emergency medicine

Mixed-methods study of EBP sustainment in a statewide service system

Gregory Aarons, Ph.D.

University of California, San Diego

4R01MH072961-10 (extended R01 project)

Evidence-based practices (EBPs) are being implemented in public service sectors with little systemic knowledge about what factors facilitate or limit their sustainment.

Moreover, many implementation efforts cease after initial grant funding ends. There is evidence that leadership, policies, resource availability, collaboration, and organizational infrastructure may be key determinants of long-term sustainment. This project uses

mixed methods to examine factors that support and/or limit sustainment of an evidence-based child neglect intervention in a large statewide public service system.

Document analysis and conversational interviews examine leadership, policy, and public-academic collaborations influence sustainment. Service-provider surveys examine leadership, organizational factors, and organizational climate for sustainment. Main outcomes include the sustained diffusion of EBP in the service system, the fidelity with which the EBP is delivered, and the extent to which provider organizations have developed the means to sustain EBP. Study stakeholders collaborate on a comprehensive theoretical model of sustainment in public service sectors that can guide future research and implementation practice.

Sample publications

- [An overview of research and evaluation designs for dissemination and implementation](#)
- [Methods to improve the selection and tailoring of implementation strategies](#)
- [The humble leader: Association of discrepancies in leader and follower ratings of implementation leadership with organizational climate in mental health](#)

Social determinants of primary care utilization among urban community mental health center patients with serious mental illness

Kristen Abraham, Ph.D.

University of Detroit Mercy

1R15MD010214-01 (new Academic Research Enhancement project)

People with serious mental illnesses (SMI) face enormous health disparities and are at risk of premature mortality due to medical conditions. Ethnic and racial minorities and women with serious mental illness may encounter even greater health risks. Increasing the utilization of primary care services is a promising way to reduce health disparities among disadvantaged populations. This mixed methods study will identify individual and interpersonal factors associated with primary care services use among a diverse sample of people with SMI receiving mental health care at urban community mental health centers. The study has the following specific aims:

1. To prospectively assess the contributions of health literacy, health insurance literacy, mental health stigma, discrimination, and mistrust in the health system on primary care utilization over the course of six months among a racially diverse sample of urban community mental health center patients with SMI.
2. To assess primary care experiences and preferences of a racially diverse sample of urban community mental health center patients with SMI as a function of whether patients received primary care in the prior six months. An exploratory aim related to Specific Aim 2 is to examine potential gender and racial/ethnic differences related to primary care experiences and preferences.

The study will employ a sequential mixed-methods design. First, a prospective survey study will be conducted to address Aim 1. Second, using a subsample of participants from the prospective study, focus groups will be conducted to better understand patients' preferences for primary care, and their personal experiences of the social factors assessed in the prospective study. The focus groups will yield critical information as to how the intersection of multiple social identities influences patients' primary care experiences and preferences. Consistent with NIMHD's goal to enhance research capacity to create a culturally sensitive workforce, the research team includes undergraduate and graduate students who will receive health disparities training research through their study involvement.

Sample publication

- [Self-efficacy and quality of life among people with bipolar disorder](#)

[A systems-based approach to disseminate and implement an effective sugar-sweetened beverage reduction intervention](#)

Jamie Zoellner, RD, Ph.D.

University of Virginia School of Medicine

5R21CA202013-03 (continuing R21 project)

This project is designed to reduce the excessive lag time along the research pipeline by speeding the translation of emergent findings from SIPsmartER, a health literacy intervention to reduce sugar-sweetened beverage (SSB) consumption. The targeted Appalachian region of Southwest Virginia for this application exceeds the national average consumption of SSB by more than three times. SIPsmartER is a theory-based, 6-month, multi-component health literacy intervention designed to reduce SSB intake. Emerging findings from this rigorously designed trial illustrate that SIPsmartER is an efficacious intervention to decrease SSB intake: intervention participants have significantly decreased SSB intake by 227 SSB kcals/day (95% CI=326, 127; $p < 0.001$) from 0 to 6 months compared to a decrease of 53 SSB kcals/day (95% CI=326, 127; $p < 0.001$) in the control group ($p < 0.001$). Furthermore, preliminary data indicate that SSB reductions are being sustained one-year post intervention.

To translate these promising effects into population-level SSB reductions, a concerted effort is needed to understand the feasibility of organizational-level adoption and implementation of SIPsmartER and to develop an implementation support system to aid delivery within existing systems. Additionally, since a system-delivered intervention would be conducted under less-controlled conditions, ascertaining individual-level effects on SSB is necessary.

We target four medically-underserved Southwest Virginia Department of Health districts and their client population, in a mixed-methods design that includes formative, process, and outcome evaluations. The goal is to have a SIPsmartER implementation support system that can be tested in a subsequent R01 type 3 effectiveness-implementation

hybrid randomized-controlled trial, with a long-term goal of broad scale SIPsmartER dissemination within public health systems to achieve population-level SSB reductions.

Sample publications

- Implementation of media production activities in an intervention designed to reduce sugar-sweetened beverage intake among adults
- One-year mixed-methods case study of a community-academic advisory board addressing childhood obesity
- The influence of parental health literacy status on reach, attendance, retention, and outcomes in a family-based childhood obesity treatment program, Virginia, 2013-2015

Targeting surgeons' decision-making for lip surgery

Carroll Ann Trotman, DDS, MA, MS

Tufts University

5U01DE024503-03 (continuing cooperative agreement research project)

Cleft lip/palate (CL/P) are among the most common of all birth defects. To correct the obvious facial disabilities of babies with CL/P, surgeons perform an initial or primary repair of the lip and nose soon after birth. Unfortunately, many patients (and caregivers) are dissatisfied with the surgical results: Patients remain with a facial disfigurement and impairment in facial soft tissue movements-particularly in facial expressive behaviors. Multiple revision surgeries during childhood and adolescence are common to improve the initial results. The psychosocial and economic burden of care on these children and their caregivers are great.

Traditionally, the decision for lip revision surgery has been based on subjective assessments of nasolabial form, and less frequently, circumoral movement but without a method to quantify the facial movements/form before surgery or after surgery. To this end, we have developed an Intervention that utilizes a novel set of dynamic and static quantitative measures and a systematic subjective evaluation to quantify facial disability for the treatment planning of lip surgery and for assessing surgical outcomes. The quantitative measures include,

1. 3D dynamic and statistical modeling of patients' mean facial movements, and,
2. 3D static facial image data,

both compared with mean control movement and static image data, respectively. As a necessary second step in this formative research, using separate prospective cohorts of patients who have lip revision and lip repair surgery, we will conduct a 'proof of concept' Phase II randomized clinical trial (RCT) with the following three specific aims.

1. To qualitatively assess how surgeons integrate the Intervention's objective measures and visual aids with the systematic subjective assessment in the decision-making process for the clinical surgical procedures of lip revision and lip repair.
2. To quantitatively assess the extent to which the Intervention changes surgeons' problem list and treatment planning goals for lip revision and lip repair.

3. To obtain estimates on means, variances, and intra-patient correlation, and to estimate surgeon-by-condition interaction effects for surgical outcomes under the Intervention and the standard of care or control conditions.

Ultimately, while this Phase II RCT is not a therapeutic trial in the usual sense of providing a patient with a therapy, it will be unique for craniofacial rehabilitation in that the focus is to optimize the design of a novel assessment, improve an individual patient's diagnostic evidence base available to the surgeon for surgical planning, and evaluate whether post-surgical results are improved with the intervention.

Mixed methods research training program

Joseph J. Gallo, MD, MPH

Johns Hopkins University

5R25104660-04 (continuing research education project)

The overarching goal of this proposal, *Mixed Methods Research Training Program for the Health Sciences*, is to provide a state-of-the-art methodology training program to enhance the mixed methods skills of investigators. Mixed methods research is defined as the collection, analysis, and integration of both quantitative (e.g., RCT outcome) data and qualitative (e.g., observations, interviews) data to provide a more comprehensive understanding of a research problem than might be obtained through either alone.

Public health researchers increasingly use mixed methods approaches without substantive training in the latest scientific techniques. Yet, an increase in applications submitted to NIH using mixed methods reflects the growing awareness of the importance of this approach in addressing population and behavioral health. The proposal is timely in that NIH (OBSSR) issued "best practices" recommendations in 2011. No other national program in mixed methods education and mentorship exists for the health sciences. The specific aims of this training program are:

1. To identify and recruit investigators (called Scholars) using mixed methods approaches to the Mixed Methods Research Training Program,
2. To provide a mentoring- based research training program in mixed methods research that addresses study designs, data collection, measurement, theme development, data analysis procedures, visualization of designs and procedures, and models of exemplary mixed methods NIH-funded studies through didactic instruction, individualized feedback and project consultation, use of online educational materials, and carefully-designed immediate and long-term assessments; and,
3. To evaluate the outcomes (both short-term and long-term) of the Mixed Methods Research Training Program using metrics of skills development, research performance, and capacity building.

We will recruit 14 investigators per year who will participate in a 3-day training program supplemented with webinars and other activities. We will match participants with resource consultants across the United States. After matching, and following an introductory webinar on mixed methods, we will provide an interactive 3-day summer

course on mixed methods research. Following the summer course, the Scholars will interact with Program Directors and consultants through on-line conversations and learning communities that will help them further develop their research training through application to their area of interest. An evaluation plan will provide individual metrics and allow ongoing program monitoring and revision.

Sample publications

- [Development of a self-rated mixed methods skills assessment: The National Institutes of Health Mixed Methods Training Program for the Health Sciences](#)
- [Integrating quantitative and qualitative results in health science mixed methods research](#)

Career and fellowship projects

[She's prepared: The impact of intimate partner violence on women's engagement in the PrEP care continuum](#)

Tiara C. Willie, M.A.

Yale University

1F31MH113508-01A1 (new predoctoral fellowship award)

A significant relationship exists between intimate partner violence (IPV) and HIV. IPV-exposed women are almost 10 times more likely to report an HIV infection. Extant research indicates multiple direct (e.g., forced sex with risky partner) and indirect (e.g., poor mental health) pathways linking IPV experiences to HIV risk. Developing ways to prevent HIV among IPV-exposed women that is not partner-dependent is needed. Pre-exposure prophylaxis (PrEP), is a daily oral medication and may be the most viable and novel HIV prevention option for IPV-exposed women. However, engaging in PrEP care can be hard including multiple steps (e.g., daily adherence, quarterly medical visits). Women's engagement in the PrEP care continuum may be disrupted by four HIV-related risk factors (economic instability, sexual autonomy, substance abuse, depressive symptoms). First, economic instability can make women dependent on their abusive partner for money and insurance, which may hinder PrEP uptake and adherence. Second, women with low sexual autonomy (e.g., freedom to express one's sexual self) may feel unable or uncomfortable using PrEP if her partner disagree with her wish to use PrEP, which can prevent PrEP uptake. Lastly, substance abuse and feelings of depression can disrupt cognition, making it difficult to engage in daily functions, which may prevent PrEP adherence.

To date, there is a dearth of studies examining the implications of IPV on women's engagement in the PrEP care continuum, despite the potential barriers associated with IPV. This is concerning since the Trans-NIH HIV- Related Research Priorities called for research addressing how violence influences experiences along the HIV prevention continuum. This F31 aims to improve the sexual health of women across these research aims:

- 1a. Examine the effects of IPV on women's engagement in the PrEP care continuum (i.e., interest, uptake, adherence, follow-up visits), and HIV-related risk factors using data from a cohort study of women (n=250),
- 1b. Explore four HIV-related risk factors as mediators linking IPV and the PrEP care continuum, and,
2. Describe women's experiences and processes along the PrEP care continuum (n=32).

The proposed research addresses a critical need to understand the relationship between IPV and women's engagement in the PrEP care continuum in order to implement PrEP care in a safe and effective way. This research will devise PrEP engagement strategies, inform intervention development, and help the fight against HIV/AIDS for women. During this 2-year research and training fellowship, the applicant will develop interdisciplinary social science skills including advancing statistical analysis skills, gaining experience in mixed-methods study design and qualitative data analysis, while refining academic and scientific communication. This comprehensive training program will prepare the applicant for a career as an independent violence epidemiologist and academic mentor conducting empirical IPV research while designing HIV prevention interventions with for women.

Sample publications

- [Examining the impact of intimate partner violence type and timing on pre-exposure prophylaxis awareness, interest, and coercion](#)
- [The implications of intimate partner violence on health-related quality of life among adults living with HIV who experienced childhood sexual abuse](#)

An analysis of psychosocial risk and protective factors: Accelerated cognitive aging and mild traumatic brain injury (MTBI) among retired NFL & former NCAA football players

Robert W. Turner, II, Ph.D.

Duke University

1K01AG054762-01A1 (new mentored research scientist development award)

Robert W. Turner II is a Research Scientist in the Center on Biobehavioral Health Disparities Research at Duke University. He has training in medical sociology, ethnographic methods, and health disparities research. His previous and current work has exposed him to theoretical perspectives and empirical approaches pertinent to health disparity and aging research among men. The current proposal is for a five-year Mentored Research Scientist Development Award (K01) from the National Institute on Aging for training and support that address gaps in his knowledge of biobehavioral factors underlying Alzheimer's Disease (AD) dementia related mild traumatic brain injury mTBI and accelerated cognitive aging. In collaboration with his mentoring team (Drs. Tim Strauman, Keith Whitfield, and Toni Antonucci) he has developed a comprehensive

training and research plan that will both fill in these knowledge gaps and prepare him for an independent research career.

The overarching goal of his K01 is to gain expertise on the interrelationships between multiple measures of psychosocial and neurocognitive factors associated with AD dementia related accelerated cognitive aging, and serve as bridge for him to establish an independent investigator career in conducting biobehavioral health disparities research in adult male populations. To accomplish this goal, he proposes four career development activities and three research aims that combine instruction with established scholars in survey research techniques; formal coursework; participation in ongoing seminars at Duke and the University of Michigan; one-to-one directed readings with mentors; and finally, conducting of a “proof of concept study” from start to finish.

Data will be collected using a mixed-method design that consists of a survey, focus groups, and in-depth interviews. The three research aims will enable him to integrate and apply knowledge gain through the proposed training activities by creating a more robust portrait of psychosocial protective and risk factors that may impact the long-term consequences of mTBI among men than previously possible. The approach used in this project will address;

- Male vulnerabilities in predicting the impact of psychosocial factors on accelerated cognitive aging, and,
- How understandings of masculinity develop across and within groups in relationship to pain, injury, and brain health.

This project will continue to build on insights he has gained through his examination of data from the Study of Retired NFL Players. By completing these aims, he will test important hypotheses and make substantial evidence based contributions to describing the process of dementia related cognitive accelerated aging resulting from mTBI. This proposal is relevant to public health because it will explore innovative approaches to address functional, cognitive, and psychosocial vulnerabilities in concussed men, and may ultimately reduce the risk of Chronic Traumatic Encephalopathy (CTE), and Alzheimer’s disease resulting from concussions. It will also inform an R-series grant proposal to study AD dementia related accelerated cognitive aging and brain imaging that Dr. Turner plans to submit in year 4 of the project.

Sample publication

- [A preliminary study of youth sport concussions: Parents’ health literacy and knowledge of return-to-play protocol criteria](#)

M-health tools to enhance treatment of teen substance abuse and mental illness

Zachary William Adams, Ph.D., HSPP

Indiana University-Purdue University at Indianapolis

5K23DA038257-04 (continuing mentored patient-oriented research award)

The goal of this Mentored Patient-Oriented Research Career Development Award is to develop the candidate into an independent investigator prepared to lead large-scale, rigorously designed studies evaluating the utility of mobile health (mHealth) technologies in improving treatment efficiency, efficacy, and reach among high-risk youth with substance use disorders (SUD) and comorbid mental illness.

Comorbidity is common in adolescence and often complicates treatment progress. Use of mHealth approaches-such as mobile applications that tailor content to patients' specific needs, enhance patient engagement, and facilitate existing evidence-based treatments-holds great promise in reducing the public health burden of addiction and mental illness. This application proposes training and Stage IA-IB intervention development research that represents a logical progression from the candidate's prior research and training to address career development goals in six areas:

1. development of mobile applications for adolescent mental health,
2. etiology and treatment of comorbid SUD and trauma-related mental illness in adolescents,
3. conduct and evaluation of clinical trials,
4. multilevel and longitudinal data analysis,
5. grant management, and,
6. research ethics.

Goals will be accomplished through high caliber didactic training, participation in national conferences and institutes, and hands-on research experience. Activities will be completed under the mentorship of an accomplished team of expert on-site investigators in the fields of adolescent comorbidity and integrated treatments, mHealth methodologies and evaluation, technology-based mental health interventions, qualitative and mixed methods research, and analysis of longitudinal, clinical trials data.

The central hypothesis of the candidate's three-component research project is that developmentally tailored mobile applications that incorporate evidence-based treatment principles can facilitate increased patient engagement in and between sessions, thus improving the efficiency, efficacy, and reach of treatments for this highly vulnerable population.

Sample publications

- Development and pilot evaluation of a tablet-based application to improve quality of care in child mental health treatment
- Mobile devices for the remote acquisition of physiological and behavioral biomarkers in psychiatric clinical research

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NIH Panel on Best Practices for Mixed Methods Research, 2nd edition

OBSSR commissioned a team to develop the original edition of this resource. To update this resource cost-effectively, OBSSR analyzed the NIH portfolio of mixed-methods social-behavioral research projects and reviewed publications from these grants. This list acknowledges those engaged in the second edition of this project.

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