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Implementing Qualitative Data Management Plans to Ensure Ethical Standards in Multi-partner Centers

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Abstract

Thorough data management is crucial for the protection of people who participate in research and researcher ability to share results with the public. The impact of inadequate adherence to data management is particularly evident in small field sites and among vulnerable populations. Community-based Participatory Research (CBPR) presents exciting opportunities for multimedia and multi-sectoral dissemination of research results and policy change, especially concerning the impact of research on health equity for underrepresented populations. In this article we discuss how we defined data boundaries and protections to adhere to ethical standards while also prioritizing data dissemination. Although complex partnerships can introduce additional risks to data oversight, data management practices can also increase opportunities for wide-reaching dissemination. We hope to contribute to the literature on data sharing in multi-partnership projects to bolster the impact of dissemination while also protecting participants and populations who chose to collaborate in research and policy practices.

Keywords

Behavioral Social Science; CBPR; Data Sharing; Informed Consent; Indigenous/Aboriginal/ Native Populations; Public Health Research; Qualitative Methods; Research Ethics; Risks, Benefits, and Burdens of Research/Beneficence and Non-Maleficence

Introduction

Community and academic partnerships involved in collaborative, qualitative research projects generate substantial data with the potential to impact health policy (Dong, Chang, Simon, & Wong, 2011; Israel et al., 2010; Wallerstein & Duran, 2006). These data often include highly confidential and sensitive narratives, requiring additional data management practices to protect research participants while allowing for cogent data dissemination. Results obtained through in-depth and open-ended interviews go well beyond those of a

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deductive questionnaire design in the inclusion of narratives of deeply personal life choices and experiences of grief, hardship, and resilience. Participants in our research told stories of struggles with poverty, addiction, domestic violence, criminal activity, family hardship, and health crises embedded within depictions of their paths to health and wellness. We documented sensitive health information from healthcare providers who serve patients impacted by health disparities. Researchers capture the words of project participants on personal topics such as these in notes, memos, audio and video recordings, full verbatim transcriptions, and coded files. Our resulting data were thickly intertwined within a personal context rendering data nearly impossible to de-identify. The interconnectedness and contextual rootedness of qualitative data presents significant challenges to data protection and management requiring new and different plans for data sharing (Cliggett, 2013).

Collection of in-depth, interconnected data hinge on collaboration with community members who support project structure and have worked together to create research questions. Researchers who conduct in-depth interviews, focus groups, mapping activities, field notes, as well as all forms of ethnographic and qualitative inquiry hold the potential to produce deeply personal and contextual data. In our project our productive recruitment of researchers and participants was directly connected with a focus on resilience. People told us that they wanted to take part in our research because they were excited to see research with this foundational perspective. Community members and other participants in research projects like ours may not approve of re-analysis or other uses of data because agreed upon participation is based specifically on the goals of the project as well as trust placed in the capabilities of the project investigators. For these reasons, every researcher involved in the data collection and analysis phases of a project must receive training on ethical standards of confidentiality, consent, and protection of data.

Data collection and protection is crucial for any type of research. Community-engaged, qualitative research taking place among multi-sectoral partners, especially those including community or tribal Institutional Review Boards (IRBs) or volunteer organizations with no IRB requirements at all, may see a need to increase data protection to avoid data breaches, which have been realized in the past (Mello & Wolf, 2010). Affiliations for each researcher may not require the same type of oversight of data. Even the term “ethics” carries substantially different meanings across disciplinary, institutional, and personal boundaries.

In this article, we provide an example for a project specific data management protocol from a community-engaged research project which is part of a large multi-university, partnership called the Center for American Indian Resilience (CAIR) funded by the National Institutes of Health’s National Institute of Minority Health and Health Disparities (NIH-NIMHD), hereinafter, *Health Resilience*. Our pilot project began with a community-engaged process whereby community researchers worked with us to define and operationalize “resilience” as it related to American Indian people living off-reservation in Arizona. Upon funding, project investigators and a research coordinator implemented a hiring strategy designed to create collaborative relations with community members who would become part of the research team as community researchers (Hardy et. al., 2015). The project coordinator was primarily tasked with overseeing consent forms and gift card incentives, organizing large amounts of data, tracking researcher hours and pay, and ensuring adherence to IRB deadlines. We hired

community members of different tribal affiliations, ages, genders, and levels of training based on their demonstrated insight and ability to listen to interview data. The research team began project work through an intensive training in rapid ethnographic assessment during which team members worked together to focus their research question, determined a sampling strategy and screening instruments, decided on appropriate research methods, and trained in research and ongoing analysis methods. Once the team completed fieldwork we possessed a data set including full transcripts and research notes for 60 interviews, 24 Wellness Maps (Hardy et al., 2014) and associated transcriptions from mini-interviews and notes, transcripts for two focus groups, and one public seminar. We also had extensive notes from ongoing analysis meetings and code lists developed with the team. Once data collection was complete the research coordinator applied a final code list to all data and the research team disseminated results through publications, presentations, workshops, and new proposals.

Dissemination of research results rests upon an ability to collectively determine how, where and to whom a team would like to communicate important results. In *Health Resilience* the team selected salient themes, analyzed them, and reported them through descriptions of aggregate data in the context of project foundations. We described a community-engaged process; explained themes that emerged throughout data collection and analysis, using illustrative quotations. To preserve anonymity, we did not include demographic details associated with any quotes. We withheld details of project participants that were identifiable. Researchers must engage a process of determining what will be communicated and how they will do this; a process requiring a balance between reporting important findings – those that may help to educate health care providers, for example – while also making sure not to reveal personal details that could be traced back to individuals. Our commitment to the safety of participant data requires consistent decision-making that sometimes results in the choice to not publish data when de-identification poses risk to participant individuals or groups.

Our sampling, project development, and analysis relied on this community-engaged process as well as trust between researchers and communities. It became clear early in the project that our ability to build trusting relationships relied on the analytical framework of resilience and positive change rather than deficits. This community build framework required additional protection of in-depth qualitative data from re-analysis that may mistakenly re-frame the data we had collected. Any re-analysis that might change the core focus on resilience might cause serious disruptions in trust, standards of confidentiality, and data quality. At the same time, we were obligated and committed to disseminate our findings of value both for the project's continued growth and most importantly for our commitment to reciprocity to those who participated in our research. We also committed to our project team and funders to disseminating results that could potentially impact policies. We provide this example to address the data ownership, analysis, and sharing components of data management (Steneck, 2007). Our suggested methods for the development of a protocol are intended to protect sensitive data while enabling timely and useful dissemination of data findings to the public.

Community-engagement and Institutional Oversight

In contrast to purely academic research, community-engaged research projects carry with them an increased need for multiple modes of data dissemination beyond academic journal articles. Communities participating in research may desire reciprocity in the form of reports or other useful information in a much shorter timeframe than the release of a journal article or book. Community-based Participatory Research (CBPR) (Israel, Schulz, Parker, & Becker, 1998; Minkler & Wallerstein, 2008; Minkler, 2010; Wallerstein & Duran, 2010;) and Rapid Assessment, Response and Evaluation (RARE) (Trotter, Needle, Goosby, Bates, & Singer, 2001; Needle et. al., 2003) projects may also result in needed and timely policy recommendations or white papers to provide support or information to community members quickly and immediately upon analysis. Tribal IRBs, for instance, ask for regular reports on dissemination for tribal members to ensure that any research conducted is mutually beneficial.

By the same token, community-engaged research also increases needs for especially strong oversight in small communities where identity breaches may have unintended consequences on the populace. One of the most difficult charges for IRB committees is the ability to anticipate a full range of potential conflicts or dangers that could result from improper data collection, storage or maintenance, and to ensure that researchers develop plans to offset any risks from the outset of a project. It is not unheard of for an outside researcher to request data for a different purpose than the intended goal of original project leads. We anticipated potential for danger in our work by thinking through possible re-use of data that might violate the trust of our resilience-focused research team. For example, what if a researcher asked to analyze our results for addiction or abuse rather than focusing on the stories of resilience involved in a one to two hour interview? In this case the author might have written an analysis of addiction and hardship instead of resilience, which would have eroded trust with participants who agreed to take part in research precisely because of a focus on resilience. The researcher may also have used data out of context in a way that misrepresented the stories of participants in how they overcame hardship, and instead painted a picture of a people mired in constant struggle and untenable challenge. A focus on only one part of the larger contextual data set could result in published materials that may represent, at best, poor interpretations of data and at worst counterproductive materials in efforts to address health disparities.

In her case for finding digital archiving solutions for sharing primary raw data, Cliggett (2013) discusses the danger of losing context and “muddling” data as one risk. The preservation of meaning through digital archives, Cliggett (2013) writes, requires metadata to indicate interrelationships between data sets. The same is true for raw data produced from community-engaged work in that the relationships between data must be preserved and represented within the intended context of community partners. The use of data from a resilience project designed to communicate poor decision-making would again be a misuse of data based on the lack of connection to project foundation and a full understanding of different aspects of data sets. In lieu of available digital archives with the potential to preserve metadata, data protection protocols strive to ensure use of data includes context and interconnections that adhere to project principles.

Community-engaged research though, is designed in part to minimize the risk of poor interpretations and unethical uses of data through collaboration. Questions of data sensitivity and protection are complicated by community-engaged research methods, which by its very nature include a collaborative process of developing research questions and recruitment strategies with a team of community-engaged partners, and subsequent recruitment of participants through personal networks of researchers who may have varying levels of training.

Data oversight needs for CBPR projects extend beyond those of projects that do not include community partners who have an equitable investment in project outcomes. The use of a protocol like this one requires additional personnel time and institutional resources. IRB representatives also may be called on more frequently for advisement than they might be expecting for other research projects. Therefore we suggest the need for invested coordination in CBPR projects that would also include personnel with dedicated time for the management of data in addition to IRB and protocol applications. Ideally, grant applications with a focus on CBPR will include resource allocation for these additional concerns. We have had the most successful outcomes when we have one person in the role of research coordinator with research training and experience who oversees project needs in close collaboration with project investigators. Our budget justifications include descriptions of the crucial need for adherence to ethical guidelines and data integrity when working with multiple community researchers.

We followed principles of CBPR and RARE in the development of *Health Resilience*. In so doing we included a training module on research ethics and the completion of IRB requirements. Our field sites are located in the Southwest United States, and in a geographic region where researchers must be especially cognizant of a history of ethical violations and risks introduced by researchers of the past (Drabiak-Syed, 2010; Mello & Wolf, 2010; Sharp & Foster, 2002; Watkins, 2001). Ethical misconduct is still fresh in the memories of many people who have been harmed by researchers who undermined the Principle of Informed Consent, and other basic tenets of human subjects research ethics, by using tissue samples for research on schizophrenia, incest, and migration studies without participant permission (Garrison & Cho, 2013; Lunshof & Chadwick, 2011; Mello & Wolf, 2010; Santos, 2008). Questions of data protection, trust, and community participation span far beyond the type of data researchers collect (Pacheco et al., 2013). Significant care and respect is needed to honor the wishes of participants to avoid ethical misconduct to adhere to standards of protection and maintain relationships and trust.

Two distinct goals of CBPR include ensuring the safety of people who participate in research, and disseminating research results to the public. In addition to multiple IRB requirements, larger center projects may also include different or conflicting requirements, and funding agency guidelines for sharing the findings of the data collection. Juggling the responsibility to protect and share data with multiple researchers located at different institutions and community settings requires protocols for the management of both. Academic researchers are required to adhere to federal and institutional guidelines including IRBs and completion of Collaborative Institutional Training Initiative (CITI) required Responsible Conduct of Research (RCR) training. Funding agencies such as the National

Institute of Health (NIH) also provide guidelines for maintaining research integrity, acknowledging this same tension between reporting results and adhering to federal rules and regulations (NIH, 2004).

Furthermore, sensitive data that involves small and/or vulnerable populations necessitates more stringent guidelines (Flicker et al., 2007; Mikesell, Bromlex, & Khodyakov, 2013; Minkler & Wallerstein, 2008). Some institutions do not have internal IRBs in which case they may affiliate with another institution to achieve IRB approval, or in some cases choose to bypass the IRB process completely as in the case of internal evaluation projects where the project may not constitute research because results are intended to improve programmatic functions. In the American Southwest we also have multiple tribal IRBs and other oversight entities that each bring their own policies, application processes, and requirements for research. Community IRBs are also on the rise among strong community organizations that are developing informal and formal processes for permission to conduct community research with people who live and work in their local area (Albert Einstein College of Medicine et al., 2012). Therefore, when a partnership becomes large and complicated, it is not unusual that Principle Investigators, the project leads, may have to obtain multiple approvals for a single project.

Our project, *Health Resilience*, included project partners representing different tribal affiliations, multiple university departments, partners from the local hospital, and other researchers not affiliated with an IRB committee. One of the Principle Investigators (PIs) of our project is an anthropologist and chose to position the pilot research project to adhere to the ethical guidelines of the American Anthropological Association (2012). Each member of the research team received training on the code for anthropological research in addition to online training through the CITI, as required by the university IRB. Researchers identified areas of overlap and possible disjuncture between AAA ethical code as well as the IRB requirements of the university IRB, the local hospital, Indian Health Services (IHS), the Navajo Nation Human Research Review Board (NNHRB), and requirements from the Hopi Tribe. We obtained permission from each of these entities to conduct research, and each team member discussed how we could adhere to all of these entities in the most respectful and protective way. These overlapping and related standards require protections of participants while also communicating our results in ways that might be beneficial to all project participants and local communities. The conversations that ensued prompted the need for additional protection in the context of CBPR. We also hired a research coordinator whose primary responsibility was to collect, file, and secure all consent forms, notes, memos, maps, and other project artifacts immediately upon the collection, in order to reduce risks of data loss or disorganization.

Tensions between Protection and Dissemination

A collaborative approach to developing a data management plan allows for conditional access to sets of data to ensure that data are used in productive ways to contribute to knowledge and support the goal of enhancing health equity. Implementation of the data management plan also requires quality oversight of data generated through community-engagement. Community-based research teams decide together how to focus research

questions, who to recruit, methods for appropriate data collection, and analysis designs. These teams usually include people who are positioned within and outside of university settings who often have different project goals and varying levels of investment in different project outcomes. While university researchers must protect unanalyzed or raw data in accordance with their IRBs, they are also accountable to community partners to share data for dissemination. In CBPR projects researchers may agree to share data with community partners for policy or community change in order to honor collaborative partnership agreements. In cases where academic journal articles take time to publish community partners sometimes ask for data sharing for timely dissemination, especially when urgent policy work is involved.

As noted above researchers must also adhere to responsibilities to the public through data sharing requirements developed by the National Institutes of Health (NIH) and National Science Foundation (NSF). Guidelines intended to ensure the reliability and public availability of research findings for information dissemination however, may conflict with needs for protection of project participants and goals of community partners. Terms of research participation are outlined in a consent form that may or may not include a statement about future use of data. When consent forms do not include a statement about future unrelated use of data, the ability for future researchers to re-analyze existing data in any form is not possible. In cases where data must not be re-analyzed project leads have the option to destroy raw data within a short timeframe. While data destruction limits the potential for ongoing analysis it may also protect data from conflicts over ownership that could put participants at risk.

Data management protocols are designed to provide further protection and oversight beyond, but not in lieu of existing IRBs. These protocols help researchers to protect vulnerable data beyond the initial phases of a growing project where leadership or questions of data ownership may shift. Primary IRBs will continue to provide guidelines for safety of data management and storage, and, if necessary, adverse event reporting. In cases where consent forms do not include future potential uses for raw data researchers must submit new applications instead of amendments to existing IRB approvals.

Such is the case when researchers who were not part of the original research team submit requests for secondary data analysis. While terms of research participation are outlined in the consent form, it may or may not include a statement about future use of data. When consent forms do not include a statement about future unrelated use of data this rules out the ability for future researchers to re-analyze existing data in any form. In *Health Resilience* consent forms were project specific so no new IRB requests were allowed. These additional layers of protection aid in the ability for multiple IRBs (including tribal or community IRBs) to be assured that raw data will not be reinterpreted based on the interests of new collaborations.

Non-university researchers share needs for protection of data, and may have different goals for the speed and style of dissemination. A community researcher may or may not share the desire or need for peer-reviewed products as the academic counterpart does, however they may be highly invested in producing policy papers that could communicate health needs in a

timely way to local entities. In this light, researchers have an obligation to the study participants to translate the findings into understandable terms and disseminate the results back to their communities. Furthermore, academically situated researchers may have a responsibility to mentor students who might work with data sets in order to continue to analyze and disseminate the results of the research.

A Project Specific Protocol for Data Sharing

Our completed data set includes over 60 interviews containing personal health and family information as well as healthcare provider discussions of individual patient cases, which introduce risk for both the provider and the patients, even when names are protected. The protection of these data is crucial for the safety of research participants as well as ongoing trust in communities. We obtained approval from multiple institutions and tribes to conduct research and safely store and share findings. What happens, then, when people outside of the core *Health Resilience* team would like to access these data to continue analysis and dissemination? This is the juncture at which a project-specific data management protocol is needed.

The overarching premise of the project specific protocol is to maintain a commitment to community-engagement by ensuring the protections of research participants and upholding standards for high-quality rigorous research practices. Our *Permissions for Access and Use of Data Sets* includes three sections: application, use of the research, and guidelines for dissemination. Within the first section, the protocol instructs requestors to present their case to a Review Team of the relevant research project including one Principal Investigator (PI) from *Health Resilience*, and at least one community researcher. A basic application is required as the first step. This application helps to contextualize the requestors' interest in accessing the data and requires documentation for the completion of IRB and CITI training completion for all of the researchers involved. In addition to information about the requestors, information about the project is also required, including a rationale for use of specific data sets and the research question or aims, and the planned outcomes (e.g. manuscripts, presentations, etc.). The Review Team will answer the following questions: 1) what is the goal of the proposed project; 2) what risks does this additional analysis introduce; 3) can the risks in question two be minimized; 4) how do the goals of this proposed project align with the goals of *Health Resilience* and CAIR. The remaining sections provide instructions on use of the data sets, and guidelines for potential publications or public presentations that result from the requestors' use of data.

Discussion

With an increase in the use of community-engaged projects as well as the development of multisectoral partnerships, especially in small field sites and among vulnerable populations, there may be a need for project specific data sharing protocols. In our project we developed our project specific protocol once our data collection had already begun, and simultaneous to when we began receiving requests for data that we could not release. In new projects we see the benefit of developing this additional protocol during ethics training in collaboration with community partners from the outset of a project and before the beginning of data collection.

This development serves to strengthen trust between project partners and allows community researchers representing many entities to bring forth concerns about the sharing of data and risks that may occur as the result. We strongly suggest that research teams in any setting consider developing and implementing plans for adherence to ethical guidelines and smooth communication between project partners in data ownership, management, and protection in the long term.

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Biographies

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Instructions for Access and Use of *Health Resilience* Data Sets

Introduction

In accordance with and in support of the Center for American Indian Resistance (CAIR), subsets of de-identified data collected for pilot projects, *Health Resilience Among American Indians in Arizona* (Northern Arizona University, NAU) may be made available to collaborating researchers for valid research purposes wherein a formal request to make use of the data is submitted through the request process.

We have designed this plan to ensure protections and standards on data sharing and management in addition to each project's Institutional Review Board (IRB) requirements. The maintenance of policies and standards of data management will ensure adherence to the goals of project research, and a commitment to community-engagement and trust between project partners and communities. Access to raw data will not be allowed unless investigators obtain permission from all project IRBs.

Section I - Application

To request access and permission to use/conduct secondary analysis data from *Health Resilience Among American Indians in Arizona* (NAU) a formal request must be submitted to the Review Team of the project including PIs from Health Resilience, one PI from CAIR, and at least one Project Researcher from the core RARE team. This Review Team will use a set of questions to assess the adherence of the researcher request with the core principles of CAIR and Health Resilience.

Part A: Requestor information

- (1) Lead researcher's name, institution, email and phone number
- (2) Researcher's relationship to CAIR and Health Resilience
- (3) Names of all other people working on the project including all co-investigators and research collaborators including data analysts and research assistants. Each member of the project proposal is required to sign a Confidentiality Statement stating that they have read and will adhere to the conditions of the Institutional Review Board. All members listed must submit proof of Responsible Conduct of Research (RCR) certification. The online training and certifications are available at no cost through the IRB offices at NAU.

Part B: Project information

- (1) Working title of the potential project.
- (2) Brief description of the research project, including the research objectives or research question.
- (3) Datasets requested for the project including rationale for use of specific datasets.
- (4) Study design or methods, and proposed analytical plan including time frame.
- (5) Budget and source of funds, if any.
- (6) Expected outputs (papers, graduate degree seeking research, conference papers, further grant applications etc.)
- (7) Proposed order of authorship, and justification.

Figure 1a

Section II. Use of research

Requests for access to data are considered by the project-specific Review Team.

If approved, the data is provided specifically for the analysis described in the application. Researchers will be required to submit brief annual reports to the Review Team from date of approval. Approval will be renewed following interim reports if work is progressing according to requestor's anticipated timeline and/or the timeline of CAIR (projects may not continue beyond funded period for CAIR).

Researchers must notify project Review Team with any substantial changes to the project by submitting a new application form and noting the amendment/s. Substantial changes include: changes to the nature of the analysis, the topic addressed, or theoretical foundation (as it relates to the overarching goals of CAIR, CBPR, and community-engaged research); requests for additional variables or data sets; and the addition of any individual to the project. New collaborators are required to sign a Confidentiality Statement prior to accessing any data.

Section III. Guidelines for public dissemination (publications and presentations)

Full acknowledgement of the source of data used must be provided in any publications or presentations that arise from access to, and use of, the data, including NIH project number, CAIR, and pilot project name and information.

Part A: Guidelines

- Researchers are required to follow their institutions' guides as well as IRB guidelines pertaining to publications and conference presentations.
- The preliminary authorship and order of authorship will be agreed upon with project PIs. Authors should ensure that research assistants, technical officers, and other 'non-authors' who contribute, including community members involved in supporting the project, are properly acknowledged. The acknowledgement may refer to any other persons who have provided comments, advice, support or other input into the paper, who are not already listed as authors. Permission should be sought from these persons before including their names.

Publications and journal submissions (including abstracts for conference presentations) must be reviewed and approved by the Review Team before submission to a journal or editor using the original application questions including the relationship between CAIR and Health Resilience goals and dissemination materials.

- In the event that a PI is not a co-author on a publication, authors must provide copies of publications to either or both the PIs for *Health Resilience Among American Indians in Arizona* and *Documenting and Promoting Resilience in Urban*

Part B: How to cite data

All publications that result from funding through CAIR must include the following acknowledgement: Collection of the urban southern/northern Arizona AI data set was funded through the Center for American Indian Resilience, Northern Arizona University (5P20MD006872). Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number P20MD006872. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Additional funding agencies should also be acknowledged if this is applicable.

Figure 1b

Figure 1. Center for American Indian Resilience

Health Resilience Among American Indians in Arizona Documenting and Promoting Resilience in Urban American Indians