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Research Methods

Institutional review board training when patients and community members are engaged as researchers

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Abstract

Background. Patient engagement efforts often rely on a participatory research approach, which means engaging patients and community members in all aspects of research. As research team members, they require familiarity with the principles of human subject protection, privacy, and institutional review boards (IRB). However, the time required for individual IRB training may be a barrier to engaging community members in participatory research. As more community members participated in research, the State Networks of Colorado Practices and Partners (SNOCAP) was faced with finding a balance between including community members as part of the research team and the significant time commitment and institutional requirements for human subjects research oversight.
Objective. Design and implement a community training on human subject protection in research.
Methods. The SNOCAP team worked with the leadership from the Colorado Multi-Institutional Review Board (COMIRB) to develop a training programme that included the ethical principles and guidelines for the protection of human subjects.
Results. The final training programme was based on the core principles of the Belmont Report: respect for persons, beneficence and justice. Privacy was taught using the Health Insurance Portability and Accountability Act (HIPAA) national guidelines.
Conclusions. The members of the High Plains Research Network Community Advisory Council were fully engaged in developing the training programme, as well as in the training itself. They were committed to the principles and guidelines for protecting the rights and welfare of human subjects. Patients and community members have become a critical part of our research team. They understand the principles of human subjects protection and privacy and incorporate these principles into their research activities.

Key words: Human subject protection, institutional review boards, participatory research

Introduction

Patient and community engagement in research have become more prominent over the past 10 years. Multiple federal funding agencies now require and support patient and community engagement in the research projects they invest in (1–3). 'Citizen Science' has begun moving discovery from the university to the community (4). Patient engagement efforts often rely on a participatory research approach, which means engaging patients and community members in all aspects of research: research question, study design, data collection, analysis, interpretation and dissemination (5,6). Through participatory research, patients and community members become part of the research team. As members, they may be required to become familiar with the principles of human subject protection, privacy and institutional review boards (IRB). IRB training may require several days of in-person training with online updates and routine renewal, a good share of which may lack relevance to the local community and research projects (7). Furthermore, the time required for individual IRB training and maintenance is onerous and may be a barrier to engaging community members in participatory research. Several organizations have produced training programmes in protection of human subjects research that are tailored to community health workers. Still, these targeted programmes require more extensive training than is needed and more time than is available to most patients and community members not employed in the health care industry (8).

The State Networks of Colorado Ambulatory Practices and Partners (SNOCAP) has used a participatory research approach for more than a decade, engaging practicing clinicians, patients and community members in all aspects of research projects. The High Plains Research Network (HPRN), a member of SNOCAP in rural and frontier eastern Colorado, is guided by a Community Advisory Council (C.A.C.) composed of farmers, ranchers, school teachers and other community members. The C.A.C. members have been active participants in the research of the HPRN for 12 years. Attending quarterly full-day meetings, the C.A.C. members provide leadership on research project selection, methods, data collection, interpretation and dissemination. C.A.C. members have presented the research at local, national and international meetings and served as co-authors on peer-reviewed manuscripts. HPRN C.A.C. members have been trained in many research aspects and each new project provides an opportunity for learning new methods, clinical topics, analyses and dissemination techniques. As the projects and research progressed, the C.A.C. took on a project in which sensitive 'human subject' data analysis demanded their analysis and input. Initially, several members completed the full IRB training on human subjects protection, privacy and the Health Insurance Portability and Accountability Act (HIPAA) (9). However, as more and more community members participated as members of the research team, SNOCAP was faced with finding the balance between including community members as part of the research team and expecting a reasonable time commitment to meet institutional requirements for human subjects research oversight.

The purpose of this article is to briefly describe our efforts to develop a method for assuring adequate human subject protection that is relevant to the type of research conducted in SNOCAP projects, as well as being respectful of patient and community member needs.

Methods

The SNOCAP academic team worked with the leadership from the Colorado Multi-Institutional Review Board (COMIRB), the University of Colorado administrative body established to protect the rights and welfare of human research subjects, to develop a programme for training that included the ethical principles and guidelines for the protection of human subjects of research, was relevant and feasible for community members and maintained the integrity of COMIRB oversight. At issue was the length and complexity of the standard COMIRB multi-hour training programme. The university required all training participants be coded as 'employees' within the system in order to gain access, and certification required annual maintenance through online or in-person training.

Members of the HPRN C.A.C., SNOCAP leadership and several research investigators met regularly to identify the necessary components for training. The type of research involvement by patients and community members in SNOCAP projects was typically limited to development of research methods; analysis and interpretation of data; and dissemination efforts such as presentation and peer-reviewed manuscripts. C.A.C. members review both qualitative and quantitative data that in a small town could make some subjects identifiable. Because patients and community members who assisted in research were not typically used for recruiting and consenting research subjects, the aspects of training that included consent processes were not included in training. While the Belmont Report was never officially adopted or endorsed by Congress or the Department of Health and Human Services, the document has served as an ethical framework for protecting human subjects for >35 years. Many of its recommendations have been incorporated into Department of Health and Human Services regulations, essentially representing minimum standards for US funding agency requirements for protection of human subjects (10). C.A.C. members agreed that the principles of the Belmont Report were well aligned with their understanding of protecting human subjects participating in medical research.

There are numerous additional ethical concepts and subcategories; however, the group felt that these three major components reflect the more important foundational values within human subjects research. While privacy may be a component of respect and beneficence, privacy was handled separately due to the formal regulations required in the USA and was covered in the training through review of HIPAA rules and regulations (9).

Results

In consultation with COMIRB, we developed a plan to train engaged patients and community members in the basics of human subjects protection based on the core principles of the Belmont Report (11). We produced a 90-minute training that included a robust conversation among the community members about their responsibility in human subjects protection and in privacy for research subjects. To gain a full appreciation of the Belmont Report, patients and community members joining the research team are strongly encouraged to read the original report or a thorough summary (12,13). The research team, working with COMIRB leadership and the C.A.C., finalized the training around how to apply the major principles of the Belmont Report: respect for persons, beneficence and justice (see Table 1). The research team brought copies of the Belmont Report, provided a short presentation on the major principles of the report and facilitated the conversation.

The C.A.C. members participated in a boot camp of sorts—they were immersed in the content or the Belmont Report, engaged in a robust conversation of the principles and became consciously committed to the guidelines for protecting the rights and welfare of human subjects. The C.A.C. pointed out that these 'human subjects'

Table 1. Community member institutional review boards training elements—the Belmont Report and Health Insurance Portability and Accountability Act

Principle	Major components	Training elements
Application of 'respect for persons'	Informed consent process	When is consent necessary? Who is consent for? Information—Does consent provide all necessary information? Comprehension—Is consent crafted in understandable language? Voluntariness—Does consent indicate that participation is voluntary? How to determine if one lacks autonomy to make a reasoned decision?
Application of 'beneficence'	Assessment of risks and benefits	Risk refers to the probability of harm; one should consider both the probability and the severity of potential harm What are the risks of harm (physical, psychological, social, and economic harms)? How can the research be improved to minimize risk and maximize benefit? What are the benefits (to the participant, to the community, to the society)?
Application of 'justice'	Selection of subjects	Is the subject pool appropriate for the research? How will the research seek to involve vulnerable populations (e.g. economically disadvantaged, youth, limited cognitive capacity)? Are the recruitment procedures fair and impartial? Are the inclusion and exclusion criteria fair and appropriate?
Application of 'privacy'	Everything is private	What is protected health information? What steps can be taken to maintain privacy in research? How does one present findings and maintain privacy?

are their neighbours, family and community members. Therefore, protecting them was more than some academic rule or regulation; they saw it was their moral responsibility to the community. The irony that the university was requiring that patients be trained to protect themselves from the university research intrigued and amused them.

The C.A.C. participates in many activities that do not require IRB oversight. Sometimes, council members do participate as co-researchers, truly full members of the research team. Now, however, prior to research activities such as reviewing data, C.A.C. members pause, restate the principles of the Belmont Report and privacy regulations of HIPAA and remind each other and the research team about respect for research subjects, privacy and confidentiality. At the community's suggestion, our IRB/HIPAA activity is included in the agenda and documented in summary notes of every meeting in which IRB-appropriate matters are discussed. This level of conversation and documentation underlies their thorough understanding of both the general and specific content of IRB training and practice.

Discussion

Patients and community members are an integral part of the High Plains Research Network research team. Together, researchers and community partners participate fully in all aspects of research projects, which means everyone must have a solid understanding of basic research methods including the principles of protecting the rights and welfare of research subjects. SNOCAP and HPRN academic partners take responsibility for training using the Belmont Report and HIPAA standards. SNOCAP oversees all research conduct, data management and confidentiality. Patients and community members commit to abiding by the principles of the Belmont Report. Protecting human subjects in the rural communities of the High Plains Research Network began as a 'kitchen table' conversation among the academic team and the C.A.C. That is, the ethics of community-engaged research reflected the ethics of day-to-day life in eastern Colorado. These ethics, now codified by a national research standard, applied personally and as a member of the research team, continue. Though there are but a few fundamental principles to be addressed, based on the diversity of communities and of research programmes, we expect that IRB training for community members of each organization will have its own unique perspective and curriculum. We look forward to conversations on these matters among our own growing community of people who do 'citizen science'.

Declaration

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Ethical approval: IRB Exempt.
Conflict of interest: none.

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