Protecting Participants in Family Medicine Research
A Consensus Statement on Improving Research Integrity and Participants’ Safety in Educational Research, Community-based Participatory Research, and Practice Network Research

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Recent events that include the deaths of research subjects and the falsification of data have drawn greater scrutiny on assuring research data integrity and protecting participants. Several organizations have created guidelines to help guide researchers working in the area of clinical trials and ensure that their research is safe and valid. However, family medicine researchers often engage in research that differs from a typical clinical trial. Investigators working in the areas of educational research, community-based participatory research, and practice-based network research would benefit from similar recommendations to guide their own research. With funding from the US Office of Research Integrity and the Association of American Medical Colleges, we convened a panel to review issues of data integrity and participant protection in educational research, community-based participatory research, and research conducted by practice-based networks. The panel generated 11 recommendations for researchers working in these areas. Three key recommendations include the need for (1) all educational research to undergo review and approval by an institutional review board (IRB), (2) community-based participatory research to be approved not just by an IRB but also by appropriate community representatives, and (3) practice-based researchers to undertake only valid and meaningful studies that can be reviewed by a central IRB, rather than separate IRBs for each participating practice.

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While medical research has resulted in advances in the treatment of diseases, there have been concerns related to the reliability of medical researchers and about the safety of research for participating subjects. Examples highlighting the reliability of investigators include cases in which data were falsified or completely fabricated. Cases leading to concern about safety include research protocols that have resulted in the deaths of research participants.

In response to the aforementioned concerns, investigators in the clinical sciences need to focus greater scrutiny on assuring research data integrity and protecting participants. Systems to verify research data and shield participants from harm have been developed for clinical trials, but few investigators in family medicine participate in clinical trial research. Instead, family medicine researchers often engage in research that involves descriptive or epidemiological investigations, and with various populations, including practice-based networks or entire communities. Additionally, many family medicine researchers conduct investigations into the process of medical education—research that can blur the lines for investigators between research and the normal evaluation of educational programs.

Variations in research settings may not be the only difference between clinical trials and educational research, community-based participatory research, and practice-based research. Many investigators working in these latter areas may believe that the research they are conducting carries little or no risk to the participants and communities and thus requires no outside oversight for the protection of research participants. Consequently, the safeguards to ensure data integrity and protect research participants in these areas of research are not as well defined or accepted as they are for clinical trials.

To address this gap, we assembled a panel of researchers with expertise in the areas of practice-based network...
research, community-based participatory research, and educational research to explore the issues of data integrity and participant safety. With support from the Association of American Medical Colleges and the US Office of Research Integrity, the group’s goal was to develop a consensus statement that could serve as a guideline to family medicine investigators engaged in educational, community-based, and practice-based research.

To reach this goal, the project managers solicited nominations from members of the North American Primary Care Research Group (NAPCRG) and the Society of Teachers of Family Medicine (STFM). From the short list of individuals recognized for their experience and leadership in these areas of research, one expert was selected for each topic. Each expert prepared a paper about the challenges of protecting participants, and these were presented at the October 2004 NAPCRG Annual Meeting. Based on input from attendees at the NAPCRG session, the papers were refined and recommendations formulated. These recommendations then were presented at the May 2005 STFM Annual Spring Conference, where the recommendations were discussed. While this report summarizes the issues and recommendations of this expert panel, the process was designed to obtain input from many members of STFM and NAPCRG.

**Educational Research**

In an audit of manuscripts submitted to *Family Medicine* during 2004, about 90% of educational research studies submitted to the journal had not undergone review by or received an exemption from an institutional review board (IRB). While there are no systematically collected data on why authors do not submit educational research for IRB approval, informal discussions with authors reveal two main reasons. One is that authors do not believe that IRB review is required for educational research. The second is an assumption that IRB review is needed only for certain types of educational research and that most educational research is exempt. These authors make the determination of exempt status on their own, without input from or review by an IRB.

**Federal Regulations**

The reality, however, is that federal law requires that educational research undergo formal review by an IRB, unless specific criteria for exemption are met. Further, the determination of whether these exemption criteria have been met is to be made by the IRB, not by the investigator. Thus, educational researchers must submit their project, or an application for exemption of the project, to an IRB for a determination of whether an exemption can be granted or full review is required.

Educators must be aware that trainees do not automatically give consent for participation in educational research simply by enrolling in a medical school or residency. Indeed, even for research with an IRB-designated exemption, it is still required that subjects be informed about the study, the intention to publish the results, and that subjects give voluntary consent for participation. Educational researchers should be cognizant of the potential for students to feel coerced to participate in educational research projects because the researchers (ie, their teachers) also assign their grades, determine their graduation status, and write letters of recommendation for them.

**Retrospective IRB Approval?**

While educators routinely evaluate courses, the results of those evaluations are typically for internal departmental or institutional use. Once educators have the intention of publishing the results outside of their institution, however, the evaluation becomes educational research, and all of the aforementioned human subjects protection considerations apply. This means that educators must often decide about the possibility of publication before they collect data from or about trainees, thus enabling an IRB to review the research before data collection begins. If the decision to publish occurs after data collection, an IRB might be unwilling to review the project because data collection already occurred and did so without IRB approval—a practice that could cause a faculty member to run afoul of institutional or federal rules.

On occasion, an IRB will grant retrospective review to an educational research project that is planned after course evaluations or trainee performance ratings have been collected. As a rule, however, researchers should not count on such retrospective reviews taking place, because the willingness to undertake such a review depends on the discretion of local IRBs. Further, a recent discussion at an open forum made it clear that some people think retrospective reviews are nothing more than an accommodation of people who are breaking rules.

In summary, educational research always falls under the purview of IRBs. Consequently, all educational research projects should undergo IRB review, and *Family Medicine* recently published a policy statement to this effect. Educational research projects may be exempt from detailed IRB review, but such a determination must be made by an IRB. For interested readers, a more-detailed discussion of rules governing protection of educational research subjects has recently been published.

**Community-based Participatory Research**

Community-based participatory research (CBPR) is defined as a collaborative partnership approach to research that involves researchers and community members in all stages of the research process, including...
conception, design, research execution, analysis, interpretation of the data and conclusions, and dissemination of the results. All partners are considered expert, and each brings knowledge and resources from different experiences. The goals of CBPR are to increase the relevance of research to a community while maintaining standards of scientific rigor, promote community capacity building, and apply the results appropriately to improve health.

The expertise of the involved community is frequently the key to the scientific value and societal relevance of the research results. CBPR is guided by the principle of sharing decision making, power, and resources among the participants. This principle of community-based participatory research contrasts with that of classical research, in which researchers are in control throughout the research process. Greater information about the principles of CBPR and value of this research are beyond the scope of this paper, but readers may learn more from several other reviews on this topic.

Guidelines for CBPR

As new approaches and models for participatory and community-based research are emerging, ethical guidelines are needed to offer protection for communities in addition to the protection of individuals. This raises questions such as how to facilitate ethical review by both the IRB and the participating community. IRBs need to consider whether they have adequate knowledge of CBPR, whether appropriate community members are included, and how they can review an application in which the researcher proposes to develop the research focus and methodology with the community. Communities face the challenges of whether a community review and approval process is in place and the level of importance of the community’s decision. Both groups need to decide how they can review an evolving process.

Research Agreements

To facilitate CBPR, it is useful to have written research agreements that are approved and signed by all involved parties. They should include research goals and objectives, methods of data collection, types of confidentiality, evaluation plans, joint interpretation of data, dissemination plans, where the data are filed (ie, in the university or community or both), future use of data and human biological material, and selection of new team members, including academic researchers, students, and community representatives. Discussion of the results with community representatives allows for joint interpretation of the data and any modifications before external dissemination. This step strengthens the validity of the results, minimizes harm (for example, external stigmatization of individuals and the community, self stigmatization, and community disruption), and maximizes benefits.

These agreements should meet three objectives. First, they should outline the protection of both the individual and the community. For example, do individuals and the community want anonymity? Do some or all of the individuals and/or community wish to be named? If individuals are named, can communities remain anonymous?

Second, they should outline how the community representatives can review and approve the proposed research in addition to, and preferably before, the IRB review. They should also outline how the final decision of the IRB will be handled in case of disagreements with community representatives.

Third, for secondary data analysis, the agreement should assure that both the community representatives and researchers are consulted and agreement is reached before data or biological samples are reanalyzed. The latter, of course, is a requirement for all research involving human subjects.

CBPR teams can benefit from reviewing current guidelines, the majority coming from indigenous communities, and using the principles in those guidelines to develop project-specific agreements. The project-specific agreements should reflect the research context, including local culture, political issues, needs, and interests and to maximize collaboration between the researchers and community partners. The experience of many teams is that the process of developing guidelines can strengthen both the partnership and the proposed research.

Practice-based Research Networks

The Agency for Healthcare Research and Quality defines practice-based research networks (PBRNs) as “a group of ambulatory practices devoted principally to the primary care of patients, affiliated with each other (and often with an academic or professional organization) in order to investigate questions related to community-based practice.” For the purposes of discussing issues of research integrity, however, one might situate research in PBRNs somewhere between clinical trials carried out in physicians’ offices and CBPR.

In PBRN research, the unit of analysis might be a practice, practice staff, clinicians, or patients. Therefore, one must consider research integrity at each of these levels of engagement. Like clinical trials conducted in physicians’ offices, PBRN research involves participants in a number of different practices whose mission is primarily patient care. Unlike clinical trials, there are often scarce resources at the practice site to carry out the research, and it is, therefore, more difficult to maintain quality control of data.
Some of the research integrity issues that have arisen in the PBRN research community include inadequate scientific design, informed consent, and protocol compliance. There have also been conflicts of interest for clinicians and staff and concerns about the indistinct border between research and quality improvement. Each of these will be discussed below in more detail.

Inadequate Scientific Design

While perhaps not readily apparent, inadequate scientific design is a research integrity issue. Poorly designed studies are not ethical because these studies may expose subjects to a potential harm with no possibility of any benefit. In addition, poorly designed studies are not ethical from a society perspective because they use scarce research resources addressing a question that cannot be answered by the study. Many PBRNs have very constrained research resources and may lack the technical research expertise to ensure an adequate research design. This problem appears to be arising less frequently as PBRNs recruit well-trained investigators, but there are still instances of networks engaging in studies that have inadequate designs or lack sufficient power to provide meaningful results. The first step in protecting participants in network-related research, therefore, is to assure that all studies will yield scientifically valid results.

Inadequate Informed Consent

Since PBRN research occurs in many sites, numerous separate IRBs may have to approve a particular study. And, because each IRB may require idiosyncratic variations on the IRB form, gaining the approval of each IRB can be expensive and time consuming. The formation of central IRBs specifically designed for PBRNs could lessen some of these informed consent barriers to conducting research in PBRNs.

Another informed consent issue is the question of who should obtain informed consent from patients. Because PBRNs are composed of primary care practices where the relationships among patients, practice staff, and clinicians can be very close, patients may feel unduly influenced to consent to a study to please the staff or clinician who asks them to participate. Indeed, participation rates are extremely high in PBRN studies. PBRN researchers must be on guard constantly for this problem and make special safeguards against this potential problem.

Compliance With Human Subjects Protections Training Requirements

Research site compliance with IRB protocol requirements for training of those who serve as investigators or staff on research projects may be challenging in PBRNs. While sufficient training in human subjects protection is imperative to ensure the integrity of research, the stringent requirements for academic investigators and university-based investigators and staff may not be necessary or appropriate for primary care clinicians and their staff who may participate in a PBRN study. For example, some IRBs may require office staff to undergo a half day of training at a central site before allowing a receptionist to simply pass out anonymous surveys. Less-rigid training requirements that emphasize the protection of patients but are more appropriate to the limited role that staff may play in the study could alleviate this barrier.

Conflicts of Interest of Practice Clinicians and Staff

As noted earlier, there can be a close relationship between clinicians and their patients. Despite the clinicians’ best intentions, patients may feel unduly pressured to participate in studies. Further, primary care practices typically receive financial support for their participation in studies, and compensation to the practice and/or practice staff and clinicians can provide yet another potential conflict. Thus, payment must be commensurate with, and not excessive for, their effort on the project. As with other research venues, incentives to all subjects, whether they are staff, clinicians, or patients, must be reasonable and must not unduly influence participation.

Is It Research or Quality Improvement?

Much of the research in PBRNs is directed toward improving the quality of primary care practice. Currently, no agreement exists concerning the standards and regulations that should guide quality improvement activities. The Hastings Center—an independent, nonpartisan, and nonprofit bioethics research institute founded in 1969 to explore fundamental and emerging questions in health care, biotechnology, and the environment—convened an expert panel to explore these issues.23 The Center has concluded that the boundaries between research and quality improvement, along with the ethical issues that are entwined with this distinction, have not been fully defined. The Hastings report pointed out that the requirements for IRB approval of research may restrict quality improvement (QI) activities. Some resolution of this dilemma and clearer direction from federal regulators would be helpful in making this distinction and assisting networks interested in joint QI projects.

Recommendations and Conclusions

Family medicine researchers should strive to reduce the possibility of breaches in participant protection and research integrity. The consensus of our group is that adoption of the following recommendations will help researchers meet these goals. While the recommendations are focused on particular areas of research where the panel believed that improvement was most needed,
it should be pointed out that the recommendations apply equally well to all areas of research.

(1) All educational research projects should be reviewed by an IRB. All journals in the discipline that publish educational research should require that authors have had prior review of their project by an IRB.

(2) Investigators conducting educational research need education about the rules and regulations governing human subjects protection in such research.

(3) IRB oversight in cases of CBPR should include attention to the protection of the reputation of a community and the possibility of stigmatization of community members in addition to protection of individual participants.

(4) Investigators conducting CBPR should assure that all research projects are reviewed and approved by community representatives in addition to or as part of an IRB.

(5) For CBPR, the dissemination plan should be anticipated and reviewed, particularly for dissemination of sensitive (ie, potentially stigmatizing) results.

(6) Data from CBPR research should be made available for additional analyses only with the consent of the participating community and the original investigators.

(7) PBRNs need to assure that projects will provide valid and meaningful scientific information before engaging in any project.

(8) Informed consent processes for PBRNs should be streamlined to reflect the reduced risk of this research (when appropriate) and allow for either central IRB approval or the acceptance of consent forms approval by another certified IRB.

(9) Site compliance standards for PBRN projects need to be individualized; training standards should reflect the complexity and risk of each project.

(10) Issues of conflict of interest should be made clear by all investigators involved in a PBRN project. Steps to reduce or eliminate this conflict should be part of every protocol considered by a PBRN.

(11) Investigators, clinicians, and regulators need to work together to define the boundaries between research that would require IRB oversight and quality improvement activities. The current confusion regarding this distinction serves as an impediment for networks that want to engage in multi-site QI projects.

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