

AKADEMINĖS PATIRTYS ACADEMIC EXPERIENCES

Debating Ethical Research with Human Subjects

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Abstract. *Drawing on our experience serving on an ethics review board in the United States, two scholars present three fictionalized examples to illustrate three issues in reviewing research proposals for the protection of human subjects. These are (1) the impetus for the creation of new knowledge on topics of significance, especially involving those considered to be vulnerable participants, (2) balancing the needs of novice and experienced researchers to design studies that contribute to their fields of interest while protecting the interests of participants and (3) disagreements among board members on the requirements for responsible conduct of research. Recommendations are provided for ethical review to the faculty who supervise student research as well as new scholars submitting proposals for ethical review.*

Keywords: *research ethics; human subjects protection; ethics review committees; Institutional Review Boards.*

Introduction

As researchers who have taught qualitative methods in a college of education in the United States, we have been involved in instructing students in preparation of applications for the review of human subjects by the Institutional Review Board (IRB) and in submitting our own applications for research to our institution's ethics review panel. We have also served as members

of the IRB Full Board, reviewing applications for research with human subjects, mostly in the social and behavioral sciences. During our service on the full board of the IRB, we reviewed proposals that involved greater than minimal risk to participants, that included participants deemed to be vulnerable, or both. The second author served on the university IRB for several decades and has conducted research on ethics, and the first author served on the board for seven years.

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In this paper, we provide insights into tensions that we observed during review procedures created by intersecting forces, including: (1) developing new knowledge on topics of significance, especially involving those considered to be vulnerable participants, (2) balancing the protection of participants with the needs of novice and experienced researchers to design studies that contribute to their fields of interest and (3) disagreements among board members on the requirements for responsible conduct of research. These observations are based on our collective personal experiences as teachers of qualitative methods, as qualitative researchers and as reviewers for the IRB. In this paper, we focus on the US context – recognizing that countries across the world have developed and continue to develop different processes to facilitate ethical review at the institutional level.

The purpose of this paper is to provide a viewpoint concerning the role of review boards in educational research that complements the perspectives offered by critics about how institutions carry out ethical peer review (e.g., Gunsalas et al. 2007; Hammersley 2009; Johnson 2008; Van den Hoonaard 2002). As other scholars have discussed (Halse 2011; Halse & Honey 2010), productive review is difficult and complex work, in which members of ethical review boards struggle to balance the needs of researchers and of participants within the context of an ongoing drive for the generation of new knowledge. Central to a productive and legitimate review of research protocols is considering both respect for participants of research projects and maintenance of the integrity of

research designs and processes. For example, sometimes what is required to ensure the validity of a survey conflicts with customary protocols for ensuring informed consent, as we elaborate later.

Members of the board that we contributed to were committed to supporting high quality research – something we expect is typical of research institutions. As reviewers, our goal was to help researchers in pursuing their scholarly interests while conducting their research in ways that minimized harm to participants and maximized benefits for humankind. We observed that the ethics board confronted questions to do with institutional legal concerns, pressures from funding sources to obtain rapid review and the continuing development of new research technologies. Members of IRB boards are aware of the need for justice in research, assuring that historically marginalized groups receive benefits from research without experiencing harmful consequences.

Given that qualitative researchers must abide by the institutional requirements for the ethical review of research with human subjects, we provide recommendations for how faculty members who supervise student research might thoughtfully consider tensions that arise in ethical review and suggest what researchers might do to assist in facilitating the review process. We argue that more collaborative and less adversarial approaches to review will support ethical educational scholarship while streamlining what can often appear to be a cumbersome and obstructive process (e.g., Hemmings 2006; Satel 2009).

Thoughtful consideration of the ethical issues involved in a potential research

study is central to the design of any qualitative study. Faculty members occupy important roles in the preparation of new scholars and researchers as both role models to their students in the responsible conduct of research (Macrina 2014) and teachers conveying to students how to conduct research of integrity. These roles involve assisting students to (1) consider relevant ethical issues involved in doing research and the requirements for the protection of human subjects, (2) understand the history of how institutional protection of research participants has been developed and the need for continuous review and updating of processes and (3) recognize how different stakeholders and audiences read and relate to the researchers' explanations of what they do.

The Institutional Context of Ethical Reviews

In the US, members of IRB boards bring expertise in a wide variety of approaches to research from multiple areas. Faculty members typically represent various fields within the social and behavioral sciences, including education, exercise sciences, psychology, family and consumer sciences, law, and social work. US federal guidelines require someone to represent the community and someone considered a "non-scientist." On occasions when particular expertise is needed to review a proposal, guests are invited to speak to the board and answer questions relevant to proposals or research procedures. In our experiences, these included a representative from legal affairs, researchers with specific expertise in administering a research

procedure (e.g., DEXA or dual energy X-ray absorptiometry, a technology for measuring bone density) and professionals with experience working with specific populations, such as prisoners. Although credited with institutional and governance service, faculty who serve on university IRB boards that meet monthly receive no reimbursement or other recompense for their work. The board chair meets regularly with the staff of the Office of Human Subjects to consider applications for new studies, continuing reviews, and amendments to existing applications.

In the past, studies involving adults that pose minimal risk to participants ("exempt") have been reviewed by one of the IRB staff members; studies involving moderate risk or vulnerable populations, such as children ("expedited"), were reviewed by a member of the board as well as an IRB staff member; applications requiring further review were submitted to the full board at monthly meetings ("full committee"). These procedures have changed recently with the revision of what has been known as the "Common Rule," which defined the three levels of review outlined above: "exempt," "expedited," and "full committee." The new rule – referred to as the "Final Rule" – is scheduled to be implemented in 2018 (see <https://www.hhs.gov/ohrp/>). This will expand the kinds of research that will be categorized as "exempt" from IRB review. At our institution, research that involves benign interventions, along with collection of data that are identifiable and sensitive information pertaining to adults, may be determined to be exempt by the IRB. This new category will continue to ensure that the privacy

and confidentiality of participants' data are maintained, and researchers are required to seek an exempt determination from the IRB. Changes will also be implemented with respect to the requirements of researchers to submit protocols for continuing review, and the ways in which consent forms are to be formatted to ensure that participants understand their involvement in research studies. The process of making changes to the Common Rule has entailed invitations for comment from researchers and the public over a lengthy period of time, with the goal of minimizing administrative burdens to researchers and ensuring the protection of human subjects.

The proposals that the full board reviews involve higher than minimal risk to participants, vulnerable participants, sensitive topics or some combination of these. We observed in our years of service that the board became increasingly involved, and sometimes mired, in lengthy conversations about the implications of new technologies for research protocols. For example, the discussions about protocols that use DEXA, an X-ray procedure with potential harm to pregnant women, focused on whether pregnancy tests should be required or optional for female participants. We also discussed the responsibilities of the IRB for input into procedures for the data repositories of genetic materials and the long-term implications for researchers wanting to conduct genetic testing on tissue samples collected and consented for other research purposes. Occasionally, the full board considered complaints about research studies or instances in which scholars did not follow university protocols for the conduct of research.

In the US, negative decisions made by the IRB are final and with no further avenue of appeal. However, university administrators do have the authority to prevent a researcher from conducting a study that has been approved by the IRB. Although we are unaware of any occasions when this has occurred, we have observed instances in which members of our local State legislature have publicly called for an end to public support of particular researchers' areas of study and teaching (see Kelderman 2009; Stomblor 2009). In these cases, the academic freedom of these researchers to pursue their lines of research – studies of sexuality, male prostitution, and queer theory – was supported by the administrators at the state institutions concerned.

Over the several decades that our institution has maintained an IRB, the process for review of research involving human subjects has transformed from an administrative unit supervised by a graduate student, to a faculty-led committee under the supervision of the vice-president for research, to an office with several staff members working with two IRB faculty committees. In its current form, the Human Subjects Office has a director who is assisted by four full-time staff members. Each IRB full board committee is chaired by a professor who works closely with the director to review applications involving more than a minimal amount of risk or participants identified as vulnerable. Because our institution has a medical school, the IRB has two separate full boards – one for social and behavioral sciences and one for clinical research. In the past, our university has had a tradition of reviewing all research involving human subjects,

including the minimal risk or “exempt” research. As noted earlier, with the implementation of the revised “Final Rule,” the IRB will decrease oversight of minimal risk research that is not federally funded. For example, research deemed to be “exempt” will not require continuing review, and what is required for consent of participants will be minimized.

Balancing Institution Liability and Research Status

Overall, the wide scope for review involves both institutional liability and research status. In the former, the protection of subjects is seen as part of protecting the institution. Members of the IRB, charged principally with protecting research participants while supporting productive research, occasionally grapple with competing institutional and research priorities. For example, when considering some experimental studies that involve administering limited amounts of alcohol to adults, we have had to distinguish between reasonable efforts to assure the safety of participants and other people and excessive restrictions on participant follow-up, intended merely to prevent unlikely lawsuits. We have read claims that some institutions refuse to approve certain kinds of research if they are seen as inviting any legal action (e.g., Adler and Adler 2002). In our experience, IRB members have had occasional discussions at board meetings to clarify whether the measures discussed merely covered feared legal action or were actually protecting people from potential harm. The hope is that adequate protection prevents lawsuits, and that approach has thus far been successful.

With respect to research status, the attention to review at an institutional level is seen to indicate the university’s regard for the importance of research. In the United States, the Office for Human Research Protections (OHRP), a unit under the auspices of the US Department of Health and Human Services, can fault institutions if they do not assure compliance with the so-called “Common Rule” – soon to be “Final Rule” – an agreement among federal agencies that the fundamental principles informing ethical research include a respect for persons, beneficence and justice. These principles, enshrined in *The Belmont Report* (1979), guide how researchers ensure that their studies involve informed consent, balancing risk and benefit, and equity in terms of how research is conducted among various populations. Institutions receiving federal funding for research are routinely audited for properly implementing federal requirements for the protection of human subjects.

Concern about managing legal and institutional issues has led to an increasing professionalization of the IRB. All researchers at our institution, whether faculty members, staff or students, are required to complete an online course that covers the background of the IRB and ethical review and which includes specific modules on protocols for conducting research with particular populations (e.g., children, medical research, prisoners and so forth). No application for research with human subjects is approved unless researchers have completed the particular modules relevant to their research, and researchers must complete periodic updates in training. Members of the IRB are also required to

complete multiple modules dealing with responsible conduct of research. Despite these efforts, creative and productive research involves breaking new ground, and the decisions made by IRBs and other ethical review committees must take new developments into account. We turn now to some illustrative decisions.

Committee Decision-Making

In this section, we provide fictionalized narratives that illustrate three issues that we observed that arose in our work reviewing proposals at full board meetings of the IRB. These are (1) the impetus for the creation of new knowledge on topics of significance, especially involving those considered to be vulnerable participants, (2) balancing the needs of novice and experienced researchers to design studies that contribute to their fields of interest while protecting the interests of participants and (3) disagreements among board members on the requirements for responsible conduct of research. In our experiences serving on the IRB, these issues are interlinked, and the scenarios below illustrate various combinations of these issues.

Scenario 1

Jane was a novice researcher who was also a very experienced teacher. She had worked as an early childhood educator for over three decades and was administering a day-care center while completing a PhD program in early childhood education part-time. Over the years, Jane's experience working with young children had convinced her that the problem of bullying could be addressed in early childhood by

assisting victims to develop skills to be more assertive. For her doctoral dissertation, she had designed an intervention program in which she and a colleague would work with caregivers at a local early childhood center to identify children who had experienced being bullied. Jane's research design entailed working with a dozen 4- and 5-year-olds over a four-day period at the beginning of the summer vacation. Children would learn how to enact scenarios in which they would take on the roles of bully and victim and be taught how to address potential bullies.

Because Jane's study involved minors, her proposal was first reviewed by two members of the IRB. These members disagreed as to whether it should go to the full board for review; given the disagreement, the IRB director forwarded the proposal for consideration by the full board. At the meeting at which the proposal was first reviewed, there was an extended discussion as to the "vulnerability" of the participants, in that they had been identified as prior victims of bullying. Several members admitted they had reservations about the study's design, in that such young children might be unable to voice their concerns and assent to their participation in the study; the youngsters also might not be in a position to stop participating should activities prove upsetting to them. Other board members expressed concern that children would be asked to enact the roles of both bully and victim; they were troubled that the children might be further traumatized by the very intervention designed to assist them. Jane and her faculty advisor were called into the room to respond to committee-members' questions. Further discussion revealed that

Jane had initially intended to conduct the study at the day care center in which she was an administrator. However, several parents had objected to their children being involved, and they mentioned to other parents that they did not want their children to be “guinea pigs” for Jane’s doctoral study. Thus, Jane had moved the site of her study to another facility where she was good friends with the administrator. After Jane and her advisor left the room, committee members agreed to table the decision on Jane’s proposal pending further information. The IRB director and several faculty members on the board agreed to meet with Jane prior to the board’s next meeting.

At this conference with Jane, it became evident that, although she was an experienced practitioner and had worked with young children in early childhood settings for many years, Jane had not conducted pilot work to explore her ideas. Indeed, although she had read work on bullying prevention programs, she had not located studies that supported the design of her intervention, and she herself had not yet collected observational data that involved bullying or bullying prevention programs. At the next meeting of the full board, members who had met with Jane reported this to their colleagues, and they noted that she had seemed unwilling to modify the design of her study to accommodate suggestions from faculty members. The board did not approve the study and advised Jane, in reworking the design of her study, to consider further the vulnerability of the participants of the study and the potential harm that the study might cause.

As board members, we work with a variety of scholars using very different

approaches to research. Some scholars are new, and if they are practitioner-scholars, such as teachers or social workers, their interests may focus on applied work. When scholars are just starting out in their research careers, they often lack a background in their areas of scholarship as well as experience in conducting research. Some of them overreach and design studies that attempt work lacking sufficient foundation to warrant potential risks to participants. Jane’s study exemplifies this, in that it involved the development of an intervention that may have posed considerable risks to vulnerable participants, for which she had not yet established a credible research justification. Although guidance from the IRB in a case such as this may be viewed as an unwarranted intervention by highly experienced practitioners who believe that they are fully capable of managing any difficulty that comes their way, the members of the IRB take their responsibility to protect vulnerable participants very seriously. The creation of new knowledge is fully supported by members of the IRB, but particular proposals are approved only where researchers demonstrate that they have adequate scientific warrant to embark on a study and sufficient expertise to carry it out.

Scenario 2

Professor I.M. Smartt, a prolific scholar in an applied social science field, received a contract in the 1990s to study the recreational patterns of elderly patients in nursing facilities in several Western countries. One premise was that more active individuals might be those most likely to

be released promptly and returned to their homes and ordinary lives. Professor Smartt developed a questionnaire to be distributed for anonymous response but also included a qualitative component to be used with a few of the sites. The professor and his team of graduate assistants observed organizational recreational activities and informally interviewed some of the people participating. Because the participants were classified as a vulnerable population, the research plan was submitted to the full IRB for review, and it was approved. The approval required that the nursing facilities provide written clearance and that the researchers obtain either participant consent or guardian consent with participant assent.

All appeared to be going well until about 10 months later, when the IRB director received an irate call from a woman in the United Kingdom. Her mother, an 87-year-old recovering from a stroke, had just told her about the conversation she had had with Professor Smartt about her recent sexual adventures with a fellow patient. The daughter was appalled, first, that her mother claimed to be sexually active, but, second, that so many torrid details had been conveyed to a stranger. The daughter, who had willingly signed a guardian consent letter, insisted that nothing in the consent form mentioned sensitive topics like sexual activity. "I agreed for Mummy to talk about her daily walks, her checkers games, her chats with the other patients, but not this, this..." she sputtered. As the IRB director talked to the researcher, his team and administrators at the cooperating sites, he also learned that Professor Smartt and his students had already begun

presenting findings from the study at academic conferences.

What went wrong here? After weeks of board meetings and sessions with Professor Smartt and his team, the following story emerged. Questionnaires, observations and interviews at the initial sites indicated that interpersonal relationships and romances occupied a sizable minority of patients, so the research team added a component to the questionnaires and interview protocols about sexual activity for the remaining sites. However, neither the consent documents nor the institutional clearance documents were changed, and no request for such a modification was submitted to the IRB. Professor Smartt defended himself by saying that sex is a form of recreation and that he was approved to study recreation. He also asserted, first, that an IRB in the United States has no real jurisdiction over activities in other countries and, second, that the contracting agency was responsible for ethical oversight, not the university's IRB.

Some of the decisions the board made here were simple compliance with federal regulations. Information knowingly collected by university faculty and staff members or by students as research data without participant consent and cooperating institutional clearance cannot be reported as research – whether funded or contracted and regardless of where in the world the information is gathered. Professor Smartt and his team were instructed to destroy any material collected with the revised questionnaire and interview protocol and to refrain from further circulating, presenting or publishing analyses based on that material. Members of the

board worried, nevertheless, about intervening in what might be valuable scholarship. They were concerned about hampering a creative scholar and losing funding sources. The oldest two board members objected to what they believed to be a tacit assumption that the elderly are asexual. After lengthy deliberation, the board invited Professor Smartt and his team to submit revised protocols with modified consent letters and institutional clearance forms to expand their investigation into romantic and sexual activities. However, the board specified that for the following five years, all IRB submissions from Professor Smartt be first approved by his department head, who was charged with supervising any developments to do with human subjects in the professor's work.

Scenario 3

Social behavioral IRBs such as the one we have served provide the peer review of research required by federal guidelines. As we have emphasized, they are composed of scholars from across the social, behavioral and professional sciences, but they also include community members and those with special expertise such as lawyers, physicians and clergy members. This diversity of membership means that people bring different viewpoints and sensibilities to their reviews of sensitive material and the involvement of vulnerable individuals in research. Being a heterogeneous group, we have different values and beliefs, and these periodically conflict.

Although we customarily find ways to reach consensus on decisions, board members occasionally dissent from the majority

vote. This is usually someone who objects to the research itself or to the procedures proposed for the study. For example, one of us has written briefly elsewhere (Preissle 2007) about the difficulty our IRB had in reviewing a study of dying mothers who had young children. The board approved the research, because most of us believed that what could be learned might itself provide some support for the people being studied and also help other families facing the same tragedy. Board members thus emphasized the potential benefits of the research. One member voted against the decision, concerned that the terminal stages of breast cancer would compromise an individual's capacity for informed consent and that proposing research in such a situation constitutes an intolerable invasion of privacy. He believed the risks were unacceptable.

In another example, three board members objected to a survey of secondary students about their tobacco use. In this case, a team of health scholars had been working with a nearby county school system on policies and practices to reduce teen smoking in what was a low income community where tobacco use was rampant. Among other things, the school system had asked the health researchers to survey their high school students to get an assessment of what youngsters were using and how often. In the state in which we live, supplying minors with tobacco is illegal, and minors who misrepresent themselves to obtain tobacco can be prosecuted. Consequently, the anonymous survey of several hundred youth was to be administered in a situation that precluded any possibility of identifying who provided what data.

To assure the broadest participation, the researchers requested the IRB to waive parental consent for the anonymous surveys of the teenagers. The researchers argued that this was a school-sponsored study and that the school officials had reviewed and approved it as part of their health curriculum. Although the scholars said they would like to have parental permission, they worried about how adding such a procedure might affect the quality of the research. Research on teen tobacco use among other populations suggested that highest use occurs among youth from lowest income and most dysfunctional family situations. These involved parents least likely to return parental consent forms because they were preoccupied with other concerns, hampered by illiteracy and such. Their children were the teens the researchers most wanted to study, and they constituted the majority of the students in this district.

A heated debate ensued about whether – if ever – parental consent to research should or could be waived. Is informed consent an absolute? Three board members who were themselves parents of young children were adamant about their position: parental or guardian consent was imperative in any research involving minors. The rest of the board, including individuals whose children were or had been teenagers, was persuaded by the argument of the scholars and the school district. Given the procedures to eliminate risk and the potential benefit of learning about tobacco-use patterns that might be addressed by improved health policy and practice, the majority of the board was inclined to approve the study. Board members then

discussed how parents might be informed about the study so that, should anyone object to a child's participation, the school could arrange for that child to be occupied elsewhere during the survey administration. This so-called "opt-out" procedure is considered by some to be an inadequate approach to obtaining informed consent. With forthcoming changes to the Common Rule, we are likely to see more of these sorts of consent arrangements. In this instance, the majority of the board finally voted to approve the study with a waiver of parental consent but did require the researchers and the school district to make every effort to inform the parents about the upcoming survey, so that those who objected to their children's participation could make their wishes known.

Summary

In these scenarios, we have offered insights into some of the complex issues arising during deliberations by those who serve as members of ethical review boards as they review research studies using a variety of research designs and methods. The scenarios included here represent a minute portion of those possible. Researchers conduct their work among a proliferation of new technologies, an increase in legal and ethical quandaries related to new research trajectories and a continued impetus for data-sharing among researchers by funding bodies. Further, participants of research studies are well-informed and frequently interested in learning the outcomes of research studies – replacing an "audience" that may formerly have been comprised of small numbers of research

scientists. Thus, the number of complex and difficult issues to be considered by members of ethical review boards is unlikely to decrease in the future.

Recommendations

In light of the ever-changing contexts in which research is both conducted and reported, we conclude by offering recommendations for the ethical review of research with human subjects to both the members of ethics review boards and the researchers whose applications for research with human subjects are reviewed. For scholars in other countries who work in the contexts in which the institutionalization of ethics review contrasts with the case of the US, we offer these recommendations for further thought with respect to (1) how ethical review might be conducted fairly and systematically in other contexts and (2) how qualitative researchers might be prepared to deeply consider ethical issues relevant to the conduct of their research. These suggestions supplement work by other scholars who have provided recommendations for ethical review of particular groups, including refugees (Perry 2011), immigrants (McLaughlin & Alfaro-Velcamp 2015) and community-based research (Cross, Pickering & Hickey 2015).

Board Members

- Be flexible and willing to negotiate with researchers;
- Integrate ethics review into ongoing scholarship. Seek further education at facilities such as the Poynter Center for the Study of Ethics and the American Institutions at Indiana University and

study the increasingly available literature on both the functioning of ethics review (e.g., Bankert and Amdur 2006; Mazur 2007), the critiques of ethics review cited in this article as well as recent scholarship on ethics in research (Tolich 2016);

- Be sure that the membership on the board is well-balanced, so that multiple research traditions are represented (e.g., qualitative, quantitative and survey methods in addition to representatives with expertise in any biomedical procedures regularly reviewed);
- Ensure that IRB staff and board members are directly accessible to researchers to promote better communication and to ensure that ethics review boards work to empower researchers to conduct quality work, rather than exercising power over researchers to regulate what work they do;
- Avoid mission creep. By focusing on the protection of human subjects, members of ethics review boards can avoid becoming involved with questions of research design outside the purview of the boards' mandated function;
- Dialogue with members of other institutions in order to learn how regulations are implemented in other contexts.

Researchers

- Attentively supervise graduate student research and teach students to prepare applications for research involving human subjects that are well-documented, clear, sufficiently detailed and internally coherent;
- Discuss ethical issues involved in all aspects of research with students (i.e.,

the principles of responsible conduct of research, including authorship and publishing, collaborating, record keeping and so forth; Macrina 2014);

- Pursue continued education on changes in institutional guidelines and the conduct of ethical research. Be familiar with the ethical guidelines established by professional associations. Ethics review committees can offer guidance for informed consent, for balancing risks and benefits and for considering justice, but many other ethical issues arise during research, and researchers should prepare for these additional challenges;
- As appropriate, and in keeping with institutional requirements, work with members of ethics review boards to ensure that protocols are updated to reflect ongoing changes in research-in-progress;
- Rather than attempt to avoid ethical oversight, be familiar with institutional requirements for research and treat suggestions and guidance from ethical review boards respectfully;
- Offer to serve on ethical review boards to learn the full scope of work entailed in ethical review, and to develop knowledge and understanding of research practices across multiple disciplines.

Conclusion

In this paper, we have discussed a few of the difficult issues and questions that we have encountered as members of one ethical review board. These questions resist easy answers and definitive methods and procedures. Our review of applications has entailed many hours of preparation in

reading lengthy protocols that frequently detail research procedures that we do not use in our own research, and about which we have limited knowledge. As scholars, however, the debates in which we have engaged in doing this work have forced us to constantly rethink our positions on a variety of topics, including what ethical research is, how knowledge production occurs, and what the rights and responsibilities of researchers and participants encompass. We are cognizant of the unconsidered implications of balancing research practices that incorporate both new technologies, such as genetic testing, with the possibilities of long-term data storage involving multidisciplinary teams of researchers spanning the globe while providing continued informed consent with participants who change their minds, grow up or both (see, for example, Stein 2009). Yet we are hopeful that continued respectful discussion among researchers, members of ethical review boards and participants will ensure that researchers continue their quests for new knowledge and that participants are respected and benefited by these efforts. We realize, however, that as reviewers, our best efforts are sometimes flawed, and protocols and procedures need to be rethought, rewritten or discarded altogether. We argue that ethical review boards must retain flexibility in dealing with new research contexts and be sensitive to the varied circumstances in which researchers do their work.

As former members of one ethical review board, we are open to learning about research designs outside our areas of expertise. We found that our fellow IRB members expressed great interest in learn-

ing about multiple approaches to seeking knowledge across disciplines. We continue to find learning about others' research both intriguing and exciting. We are passionate about the need for quality research to solve

problems in the world in which we live. We conclude by encouraging researchers to become involved in both learning about the work of ethical review of research and doing it themselves.

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TYRIMŲ SU ŽMONĖMIS ETIŠKUMO DILEMOS

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S a n t r a u k a

Šiame straipsnyje autorės, remdamosi įgyta patirtimi dalyvaujant etikos vertinimo komisijoje Jungtinėse Amerikos Valstijose, gilinais į su žmonėmis atliekamų tyrimų etikos klausimą. Autorės pristato tris fiktyvius pavyzdžius, kurie atskleidžia ginčytinas sritis, kylančias tyrimų pasiūlymuose žmonių, kaip tyrimo dalyvių, apsaugos klausimu. Straipsnyje pateikiama pavyzdžių, kurie iliustruoja: 1) paskatą įgyti naujų žinių iš naujų temų įtraukiant tuos asmenis, kurie gali būti laikomi pažeidžiamais tyrimo dalyviais; 2) naujų ir patyrusių tyrėjų siekį sukurti tokį tyrimo

dizainą, kuris atitiktų jų interesų lauką, tačiau nepažeistų ir tyrimo dalyvių interesų; 3) tarp komisijos narių kylančius nesutarimus dėl reikalavimų, būtinų norint atsakingai atlikti tyrimą. Straipsnyje taip pat pateikiama etikos vertinimo rekomendacijų tiek fakultetams, atsakingiems už studentų tyrimus, tiek pradantiems tyrėjams, teikiantiems savo tyrimų pasiūlymus etikos aspektams vertinti.

Pagrindiniai žodžiai: tyrimo etika, tyrimo dalyviai, etikos priežiūros komitetai, institucinė vertinimo komisija.

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