

behooves any manager to know what the procedures are ahead of time and what will happen so you can be ready to act quickly.” ■

Challenges of community engaged MH research

IRBs should avoid overprotection of community partners, experts say

Applying community engagement to mental health research can help researchers about design studies that incorporate the priorities of people with mental illness and arrive at the best strategies for working with them.

But IRBs can hinder this type of research by seeing the population as too vulnerable to fully participate and by requiring “paternalizing” protections not just for participants, but for peer evaluators who assist in the study, says a researcher who has specialized in community-engaged mental health research for more than 20 years.

“IRBs may overreach on protection of vulnerable populations that want to participate in research,” says **Jean Campbell**, PhD, a research associate professor with the Missouri Institute of Mental Health in St. Louis. “They assume (peer evaluators) are part of the patient population, as opposed to the research population.”

The push for community engagement in research in general has intensified in recent years, out of a sense of respect to the communities being studied, but also because it can help strengthen studies and aid in recruitment, says **James DuBois**, PhD, DSc, director of the Center for Research Ethics and Integrity at the Albert Gnaegi Center for Health Care Ethics at St. Louis University.

DuBois, who specializes in mental health research ethics, says that as he speaks with mental health consumers, he is struck by how their priorities about research differ from those of investigators.

For example, he says research tends to focus on efficacy of drugs, with less attention given to side effects that can be so disturbing to patients that they discontinue taking the medications.

In the area of mental health research ethics, DuBois says, the vast majority of NIH-funded studies focus on decision-making capacity.

“I think it’s good research, I think it’s an important topic,” he says. “Studies clearly show that you can

have a diagnosis of bipolar disorder or schizophrenia and frequently retain decision-making capacity. So in one sense, you could say it’s de-stigmatizing.

“But I know some mental health consumers who say that the very fact that this is the topic they keep studying is stigmatizing, because it reinforces the idea that they don’t have decisional capacity.”

Treating evaluators as vulnerable

He says that while IRBs are most concerned with decisional capacity and undue influence, mental health consumers tend to focus more on a study’s benefits, whether payment for participation fairly compensates subjects and whether subjects face the possibility of being randomized to placebo or being asked to undergo a washout period.

Because of these differences, DuBois says it’s important to include people with mental illness at the earliest stages of research projects.

But building in this type of involvement can raise challenges that don’t come into play when dealing with other communities. Because of concerns about confidentiality, it may be as difficult to recruit mental health consumers to join an advisory board or to act as a peer evaluator as it is to recruit subjects.

Campbell says she sometimes must deal with gatekeepers just to put up posters in a community mental health center looking for workers. “I’d have to go through case managers who would try to evaluate whether people were well enough to do this work.”

And IRBs may put extra restrictions on how they can participate on the research team.

“There is some assumption that the peer evaluators aren’t going to maintain confidentiality as well, even if we show them the training that they’re given,” Campbell says. “IRBs worry that (participating) may endanger their mental health — the peer evaluators’ mental health. These things aren’t true, but they are the type of things that an IRB would question.”

As one example, Campbell says, a research project that wants to post pictures of its staff, including peer evaluators, on a website might prompt concerns that the confidentiality of the peer evaluators is being breached, even if the evaluators give permission for the use of the photos.

“(The IRB is) concerned that you’re violating their confidentiality as a patient, which doesn’t make sense,” she says.

Rigorous training ‘positive’

Although tailoring human subjects protection training to lay people is a frequent concern in all types

of community research, Campbell says she doesn't view it as an insurmountable problem. She requires community research partners to take the online CITI course in protection of human subjects, even in some situations where an IRB doesn't require it.

"Yes, it is somewhat of a barrier, but I think it's good for people," she says. "I believe in the most rigorous training people can have. If you make the commitment to train people not just for your particular project, but for them to potentially develop leadership in their community or leadership as peer evaluators, then that's a positive step."

She does believe in making some accommodations for community research staff when needed. For example, Campbell's group developed a glossary of research terms to train peer evaluators. Even if the terms don't come up in their duties, they also may serve on an advisory board or other capacity where they're speaking with research professionals and need to know what the terms mean.

DuBois believes that advisory boards are an important tool of community engagement in mental health studies, particularly because IRBs tend to lack sufficient representation on their boards to address the community's ethical concerns.

"My impression is most IRBs don't have even one community member who could represent mental health consumers well," he says. And DuBois argues that having one mental health consumer on the board would still be inadequate, since there are diverse perspectives in this community.

"If you ask me what IRBs might ask of researchers, it's 'Have you created a community advisory board? Have you consulted with people from the community that you plan to recruit from?' It seems to me that that's a good starting point."

REFERENCE

DuBois JM, Bailey-Burch B, Bustillos D, et al. Ethical issues in mental health research: The case for community engagement. *Curr Opin Psychiatry* 2011 May;24(3):208-14. ■

High schoolers getting schooled in protections

Through science fairs, special schools and summer programs, they get experience with IRBs

As high school students get exposed to more sophisticated science and health programs,

some are also having their first encounters with human subjects protection issues.

In science fair projects, in special science and health schools and through outreach programs from research institutions, they're doing social and behavioral studies and being taken on to help established scientists with medical research.

While the number is not necessarily large, observers say aspiring investigators already are interacting with IRBs.

Rebecca Dahl, PhD, CIP, manager of the human subjects protection program at Children's Hospital Los Angeles, says she recently was approached about allowing a high school student who was participating in a summer research program to be added to a protocol.

"They wanted to have the student assist them," Dahl says. "And people were wondering what to do and how to go about the proper process."

Dahl says that she would be very cautious about what type of assistance a high school student would be able to provide.

"I would have to determine if what the student is doing is really at the level of knowledge and understanding so that they can perform things where they can feel successful," she says.

Those tasks might actually include interaction with subjects — handing out surveys or answering simple questions — as long as they were closely supervised by an investigator. And she says they would require the same type of training required of older research staff.

"But remember, most of these kids, although they're screened very carefully to even be involved in the summer programs, they're not screened for research knowledge and they don't get that, necessarily, in the high schools."

High school IRB

At some specialty high schools, however, human research ethics is actually part of the curriculum.

Judith Scheppler, PhD, is coordinator of student inquiry and research for the Illinois Mathematics and Science Academy in Aurora. Her students conduct their own research projects, as well as working off-site with established researchers at area institutions such as the University of Chicago, Northwestern University and Fermilab.

The school requires that students working off-site be written into investigators' IRBs proposals and that the school receive a copy of the outside IRB's approval letter.

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