

**Report from Research Plank
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ISSUE:

I. INVOLVEMENT OF CONSUMER/SURVIVORS AS RESEARCH PARTNERS

A. Barriers:

1. Not believing in themselves or their knowledge of the language and not knowing that they can be involved and have a voice.
2. Not being recognized and appreciated for having life-experience knowledge. Currently there is a feeling of being a “token” member of a project.
3. Not being asked the right/important questions. Will the results really be what they are looking for?
4. Consumer leaders are not paid equally, or not paid at all, for research participation.
5. Often, transportation supports do not exist for consumer research participation.
6. There is a clash between the research culture and consumer culture. There is considerable misunderstanding between the two cultures; as a result the collaborative effort may fail.
7. Collaboration between non-consumer researchers and consumer researchers would be best or that consumers should use advisors of their choice while doing research.)
8. Consumers struggle to be included in research.

Diversity . . . :

1. . . . needs to be considered. In some geographic locations there is an assumption that everyone believes the same thing.

Types of diverse groups:

1. A person’s values have an effect on their research and the questions that they ask. Diversity exists in values and beliefs.
2. Race
3. Sexual preference
4. Age
5. Geographical location
6. Economic levels
7. Disabilities
8. Cultural differences, including between the research culture and consumer culture.
9. A person’s values have an effect on their research and the questions that they ask. Diversity exists in values and beliefs.
10. Other disempowered groups.
11. Consumers struggle to be included in research.

Suggestion: Focus on the points of power — for example, funding sources, policy makers, press/journalists. If diversity is the issue, be sure that only groups who have taken diversity into consideration will receive money.

Suggestion: Consumer research should be on every consumer policy and advocacy plank.

If you don't count people, they don't matter; they are not represented in research.

Consensus and Recommended Actions:

1. Organize, educate, and empower consumers to recognize the value of research on all levels.
Research can be the voice of consumers.
 - a. Consumers involved in research should reach out to advocacy to support consumer issues.
 - b. Fund support for education of consumers around research.
 - c. Provide education of consumers involved in the research projects.
 - d. Develop technical assistance center for consumer research training and a clearinghouse for collection of consumer research data.
 - e. Fund training institute to train consumers in research.
 - f. Organize conference on consumer research to share results.
 - g. Educate around different models of consumer involvement in research.
2. Meaningful (not token) involvement of consumers:
 - a. Consumers should work for representation in setting research agenda (policy making, funding and publications)
 - b. Educate participants of research all along the way in regard to the research process and share research findings with the consumer community.
 - c. Create standards of excellence of consumer involvement in research.
 - d. Evaluate quality of consumer participation in research projects.
 - e. Identify and recognize exemplary consumer research and consumer involvement in traditional research projects.
3. Promote values of consumer partnerships in research:
 - a. Foster partnership with other disability and health advocacy movements. Develop standards of excellence in involvement and advocate for change.
 - b. Foster partnership with existing mental health organizations with common goals.
 - c. Develop a directory of consumers involved in research.
4. Dual focus on developing consumer research opportunities and collaborative projects.
5. Link measures of recovery developed by consumers to the following:
 - a. Biomedical research
 - b. Pharmaceutical research
 - c. Evaluation of traditional mental health services
 - d. Policy research
 - e. Advocacy research
6. Challenge slanted data and statistics:
 - a. Letters to the editor
 - b. Doing research to challenge the statistics (independent alternative analysis)
 - c. Conducting alternative research
 - d. Writing critiques
 - e. Reviews of the literature in all forms of publications.

7. Recognize the value of qualitative and quantitative research (mandate both). Use qualitative research to validate quantitative research.
8. Equal pay for equal work at all levels of research participation of consumers.
9. Provide access to research data for consumers and broadly distribute research data to consumer research participants.
10. Fund development of consumer instruments and scale.
11. Promote the collection of data (age, gender, disability, color, sexual preference) relevant to diverse consumers and make sure that research protocols are culturally competent and sensitive to language, regional differences of participants, etc.

II. ISSUE: PROTECTION OF RESEARCH PARTICIPANTS

Topics for discussion:

- A. Informed consent
- B. Consumer access to information
- C. Confidentiality and security
- D. Institutional Review Boards – review of boards for ethical issues
- E. Identifying unethical research practices
- F. Option out of information system
- G. Laws and penalties for privacy/confidentiality violations
- H. Data removal for consumer records if the consumer is no longer involved in mental health services.

Consensus and Recommended Actions:

Suggested statement: Oppose consumer participation in challenge studies, washout studies, placebo issues and unethical practices, etc. Use direct intervention to discourage participation. This will create a direct link to advocacy and activist organizations.

Discussion: The group engaged in conversation about the language of the statement as it relates to a consumer's right to decide whether or not he or she wants to participate in "high"-risk research. Members of the group were concerned that the statement would be watered down by not using the word "oppose"; however the group felt strongly that consumers have the right to decide for themselves. If the statement is strong it will at least create conversation. The action can involve discouragement rather than opposition. There was a disagreement about this issue as well: the group does not want to take a parental role, but rather feels that the consumer needs to be fully informed in order to make his or her own decision about participation. Informed consent and informed choice is the real issue.

The group reached consensus on the following statement:

1. Oppose challenge studies, washout studies, placebo issues and unethical practices, etc., because they cause a great risk to the individual.
2. Ban the use of individuals with diminished capacity in all research.

In regard to the use of the concept of “risk,” the group felt the standards of risk needed to be clear and consistent. Researchers have a classification regarding degrees of risk that is universally known but the definitions of risk need to be clear.

What are we talking about when we say “diminished capacity”? Informed consent is the true issue; diminished capacity suggests that someone else is making a decision for another. How much education does a consumer need? The group could not get consensus on the wording of this statement. One suggestion was to examine the existing procedures and put together “best practices.” Is someone who has diminished capacity an individual under another person’s guardianship? How someone comes under guardianship differs from state to state, and guardianship does not necessarily indicate diminished capacity.

3. We propose a consumer commission to review human subject protections and identify both exemplary and unethical practices and, finally, develop consumer human subject protection statements and policies.
4. We oppose the unethical utilization and victimization of consumers in research and oppose the use of consumers in unethical research.

Discussion: Some discussion ensued regarding pharmaceutical use and the Food and Drug Administration (FDA), particularly when there can be significantly negative side effects and a drug is still approved by the FDA. There was additional dialogue regarding how frequently consumers are not informed of risk, especially where pharmaceutical companies are concerned. There aren’t too many people who are designing research practices who have been studied themselves.

5. We demand meaningful (not token) consumer inclusion on the National Bio-ethics Committee (NBEC), and any other commissions or committees that have been established to examine similar issues (setting policies regarding human-subject protections for mental health consumers).

Informed Consent to Research

The following statements were made during a brainstorming session:

- What sort of information should be on the consent form? There must be full disclosure of the risks and benefits involved in the study.
- Disclose long-term side effects or possible side effects; this information needs to be on informed consent protocols.
- There is a problem when research subjects are recruited from emergency rooms.
- There should be an opportunity for re-disclosure and a second informed consent during the research project. It is a process and that process should be ongoing.
- There should be a standardized consent form that includes consumer input to ensure that it is fully intelligible to all the individuals who will be signing it (big type and simple language).
- Determine the capacity of a subject to understand the informed consent statement. Make sure the informed consent process actually does inform the subject and that the subject understands. Make those administering consent responsible for making sure that the consumer is thoroughly informed and understands.
- When researchers develop consent forms, there is a conflict of interest.
- An independent national commission should determine what information is in the informed consent statement. There should be a local consent monitor (a trained consumer) not connected with the research.

- Informed consent must not be a ritualized formality to protect the researchers from lawsuits. Informed consent must be designed to protect the subject, not the research administrators.
- All research must be voluntary. A subject has the right to walk away from a research project. Consent is not an obligation to stay with the research until the end.
- What happens to the subject after research funds are depleted? What recourse is there for subjects during or after the study? Who is sponsoring the research? Is follow-up care given to subjects? This information should be included in the informed consent statement.
- There should be an ombudsperson attached to a research project.
- Informed consent should exist for all data collection and disclosure to ensure confidentiality. Coerced consent (waiving your rights in order to receive benefits) should not be permitted.
- Sharing data between agencies should not be permitted without written permission from the subject/consumer.
- There should be an opportunity to opt out of a Management Information System and still receive benefits.
- Researchers should not put the good of the public ahead of the needs or good of an individual.

6. We believe that in no instance should the public good be placed before the civil rights and well being of an individual in research.

Institutional Review Boards (IRB's)

The following statements were made at a brainstorming session:

- IRB's are not independent in most cases (vested interests).
- There are no national standards for Institutional Review Boards.
- The recommended IRB national review board should have representatives from the research subject communities. There should be local review boards that are held to national standards. Then there must be review and enforcement (accountability) of national research standards.
- There must be meaningful inclusion of consumers as representatives on Institutional Review Boards.
- There should be a core group of trained consumers who act as consultants and who rotate on and off the board. There must be at least two consumers on each board.
- There must be informed consent for any data collection, not just research.
- All forms of research need to be reviewed.
- There is no organized or uniform system to avoid Institutional Review Board redundancy, but this is not unduly burdensome.
- There is currently no follow-up on review board decisions. There must be follow-up by independent agents.
- There are differences in values between professionals and consumers
- Board members should be bonded as a form of accountability.

Discussion: There was discussion about whether or not the suggested checks and balances already exist. One individual believed that there was just the appearance of checks and balances, while several others believed that they truly exist. Questions were raised as to whether there are unethical behaviors on these review boards and whether conflicts of interest exist.

7. There is a need for meaningful representation of consumers on IRB's, and consumers need to be trained to be on boards. All forms of research need to be reviewed.

Research Design Issues

The following comments were made during a brainstorming session:

1. Issues of Recruitment
 - a. remuneration
 - b. randomization
 - c. waiting list
 - d. withholding services
 - e. media advertising
2. In issues of recruitment, crossover, withdrawal, selection, and use of control groups, the values and well-being of consumers should be held above the “gold standard” of scientific research.
3. Researchers should respect consumers who decide not to participate, and should not continue to contact them.
4. Educate consumers about recruitment practices. Develop a booklet or fact sheet to inform research respondents of questions to ask.
5. Identify the most important areas for consumer research.
6. Develop fidelity models to research consumer-run services.
 - a. Define what services are offered in consumer-run programs.
 - b. Determine what are the common ingredients in all consumer services
7. Review past research on peer programs.
8. Negative outcomes of coercion, seclusion and restraints should be studied.
9. Promote new research on consumer networks.
10. Promote dialogue process between consumers and researchers (Center for Mental Health Services fund).
11. Research designs must have qualitative and quantitative data and must have meaningful consumer involvement at every level of the process.
12. Educate consumers about research.
13. Eliminate the use of stigmatizing language in all research: for example, “chronics,” “mentally ill,” “schizophrenics.” Make the scientific community more sensitive to language as it relates to consumers. Contact editorial boards, etc.