

DBSA Consumer and Family Survey Center 2012 Research Permissions & Privacy Survey Summary Report: November 2012

BACKGROUND

Federal regulations to protect research participants allow researchers to sometimes use medical records for research without asking each patient or consumer for permission. But using records for research without individual consent is only allowed if:

- The research does not involve more than minimal risk to patients or consumers.
- Using records information would not adversely affect patients' or consumers' rights.
- It would not be practical to get written consent from every person whose records would be used.

Ethical review panels (called Institutional Review Boards or IRBs) are responsible for deciding if these criteria are met and if any proposed research is important enough to outweigh any potential risk to patients or consumers. Those review panels are supposed to consider the perspectives of people who might be affected by the research—how that particular group would view the importance of the research and the potential risks. But those panels usually review a wide range of research in different areas, so they cannot include representatives from every group that might be affected—like people who live with mood disorders or other mental health conditions.

The purpose of this survey was to understand the views of people who live with mood disorders (and their families) about research using different types of health records. The survey described a series of hypothetical studies. For each hypothetical study, survey respondents were asked questions about the criteria that ethical review panels are supposed to apply:

- Is this research important?
- Is the risk to patients or consumers minimal?
- Should every patient or consumer have to give consent for her/his records to be included?

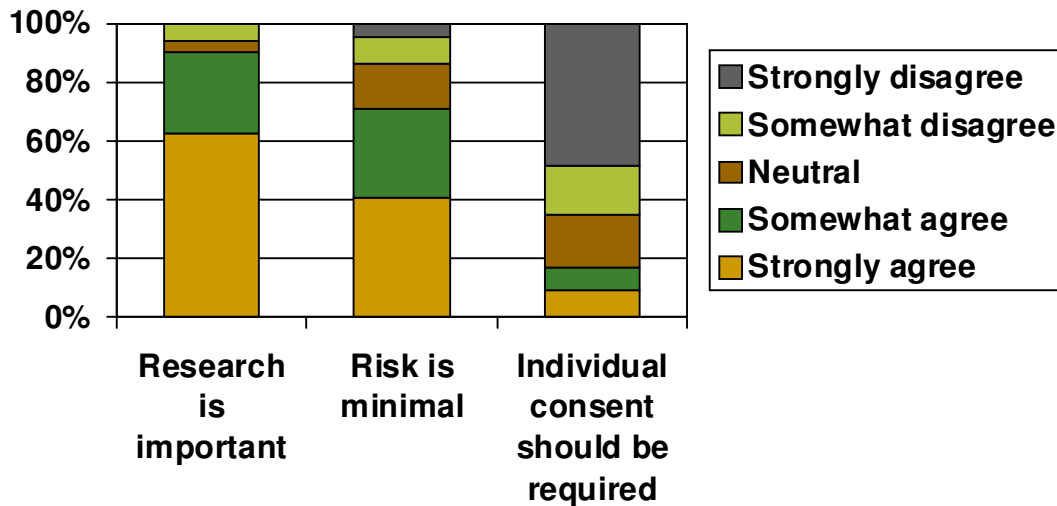
The last part of the survey asked about another privacy concern that often comes up in mental health research: Should researchers break confidentiality if a person participating in research reveals thoughts about harming her/himself or other people? Different ethical review boards have made different decisions about this question.

This survey was posted on the DBSA website from June 12, 2012, to October 25, 2012. 133 people responded. Because we do not collect personal information in our surveys, we cannot describe the specifics of the people how responded (age, sex, etc). So this should be considered a “convenience” sample (people who chose to respond) that may not necessarily represent all people who live with mood disorders or even all visitors to the DBSA website. A copy of the survey can be found at www.DBSAlliance.org/PandP2012.

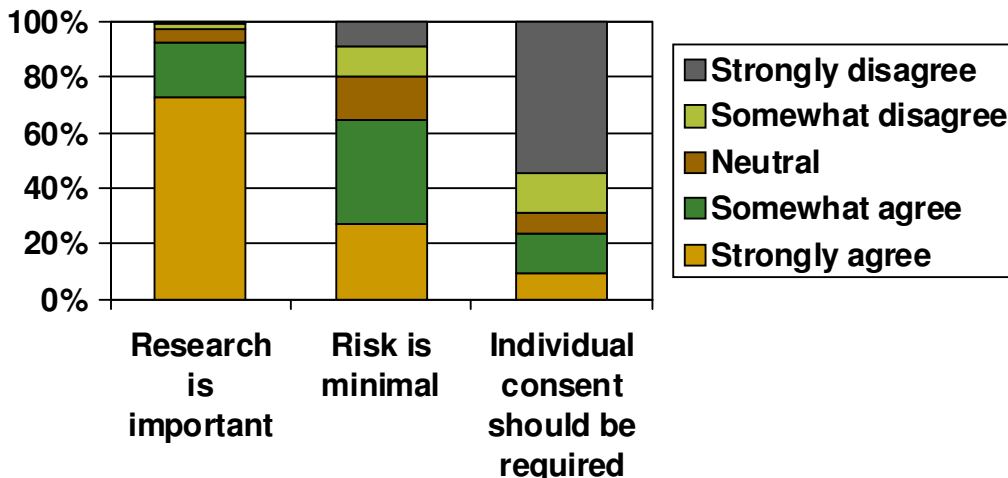
SURVEY RESULTS

Bipolar Disorder in Children

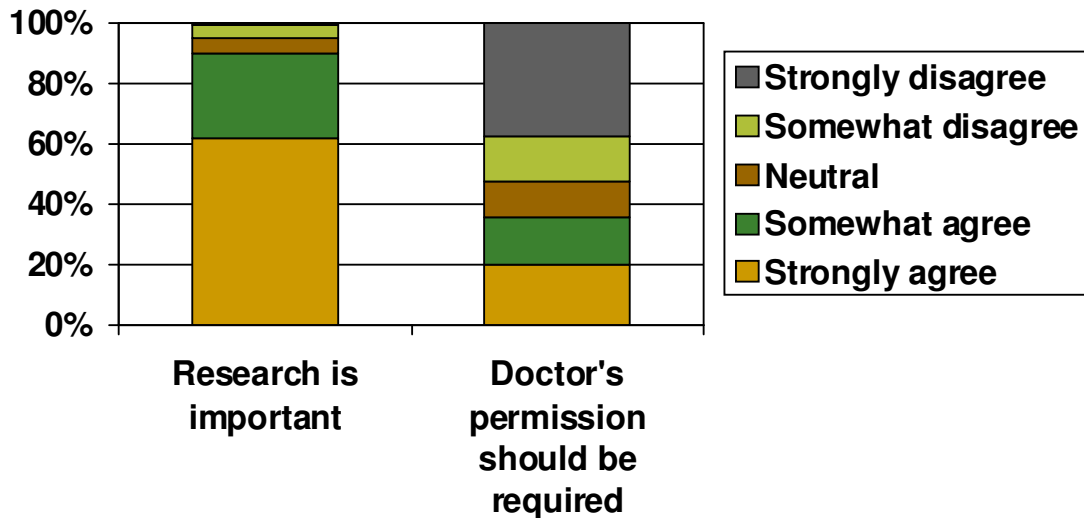
The first hypothetical study would examine how diagnosis of bipolar disorder in children varies between doctors or therapists or between different areas of the country. This research would use insurance company records (diagnosis codes, not doctors or therapists actual notes) to study how often different doctors or therapists make diagnoses of bipolar disorder in children. Survey respondents generally agreed that this research would be important and that risk to patients or consumers would be minimal. A majority agreed that getting written consent from each individual was not necessary.



The next hypothetical study would examine how doctors or therapists diagnose bipolar disorder in children and whether they follow standard diagnostic systems (like the DSM-IV). This research would use doctors or therapists actual notes to examine what doctors or therapists record when they diagnose bipolar disorder. Responses were similar to those for the first study that would use insurance records only. Survey respondents generally agreed that this research would be important and that risk to patients or consumers would be minimal. A majority agreed that getting written consent from each individual was not necessary.

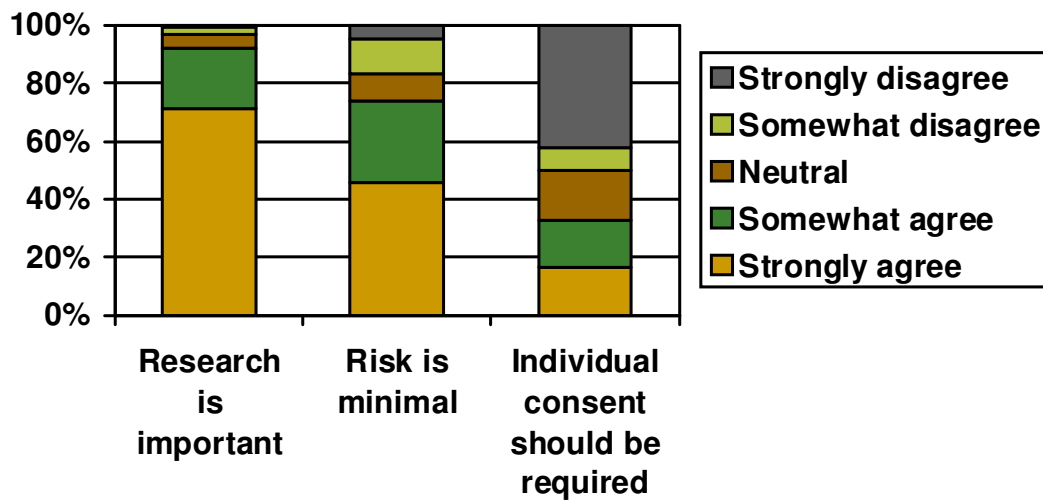


The next hypothetical study would contact families of children who had received diagnoses of bipolar disorder and ask them to complete standard assessments of symptoms. This information would be used to test how doctors' or therapists' diagnoses agreed with standard research measures. For this hypothetical study, we asked whether researchers should have to get permission from each doctor or therapist before contacting her or his patients. Most respondents believed that this research would be important. Almost half believed that patients or consumers should not be asked to participate in research without prior permission from a doctor or therapist.



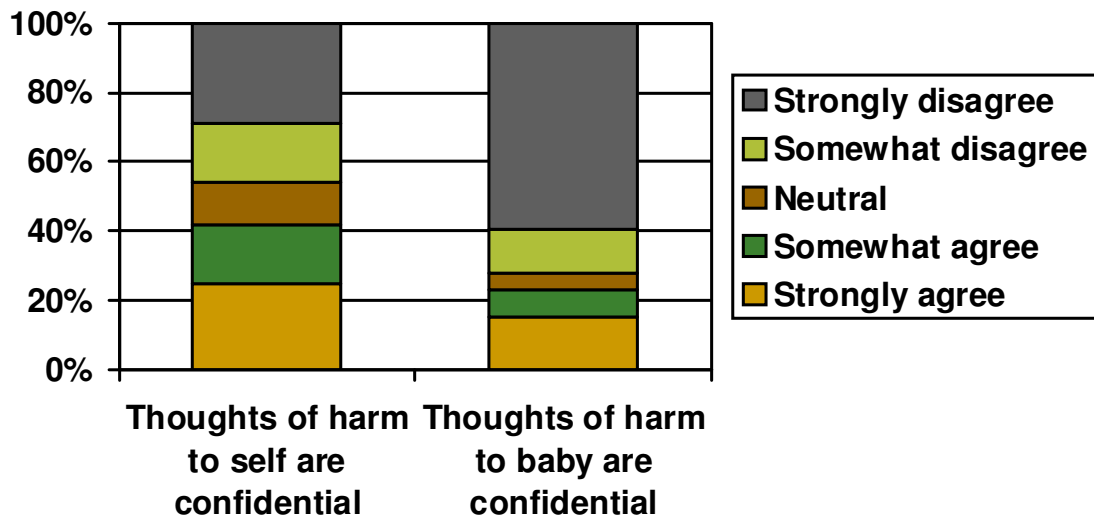
Suicidal Thoughts

The next hypothetical study would examine whether warnings about antidepressant medications possibly causing suicidal thoughts actually decreased use of antidepressants—and whether that change would increase or decrease the rate of suicide attempts. For this hypothetical study, researchers would use summary information about rates of antidepressant use and rates of suicide attempts from large health systems to examine how antidepressant use and suicide attempts changed after warnings were publicized. Survey respondents agreed that this research would be important, and most agreed that the risk to patients or consumers would be minimal. Most did not think that every individual in these health systems should be asked for permission to use records, but almost one third did think that permission or consent should be required.



Postpartum Depression

The next hypothetical study would evaluate a psychotherapy program for postpartum depression. In a study like this, participants might reveal thoughts about harming themselves or their babies. The survey asked whether researchers should be bound to keep that information confidential—or whether they should break confidentiality and give that information to mothers' regular doctors or to crisis workers. Survey respondents generally believed that information about possible risk to babies should not be kept confidential—although almost one quarter thought that information should be kept confidential. Survey respondents were very evenly divided about whether researchers should or should not break confidentiality if research participants revealed suicidal thoughts.



SUMMARY AND CONCLUSIONS

Survey respondents generally believed that this type of research could be important. Responses to this question were similar across the different hypothetical studies.

In all cases, the majority believed that the risk to patients or consumers from using records in research would be minimal (a central requirement of the federal regulations). The primary risk of this type of research is violation of privacy. We did not provide detailed information about how researchers might protect against risk. Nor did we ask about the specific risks that patients or consumers might anticipate. It would be helpful to understand whether patients or consumers are primarily concerned about the risk from researcher themselves using information—or about the risk of that information being accidentally released or disclosed to others.

Opinions about whether individual consent should be required did not seem to depend on practical considerations. For some of the hypothetical studies, asking permission would require contacting thousands of people (difficult, but not impossible). For the last study about suicide rates, getting permission would mean contacting millions of people (probably not possible). Survey questions did mention the number of people who would be contacted, but this point was not emphasized in the survey questions. It is possible that survey respondents did not notice this aspect of the questions. But it is also possible that survey respondents do not agree with how researchers or review boards typically decide what it means to say “research could not practicably be carried out” (the language in the federal regulations).

Survey results regarding how researchers should respond to thoughts of self-harm are the least clear, but may be the most important. Research review boards have struggled with this question, sometimes deciding in favor of privacy and sometimes in favor of a “duty to protect”. Survey respondents appeared about as equally divided as review boards have been. Results of this survey will not give review boards clear guidance about the best approach, but they will help those boards see that this decision involves a difficult balance between competing ethical principles. Choosing either policy (preserving confidentiality OR revealing information in the interest of safety) will mean sacrificing an important principle. We cannot say that either choice is completely “right”.

NEXT STEPS

These results will be shared with mental health researchers and with research review boards at universities and healthcare systems. We hope that this begins an ongoing process of bringing the patient or consumer voice into the research process.