SOCIAL, BEHAVIORAL, AND EDUCATION RESEARCH (SBER) RISK ASSESSMENT

Annotated Bibliography

The Harvard Catalyst Social, Behavioral, Education Research (SBER) Subcommittee of The Regulatory Foundations, Ethics, and Law Program

Created: January 2016
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AAA</td>
<td>American Anthropological Association</td>
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<tr>
<td>AAPOR</td>
<td>American Association for Public Opinion Research</td>
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<td>ANA</td>
<td>American Nurses Association</td>
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<td>APA</td>
<td>American Psychological Association</td>
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<td>ASA</td>
<td>American Sociological Association</td>
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<td>APSA</td>
<td>American Political Science Association</td>
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<tr>
<td>CBPR</td>
<td>Community-based participatory research</td>
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<td>CEnR</td>
<td>Community-Engaged Research</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HRPP</td>
<td>Human Research Protection Program</td>
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<td>HSP</td>
<td>Human Subject Protection</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>NASW</td>
<td>National Association of Social Workers</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NSF</td>
<td>National Science Foundation</td>
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<td>OHA</td>
<td>Oral History Association</td>
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<td>OHRP</td>
<td>Office for Human Research Protections</td>
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<td>SBER</td>
<td>Social, Behavioral, and Education Research</td>
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INTRODUCTION

The Harvard Catalyst Social, Behavioral, Education Research (SBER) Subcommittee of The Regulatory Foundations, Ethics, and Law Program is charged with identifying and addressing regulatory concerns pertaining to SBER, and specifically potential risks, harms, and impacts. The subcommittee also serves as a sounding board for SBER-related issues across the Regulatory Foundations, Ethics, and Law Subcommittees. The SBER Subcommittee, which includes IRB professionals with relevant experience, develops practical solutions for implementation at Harvard Catalyst member institutions to address regulatory requirements, protect research participants, promote best practices, and understand SBER’s role in clinical research. Tools and resources developed by the SBER Subcommittee are also made publically available to institutions outside of the Harvard system.

The SBER Subcommittee has developed several training and teaching tools specific to SBER-related research. One tool is this annotated bibliography which was created to provide investigators, research teams, and Institutional Review Boards (IRBs) with current curated literatures on how to evaluate risk in a consistent manner.

One of the five requirements of the Federal Policy for the Protection of Human Subjects, known as the “Common Rule,” is that an IRB minimize risks associated with study participation, determine whether “risks to subjects are reasonable in relation to anticipated benefits,” and determine whether subjects are adequately informed about “any reasonably foreseeable risks or discomforts.”¹ This annotated bibliography is intended to help IRBs, IRB staff, and researchers assess, rate, and quantify potential risks within SBER studies. Our intent is that this annotated bibliography will help build a framework for an investigator’s protocols before they are submitted to an IRB. In addition, this tool may also be useful to IRB administrative staff or IRB reviewers who regularly render risk determinations as part of application intake, during pre-review of submissions, or as part of an IRB review of a research project.

SEARCH STRATEGY

Through a preliminary review of the existing publically available literature, terms were identified and used to develop the search criteria (see Appendix B for search keywords and search engine details). Using these criteria, the literature on risk assessment associated with SBER was reviewed. The information included in this document was selected by the SBER Subcommittee based on extensive review of content-specific articles and was confined to literature identified with abstracts or summaries published between 2001 through 2012. Beginning in April 2014, the subcommittee brainstormed keywords and topics to be used to “tag” the articles. This list can be used along with the articles below, as well as with additional literature reviews to help select articles that fit specific needs. The list is ever evolving; you are welcome to add new tags as you see fit. See Appendix C for the final key word tag list.

While preparing to develop this risk assessment bibliography, the SBER Subcommittee found a paucity of useable articles. In addition to the limited number of the articles, many of them were judged to be out of date, included information that had a known flaw, or omitted some important considerations. While the subcommittee still reviewed a number of those articles, all members did not necessarily agree with their content. Nevertheless, the subcommittee concluded that some of those articles still added value and elected to include them in this document despite their potential shortcomings.

The abstracts/summaries in this document are reproduced exactly as published. Please note that any typographical errors, etc., from an article were not corrected by the subcommittee in this bibliography.

**BACKGROUND**

The National Institutes of Health (NIH) defines SBER as research on behavioral and social processes involving the study of humans or animals functioning at the level of the individual (e.g., behavioral factors such as cognition, memory, language, perception, personality, and emotion), small group, institution, organization, community (defined by geography or common interest), or population.²

Risk assessment means a qualitative and quantitative evaluation of the risk posed to human health and/or the environment, the actual or potential presence and/or use of specific populations.³

An IRB must decide whether an anticipated benefit justifies asking a person to undertake the risk(s) associated with study participation, while also taking into account different subject populations and individual differences among subjects. When identifying potential risks, IRBs and researchers should consider all types of risk: physical, psychological, social, legal, economic, and others. The risks most commonly associated with SBER are: time- and situation-specific, variable and subjective, less predictable than many risks associated with participation in a biomedical research study, and often are unknown as there are little or no empirical data on the likelihood of risk associated with SBER. Common potential risks that an IRB should consider when reviewing a SBER study include potential breach of confidentiality, violation of privacy, validation of bad behavior, risk of harm to others, physical harm, emotional or psychological distress, legal harm, financial harm, and social harm. The primary source of risk in SBER often results from a potential breach of confidentiality.

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It is well established that evaluation of the risk/benefit ratio requires focusing on the potential risks associated with study participation and on the immediate or reasonably foreseeable risks. When focusing on the risks directly associated with study participation, IRBs should consider only those risks and benefits that may result from the research, not any potential risks or benefits a subject would receive even if not participating in the research. When focusing on immediate or reasonably foreseeable risks posed to study participants, federal regulation prohibits an IRB from considering possible long-range effects of applying knowledge gained in the research.  

IRBs and researchers share the responsibility of ensuring risks associated with study participation are minimized. There are many mechanisms to minimize risk, such as requiring the principal investigator to obtain a Certificate of Confidentiality, ensuring adequate consent processes, restricting access to data, waiving documentation of consent if appropriate, requiring timely scoring/review of mental health assessments by qualified personnel, requiring post-approval monitoring, and employing appropriate safeguards to protect data.

In addition to this annotated bibliography, the Harvard Catalyst SBER Subcommittee SBER 301 slides, “IRB Assessment of Risks Associated with Social, Behavioral, and Educational Research” may prove helpful in providing more guidance on determining risk.

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RISK ASSESSMENT IN SOCIAL BEHAVIORAL RESEARCH


TAGS: Students; IRBs; deception research; behavioral research; Risk: Psychological, privacy/confidentiality

Abstract
Social research takes place in a social context. Researchers must therefore take into account many ethical and political considerations alongside scientific ones in designing and executing their research. Often, however, clear-cut answers to thorny ethical and political issues are hard to come by.


TAGS: Stigmatized populations; illegal behaviors; domestic violence research; minimizing risk; retention; Risk: Emotional distress, physical

Abstract
Intimate partner violence (IPV) research has expanded dramatically in the past 2 decades. However, updated ethical guidelines to protect the safety and autonomy of research participants, study data, and the research team are still lacking in this evolving area of research. This article presents general concepts in research ethics and the specific challenges and strategies for IPV research related to recruitment and retention, maintenance of women’s safety, privacy, and confidentiality, and their voluntary participation as well as assessment of benefits and risks, strategies to minimize risk, the Certificates of Confidentiality, and training of the research team. This area of nursing research is critical for developing practice guidelines and improving the health and quality of life of abused women.


TAGS: Persons with stigmatized health conditions; substance abuse research; illegal behaviors; minimizing risks; Risk: Legal, privacy, unexpected

Abstract
The paper presents an analysis of policy directives needed to respond to threats of harm (e.g., violence against third parties) that may arise in the course of conducting descriptive epidemiological research with high-risk populations. It identifies two key areas where new policies must be developed to guide researchers conducting such investigations. The paper
recommends that: (1) an NIH consensus panel be convened to set standards, analogous to Common Toxicity Criteria (CTC) criteria, to classify the severity of different types of indirect, non-research-related risk; and (2) case-based training modules be developed and incorporated into public health research ethics courses and training programs, to enhance researcher judgments in determining the likelihood of harm in different situations. In addition, researchers, Institutional Review Boards (IRBs) and community advisory groups must consider the issue of staff safety and the effectiveness of available responses to reduce the threat of harm. The author reviews and discusses implications for informed consent and IRB review.


TAGS: Persons with stigmatized health conditions (HIV); international/local context; Risk: Legal, stigmatization, physical

Abstract
Assessing social risks has proven difficult for IRBs. We undertook a novel effort to empirically investigate social risks before an HIV prevention trial among drug users in Thailand and China. The assessment investigated whether law, policies and enforcement strategies would place research subjects at significantly elevated risk of arrest, incarceration, physical harm, breach of confidentiality, or loss of access to health care relative to drug users not participating in the research. The study validated the investigator's concern that drug users were subject to serious social risks in the site localities, but also suggested that participation in research posed little or no marginal increase in risk and might even have a protective effect. Our experience shows that it is feasible to inform IRB deliberations with actual data on social risks, but also raises the question of whether and when such research is an appropriate use of scarce research resources.


TAGS: Adolescents (teenagers); Risk: Legal, privacy

Abstract
Promotion of adolescent health requires well-designed scientific studies that determine the prevalence of the problem of interest, identify risk and resilience factors, and evaluate methods for prevention and intervention. Many adolescent-related health problems are typically considered sensitive by society (e.g., sexual and substance use behaviors), thus further complicating the research process. Using the principles of the Belmont Report as its framework, this paper draws on developmental theories to discuss ethical issues specific to the conduct of research with adolescents. Our ability to use developmentally sensitive research practices will be enhanced by further understanding of issues associated with risk and benefit assessment by the adolescent, their parents, and institutional review boards, and by delineating ways to ensure that
adolescent participants are adequately protected and have a developmentally affirming experience.


TAGS: IRBs; Community-based participatory research (CBPR); research ethics; guidance; Risk: Stigmatization, communal

Abstract
Access barriers to effective ethics review continue to be a significant challenge for researchers and community-based organizations undertaking community-based participatory research (CBPR). This article reports on findings from a content analysis of select (Behavioral, Biomedical, Social Sciences, Humanities) research ethics boards (REBs) in the Canadian research context (n = 86). Existing ethics review documentation was evaluated using 30 CBPR related criteria for their sensitivity to relevant approaches, processes, and outcomes. A linear regression was conducted to determine whether specific organizational characteristics have an impact on the CBPR sensitivity: (1) region of Canada, (2) type of institution (university or a healthcare organization), (3) primary institutional language (English or French) and (4) national ranking with respect to research intensiveness. While only research intensiveness proved statistically significant (p = .001), we recognize REB protocol forms may not actually reflect how CBPR is reviewed. Despite using a single guiding ethical framework, REBs across Canada employ a variety of techniques to review research studies. We report on these differences and varying levels of sensitivity to CBPR. Finally, we highlight best practices and make recommendations for integrating CBPR principles into existing ethics review.


TAGS: Students; observational research; focus groups, interviews; secondary subject; Risk: Privacy/confidentiality

Abstract
This article examines the many ethical challenges that are specific to qualitative research. These challenges concern the issues of informed consent procedures, the researcher-participant relationship, risk-benefit ratio, confidentiality and the dual role of the nurse-researcher. Each challenge will be examined and practical examples of how it was dealt with, using examples from a multiple case study, will be described.

TAGS: Community; community-based participatory research (CBPR); international/local context; Risk: Societal, privacy/confidentiality

Abstract
Institutional review boards are increasingly meticulous about informed consent and risks and benefits to study participants. Concurrently, heated debate in a number of fields has advanced the notion of community risk and benefit. When research is conducted in communities, and the results may “do harm to” communities socially, economically, or medically, should informed and voluntary consent be obtained from communities as well? We argue that for demographers – by definition interested at the phenomena at the population level – concern for individuals as a part of communities is critical to the research process. Questions of community consent, confidentiality, and participation will be pushed to the fore as demography delves into new areas and methods of investigation. This paper provides a brief overview of the historical development of ethics in human subject’s research and the subsequent ties to community-level concerns. Drawing on current examples from a variety of settings, we explore definitions of community, the scope and viability of community participation in research, and the implications of these for demographic enquiry. We find that in contrast to substantive debates, little attention has been given to ethical issues in the demographic research process. Research accountability to communities, including the documentation of community risks and benefits, and community representation and consultation in the research process are recommended.


TAGS: Research ethics; behavioral research; research ethics; guidance; stigmatized populations; minimizing risk/risk assessment; Risk: Psychological, emotional distress, reputation, confidentiality, social, privacy/confidentiality, physical

Abstract
The article discusses psychological and social risks of behavioral research. Risks to human subjects associated with participation in research are an important consideration in the design of studies and in the informed consent process. Yet, there are significant gaps in the knowledge about the psychological and social risks of behavioral research. The review of federal regulations governing research with humans and empirical work pertaining to behavioral research risks shows that researchers have little data on the frequency of specific psychological and social risks and on the implications of these risks for research subjects who experience them.

TAGS: Behavioral Research; research ethics; secondary subjects; Risk: Privacy/confidentiality, communal

Abstract
In psychosocial and health-behavioral research, we often request that research participants provide information on significant individuals in their lives, so-called ‘‘third parties’’. Recently there has been a greater recognition of privacy issues and risks in research pertaining to third parties. Reaction on the part of USA federal regulatory authorities to one study [Amber, D. (2000). Case at vcu bring ethics to forefront. , 14, 1], which attempted to collect survey data about the psychiatric history of respondents’ parents, has generated such concern and caution that longstanding practices for the collection of social determinants of health data are being questioned and are at risk of being disallowed by Institutional Review Boards (IRBs). In this paper, we consider third party research rights and risks from the perspective of social and behavioral scientists. Focusing on research about health and quality of life, we first discuss the rationale for research methods that elicit contextual information about family members, friends, co-workers, and other social contacts. Second, we discuss the matter of ‘privacy’ and its central role in the current third party rights and risks dialogue. Next, we describe ways to effectively manage third-party information, building upon current recommendations by the Office for Human Research Protections (OHRP) and Botkin’s [(2001). Protecting the privacy of family members in survey and pedigree research. Journal of the American Medical Association, 285(2), 207–211] treatment of the matter for survey and pedigree research. Lastly, we discuss the implications of applying these data collection and management strategies in social and behavioral research. We assert that these recommendations protect the rights of, and minimize the risks to, third parties without impeding social and behavioral health research.

Disclaimer: Figure 2 does not fully reflect the text.


TAGS: Population in crisis; crisis research; Risk: Unexpected

Abstract
Research is vital to accurately describe phenomena in humanitarian emergency situations and to evaluate the effectiveness and appropriateness of interventions. Although the ethical principles of justice, beneficence and respect for autonomy respect for persons should be upheld in research, their application in emergency situations may differ from non-emergency situations. Just like in non-emergency situations, research in emergency situations should be conducted in the best
interest of the victims or future victims. The research should not unnecessarily expose human subjects and the researcher to careless harm, and should be of adequate scientific rigor. Victims of emergency situations are vulnerable populations that need special protection from exploitation. Technical competency to conduct research in emergency situations should include the ability to conduct a fair risk-benefit assessment in order to come up with a risk management plan, and being culturally sensitive to the needs of the victims of the humanitarian crisis. In emergency situations, the roles of Institutional Review Boards (IRBs) may have to be modified without compromising the ethical standards that health researchers have globally attempted to achieve.


TAGS: Survey research; observational research; focus groups, interviews; research ethics; Risk: Psychological

Abstract
Decision-making about the ethics of qualitative research is problematic where the research design is emergent and the balance between risks and benefits for research subjects are difficult to ascertain prior to study implementation. The discourses of health/medical research ethics and those of social research are shown to be divergent and, furthermore, where ethics committees tie themselves to the health/medical model of ethical decision-making, qualitative research approaches can be disadvantaged. Having demonstrated the dual discourses and their relevance to qualitative research ethics, a critical review of current approaches to maximizing the success of qualitative research proposals being considered for approval by ethics committees is undertaken. This leads to a call for a system of monitoring qualitative research so that the "benefit to risk" ratio is always on the side of benefit. This has implications for the ways in which ethics committees are organized and the ways in which they function.


TAGS: Focus groups, interviews; qualitative research methods; therapeutic misconception - coercion; research ethics; Risk: Emotional distress, anxiety, reputation, privacy/confidentiality

Abstract
An increasing volume of qualitative research and articles about qualitative methods has been published recently in medical journals. However, compared with the extensive debate in social sciences literature, there has been little consideration in medical journals of the ethical issues surrounding qualitative research. A possible explanation for this lack of discussion is that it is assumed commonly that qualitative research is unlikely to cause significant harm to participants. There are no agreed guidelines for judging the ethics of qualitative research proposals and there is some evidence that medical research ethics committees have difficulty making these
judgments. Our aim was to consider the ethical issues which arise when planning and carrying out qualitative research into health and health care, and to offer a framework within which health services researchers can consider these issues. Four potential risks to research participants are discussed: anxiety and distress; exploitation; misrepresentation; and identification of the participant in published papers, by themselves or others. Recommended strategies for reducing the risk of harm include ensuring scientific soundness, organizing follow-up care where appropriate, considering obtaining consent as a process, ensuring confidentiality and taking a reflexive stance towards analysis. While recognizing the reservations held about strict ethical guidelines for qualitative research, we argue for further debate of these issues so that the health services research community can move towards the adoption of agreed standards of good practice. In addition, we suggest that empirical research is desirable in order to quantify the actual risks to participants in qualitative studies.


TAGS: Minimizing risk; Risk: Societal;

Abstract
The ethical conduct of Community-Engaged Research (CEnR), of which the Community-Based Participatory Research (CBPR) model is the partnership model most widely discussed in the CEnR literature and is the primary model we draw upon in this discussion, requires an integrated and comprehensive human subjects protection (HSP) program that addresses the additional concerns salient to CEnR where members of a community are both research partners and participants. As delineated in the federal regulations, the backbone of a HSP program is the fulfillment of nine functions: (1) minimize risks; (2) reasonable benefit-risk ratio; (3) fair subject selection; (4) adequate monitoring; (5) informed consent; (6) privacy and confidentiality; (7) conflicts of interest; (8) address vulnerabilities; and (9) HSP training. The federal regulations, however, do not consider the risks and harms that may occur to groups, and these risks have not traditionally been included in the benefit-risk analysis nor have they been incorporated into an HSP framework. We explore additional HSP issues raised by CEnR within these nine ethical functions. Various entities exist that can provide HSP---the investigator, the Institutional Review Board, the Conflict of Interest Committee, the Research Ethics Consultation program, the Research Subject Advocacy program, the Data and Safety Monitoring Plan, and the Community Advisory Board. Protection is best achieved if these entities are coordinated to ensure that no gaps exist, to minimize unnecessary redundancy, and to provide checks and balances between the different entities of HSP and the nine functions that they must realize. The document is structured to provide a "points-to-consider" roadmap for HSP entities to help them adequately address the nine key functions necessary to provide adequate protection of individuals and communities in CEnR.

TAGS: Persons with stigmatized health conditions; crisis research; survey research; psychiatric disorder research; research ethics; routine psychological tests; Risk: Stigmatization, anxiety, depression, suicidality, privacy/confidentiality

Abstract
Our laboratory recently confronted this issue while conducting research with undergraduate students at the University Of Waterloo (UW). Although our main objective was to examine cognitive and genetic features of individuals with schizotypal personality disorder (SPD), the study protocol also entailed the completion of various self-report measures to identify participants deemed at increased risk for suicide. This paper seeks to review and discuss the relevant ethical guidelines and legislation that bear upon a psychologist's obligation to further assess and intervene when research participants reveal that they are at increased risk for suicide. In the current paper we argue that psychologists are ethically impelled to assess and appropriately intervene in cases of suicide risk, even when such risk is revealed within a research context. We also discuss how any such obligation may potentially be modulated by the research participant's expectations of the role of a psychologist, within such a context. Although the focus of the current paper is on the ethical obligations of psychologists, specifically those practicing within Canada, the relevance of this paper extends to all regulated health professionals conducting research in nonclinical settings.
CONCLUSION

One of the most enduring dilemmas that IRBs and investigators face is not only the challenge of evaluating the risks associated with study participation, but also ensuring that potential risks are minimized and are reasonable in relation to the potential benefits associated with study participation. Researchers need a basic awareness or perhaps a deeper understanding of the role that potential risks, harms, and/or impacts associated with the research may have. Hence, there is a growing need for researchers to consider factors likely to contribute to increased risk and how it can impact not only the conduct, but also the interpretation of the research. Through greater understanding of risk assessment, researchers can better equip themselves with the necessary skills to enhance effectiveness and ability to reduce the possibility of harm, while employing best practices to minimize risks and inform subjects about them.

It is hoped that this resource will make a meaningful contribution to IRBs and investigators toward building a stronger foundation to advance their understanding of the unique characteristics of the risks associated with SBER and how those risks frequently differ from those associated with biomedical research.
ADDITIONAL RESOURCES


Harvard Catalyst Social, Behavioral, and Education Research (SBER) Committee: http://catalyst.harvard.edu/programs/regulatory/sber.html


APPENDIX A

Additional Suggested Resources:

American Anthropological Association:
http://aaanet.org/cmtes/ethics/IRB.cfm

Behavioral Sciences (HS102):
http://www.slideshare.net/jogiitr/behavioral-science

http://iaspub.epa.gov/sor_internet/registry/termreg/home/overview/home.do

Certificates of Confidentiality Kiosk:

Introduction to Behavioral Science:
https://www.youtube.com/watch?v=7_4o26enmGs

National Science Foundation:

NIH:
https://obssr.od.nih.gov/about_obssr/BSSR_CC/BSSR_definition/definition.aspx

http://obssr.od.nih.gov/about_obssr/BSSR_CC/BSSR_definition/definition.aspx#bfr

NIH Office of Behavioral and Social Sciences Research:
http://obssr.od.nih.gov/index.aspx
APPENDIX B

Search Keywords: IRB Assessment of Risk; Non-Medical Research; Social and behavioral research.

The Key Word Tag List listed here is the one the group used to develop this resource. The committee developed the tags through numerous rounds of brainstorming then edits were made based on review of the articles. The tag list can be used to organize articles and may be used for future review of articles. As research is always evolving, you can add or update tags.

**Key Word Tag List (Version 5/29/2015)**

**Research Populations:**
- Students
- Adolescents (Teenagers)
- Pediatrics
- Young adults
- Senior citizens
- Pregnant women
- Immigrant populations
- Indigent peoples
- Race/Ethnicity
- Persons with stigmatized health conditions
- Stigmatized populations
- Population in crisis
- IRBs
- Community
- IRB chairs and review boards

**Risk:**
- Economic risk
- Legal risk
- Dignitary risk
- Psychosocial risk
- Psychological risk
- Societal risk
- Risk of stigmatization
- Financial risk
- Risk of emotional distress
- Risk to employability
- Risk of anxiety
- Risk of depression
- Risk to insurability
- Physical risk
- Risk of suicidality
- Risk to reputation
- Risk to privacy/confidentiality
- Unexpected risks
- Minimizing risk/risk assessment
- Physical risk to research team
- Communal risks
- Social risk
- Risk to researchers
- Therapeutic misconception
- Coercion

**Kind of Research (topics, disciplines, methodologies):**
- Data mining
- Deception
- Crisis/emergency
- End of life issues
- Survey/Telephone
- Observational
- Social anthropology
- Behavioral economics
- Internet
- Social Media
- Employees
- Focus groups, interviews
- Terrorism
- Substance abuse
- Psychiatric disorder
- Edges of research
- Business
- Microfinance
- Gang violence
- Illegal behaviors
- Prisoner
- Community-based participatory research (CBPR)
- Public health
- Domestic violence
- Genetic
- Qualitative research methods
- Behavioral

**Open (related keywords):**
- Research ethics
- Routine medical tests
- Routine psychological tests
- Regulations
- Guidance
- Retention
- Scientific merit
- Secondary subjects
- Qualitative research
- Research methods
- Community-based research
- Adequacy of IRB review
- Perception of IRB review processes
- IRB review process for CBPR
- Parental permission
- Impaired decision making capacity
- Study design guidance for adolescent research
- International/local content

APPENDIX

The Key Word Tag List listed here is the one the group used to develop this resource. The committee developed the tags through numerous rounds of brainstorming then edits were made based on review of the articles. The tag list can be used to organize articles and may be used for future review of articles. As research is always evolving, you can add or update tags.
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CONTACT US

All articles are publically available on Pub Med. Copies of the materials are freely available. Please send any suggestions, feedback, or questions regarding this annotated bibliography to regulatory@catalyst.harvard.edu and visit the SBER Subcommittee webpage.
ACKNOWLEDGMENTS

We thank The Harvard Catalyst Social, Behavioral, Education Research (SBER) Subcommittee of The Regulatory Foundations, Ethics, and Law Program that made this bibliography possible.

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