

Risks and Harm:

In the context of sexuality and health research with LGBT youth

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Overview

- Need for research on “risky” and “sensitive” behaviors with youth
- Need for research with youth populations that are ~~vulnerable~~ experience health disparities.
 - Implications of avoiding such research
- What are the risks (and benefits) associated with this social and behavioral research?
- Is this research minimal risk as currently (un)defined.
- Case study of Project Q2

Need for research on “risky” and “sensitive” behaviors with youth

- Adolescent health risk behaviors, specifically substance use, conduct problems, and sexual risk-taking, are primary contributors to direct and indirect causes of morbidity and mortality^[1-3].

Diagnoses of HIV Infection among Adult and Adolescent Males, 2007–2010—46 States and 5 U.S. Dependent Areas

Of the 190,814 diagnoses of HIV Infection among adults and adolescents during 2007 through 2010:

77% were in males

75% of diagnosed HIV infections in males were attributed to male-to-male sexual contact

19% of diagnosed HIV infections in males were among those aged 13-24 years

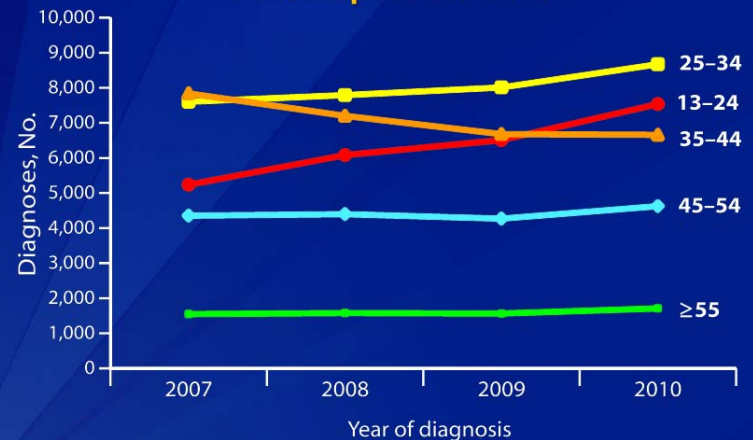
89% of diagnosed HIV infections in males aged 13-24 years were attributed to male-to-male sexual contact

In 2010, **61%** of HIV infections diagnosed among adults and adolescents were attributed to male-to-male sexual contact

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing risk factor information, but not for incomplete reporting. Data exclude men who reported sexual contact with other men and injection drug use.



Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2007–2010—46 States and 5 U.S. Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing risk factor information, but not for incomplete reporting. Data exclude men who reported sexual contact with other men and injection drug use.



Implications of avoiding research on risky behaviors among youth

- 74 CDC endorsed evidence-based HIV prevention programs (including 17 for youth), there are none for adolescent MSM and only one “good-evidence” behavioral intervention for emerging adult MSM^[4,5].
- Most prevention funders require evidence of program effectiveness; the absence of such research on adolescent MSM effectively eliminates major sources of programmatic funding for this high risk group.
- Researchers shy away from research on adolescent MSM because of the belief (experience) that they could not receive IRB approval. IRB decisions are often motivated by value-laden concepts absent supportive evidence.

What are the risks in social and behavioral research with youth in this area?

- The Society for Adolescent Medicine (SAM)^[6] reviewed the literature in this area and concluded the primary risks are:
 - Promoting or inducing unhealthy behavior (e.g., initiating sex after answering a survey of sexual behavior) is sometimes raised as a potential risk, but the SAM review of the literature dismissed this notion.
 - Loss of privacy or confidentiality (ANPRM data security rules address this).
 - Negative psychological reaction to participation.

Psychological Risks

- Sometimes used by IRBs as rationale for study to be deemed greater than minimal risk.

We will be asking you personal questions about your sex life, mental and emotional health, any alcohol or drugs you may have used, and potentially criminal behavior. Although this information is confidential, **some of these issues could make you feel uneasy or embarrassed.** If there are questions you do not want to answer, you do not have to do so. You can stop taking part at any time. A staff member will be available if you want to talk about anything that comes up during the interview. **We will also refer you to counseling services if you want.**

What are the risks of a negative psychological reaction to social and behavioral research?

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INVITED ESSAY

Ethical and Regulatory Issues with Conducting Sexuality Research with LGBT Adolescents: A Call to Action for a Scientifically Informed Approach

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Abstract Lesbian, gay, bisexual, and transgender (LGBT) adolescents experience disparities in mental and sexual health. There is also a lack of research on this population relative to other adolescents, which limits our ability to effectively address these health disparities. Researchers may unfortunately avoid conducting research with this population because of anticipated or actual experiences with difficulties in obtaining IRB approval. A case example is provided to illustrate the ethical and regulatory issues related to research with LGBT adolescents. Relevant U.S. federal and local regulations related to research on sexual and mental health with adolescents is then reviewed. Data are presented demonstrating that requiring parental consent for LGBT youth under age 18 would likely alter study result. Data are also presented on participants' appraisals of the risks and discomforts associated with research participation. The provision of such empirical data on the risks of research participation is consistent with the goal of moving the IRB process of risk/benefit assessment from being entirely subjective to being evidence-based. Finally, recommendations are provided on how to approach these issues in IRB applications and investigators are called to help to build a corpus of scholarship that can advance empirical knowledge in this area.

Keywords Gay youth · Homosexuals · Lesbians · Bisexuals · Ethics · Institutional review boards

Introduction

Regulatory boards charged with protecting human research subjects, such as institutional review boards (IRBs), have had an increasing influence on the conduct of research involving human subjects. Within the U.S., the IRB system is struggling to manage an expanding mission that extends beyond assessments of risk–benefit ratios to also sometimes include responsibility for managing conflicts of interest, compliance with regulations regarding accessing health records, assuring research protocols correspond to grant applications, and others (Gunsalus et al., 2007). At the same time, the scientific enterprise is becoming increasingly specialized, thereby diminishing the likelihood that any given IRB will have a member with expertise in the protocol under review. The implications of this so-called “mission creep” for researchers is that every aspect of the design and conduct of their study may be subject to modification by IRB members who are not subject-matter experts. Particularly in value-laden areas of scholarship, such as sexuality research, this creates the potential for individual values to threaten academic freedom and the quality and conduct of research that has the potential to improve sexual health.

The goals of this invited article are ambitious—a call to action to sexuality researchers to improve the IRB review of sexuality research by transforming it into an evidence-informed process. Transforming this process will require sexuality researchers to become experts in the ethical and regulatory issues involved in

Project Q2

- Funding: American Foundation for Suicide Prevention (waves 1-4), William T Gran Foundation (waves 4, 5, 6), David Bohnett Foundation (wave 5), NIMH (males: waves 7, 8), Northwestern (females waves 7, 8).
- Aim: To understand factors that increase risk for mental health problems, substance use, and HIV among LGBT youth. Increase understanding of the development of sexual orientation.
- Longitudinal (8 waves over 4 years) with CASI self-report and structured psychiatric interviews.
- Target sample 250 in age range 16-20 at baseline

What is the participants experience?

- Project Q2 4th wave interview asked, “We are trying to understand what it is like to participate in one of our research studies. How did you feel answering the questions about...”

Table 3 Participants reactions to answering study questions among participants of all ages at 1-year follow-up interview ($N = 181$)

	Sexual behavior (%)	Drug and alcohol use (%)	Mental health and suicide (%)
Very comfortable	39.8	51.4	44.2
Comfortable	49.2	39.2	44.2
Uncomfortable	8.3	6.6	9.4
Very uncomfortable	2.8	2.8	2.2

Consistently low reports of distress

- Our findings of very few participants who report being uncomfortable answering these questions is consistent with past research:
 - Fendrich et al. (2007): adult men who have sex with men answering questions about sexual behavior and substance use^[7]
 - Jacomb et al. (1999): adults participating in a mental health survey^[8]
 - Jewkes et al (2012): adults in study of HIV and gender-based violence in South Africa^[10].
 - Langhinrichsen-Rohling et al. (2006): adolescents answering questions on drug use, suicidal behavior, and physical and sexual abuse^[9].
 - Kuyper et al (2012): youth completing measures on sexuality^[11].

Is this research minimal risk?

- Subpart D governs research with children, and the minimal risk standard (defined in Subpart A) determines what kinds of research can be conducted.
 - §46.408: Waiver of parental permission can be issued when research risks are minimal (or only a slight increase over minimal) and
 - The research could not practically be carried out without the waiver (§46.116d)
 - Parental permission is not a reasonable requirement (e.g. runaway, abused children) (§46.408c).

Minimal Risk

Project Q2

- “Did you feel like answering any of these questions made you more uncomfortable than a typical visit to your physician, doctor, psychologist, or counselor.”
- 54% “No, it was more comfortable answering these questions”
- 35% “About the same”
- 11%, “Yes, more uncomfortable answering these questions”

Is being uncomfortable a risk?

- 27% of children sometimes feel scared or afraid in their daily lives^[12].

What are routine experiences in medical and psychological procedures?

- Routine medical and psychological procedures involving children include blood draws, screening for mental health problems, indications of abuse or neglect as well as tests to assess cognitive, social, academic, behavioral and emotional functioning. Questions about substance use, depression, and sexuality are part of routine medical and psychological examinations for children beginning in early adolescence^[13].

Problems applying minimal risk standards to research with youth

- 2 IRBs (University of Illinois at Chicago [UIC] and a Community Based Organization [CBO])
 - 8/06- Submission to CBO IRB (primary data collection site)
 - 9/06- Submitted to UIC for Departmental Review
 - 9/06- IRB approval by CBO
 - 6 months and 4 rounds of review with UIC
 - Much of it had to do with determining the “risks” of the study, until they ultimately decided it was “only a slight increase over minimal risk” without articulating what these risk were.
 - 3/07- UIC IRB approved with CoC
 - 4/07- CBO IRB approval of amended protocol
(month 10)...the work can begin

Benefits of research participation

- 45 CFR 46 specifies that a basic element of informed consent includes “A description of any benefits to the subjects or to others which may reasonably be expected from the research.”
- “Benefit” is not clearly defined.
- NIH Intramural Protocol Review Standards states that “A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject [direct benefit], or something that will contribute to the acquisition of generalizable knowledge [social benefit].”

Benefits of Research Participation



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	Age: 16-17 (n=52)		Age: 18-20 (n=221)	
	Mean	SD	Mean	SD
It made me feel like part of something important	1.6	0.7	1.8	0.8
It made me feel like I am helping my community	1.8	0.7	1.7	0.8
It helped me to have someone to talk to about my experiences	1.8	0.8	2.0	0.9
It made me feel like I am helping other young men like myself	1.8	0.8	1.8	0.8
It gave me the opportunity to meet successful LGBT adults	2.0	0.9	2.0	0.9
It helped to know people care about other young men like myself	1.6	0.7	1.8	0.8
Answering the questions helped me reflect on who I am	1.8	0.8	1.8	0.9
Participating in Crew 450 made me feel supported	1.6	0.8	1.8	0.9
Participating in Crew 450 helped me to think about my behavior	1.8	0.9	1.7	0.9

Scale: 1=Strongly Agree; 2 = Agree; 3 = Neutral; 4 = Disagree 5=Strongly Disagree

- No significant differences between age groups for any item ($p > .05$)

Thank you funders and project staff!



American Foundation *for* Suicide Prevention



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