



FORDHAM UNIVERSITY
THE JESUIT UNIVERSITY OF NEW YORK

THE CENTER FOR ETHICS EDUCATION
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Ethics & Social Justice in Research Involving Vulnerable Populations

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Adolescent Health Risks

CDC Surveillance Data 2009 & 2011

- 16% had seriously considered & 8% had attempted suicide; 13% died from suicide; 16% from homicide
- 47% had sexual experience; 34% were sexually active; 8% forced to have sex
- 517,174 cases of STI & 2,036 cases of HIV among youth 15 – 19 years
- 71% had consume alcohol (20% before age 13); 40% used marijuana; 8 – 11% cocaine, inhalants, Ecstasy
- 20% LGBT youth are victims of physical assault; 40 – 80% have been verbally or physically harassed



Yet, investigators face institutional barriers to conducting health-risk research among adolescents



Absence of evidence-based prevention & treatment programs



Justice

Adolescents have the right to participate in research that will protect them from receiving developmentally untested, inappropriate and unsafe health interventions



Barriers to Adolescent Risk Research

- Ambiguous minimal risk and informed consent language in federal regulations
- Institutional over-estimation of risk and risk aversion
- Bias regarding “deviant” nature of risk behaviors
- Failure to permit guardian permission waiver



Minimal Risk

Definition: “the probability and magnitude of physical or psychological harm does not exceed that which is **ordinarily encountered in daily life or in the routine medical, psychological examinations or tests**”



Distinguishing Research Vulnerability from Social Vulnerability:

- CFR 46.111 vaguely requires “additional safeguards” for “populations vulnerable to coercion or undue influence”
- Failure to distinguish between vulnerabilities in participants lives & research vulnerabilities lead to risk over-estimation

Fisher et al (SRCD Report 2013): NAS (2014)



§ 46.110 Expedited Review

Over-estimation of Informational Risk

- IRBs should evaluate the adequacy of confidentiality protections not the risks if such protections were not in place!
- IRBs should classify as minimal risk protocols that include “reasonable and adequate procedures that are implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal”

<http://www.hhs.gov/ohrp/policy/expedited98.html>



Minimal Risk Myths

Survey questions regarding sexual/gender identity, sexual behavior, substance use, victimization or feelings of anxiety or depression

- Are not encountered in daily life and health examinations
- Answering questions causes anxiety
- Participating in surveys or prevention programs will encourage minors to engage in risk behaviors



Debunking Myths: What do we Know

- Routine pediatric and psychiatric visits include: Physical and social history questions regarding sexual health, substance use, sleep disorders, anxiety, depression (Fisher, Kornetsky & Prentice, 2007; SACHRP, 2005)
- School health curricula includes information on sexual behaviors, substance use, conflict resolution; as well as information on school staff who handle harassment, bullying, or discrimination complaints.
- Adolescents are daily exposed to TV & Movie coverage on these issues
- *Many utilize social media to gain knowledge and social support*



Goodness-of-Fit Ethics

(Fisher 2002, 2004; Fisher & Goodman, 2009; Fisher & Ragsdale, 2006)

Research vulnerability is joint product of participant characteristic and research procedures

- What special life circumstances may render participants more or less susceptible to research risk?
- Which aspects of the research design may create or exacerbate research risk?
- What procedures can be implemented to reduce such risks



Evidence-Based Ethical Procedures

Draw on Participant Perspectives using “Opinions in Progress” Approach

- Over or under-estimation of participant & community risk
- Participant and community benefits
- Clarity and language appropriateness of consent information
- Appropriate confidentiality, referral and disclosure policies
- Fair and non-coercive incentives



GFE: Co-Learning

Fisher, 1999, 2002

Investigator

- Knowledge base
- Scientific method
- Testable hypotheses
- Ethical procedures available to protect participant rights and welfare

Participant Expertise

- Health priorities
- Cultural values
- Fears and hopes about the general or specific scientific enterprise
- The real world context in which hypotheses will be studied



Debunking Myths: What do we Know

- 86% of 7th – 12th graders in a general population study disagreed with statements :Answering survey questions might make teens believe it is okay or cause teens to decide to use drugs or think about suicide (Fisher, 2003).
- 82% thought such questions would not upset teens (Fisher, 2003).
- 90% of LGBTY judged answering surveys on sexual behavior, substance use, and mental health and suicide as more or as comfortable as a typical visit to their practitioner (Mustanski, 2011; Fisher 2014)
- LGBT 15 – 19 years thought LGBT focused survey studies were a form of social affirmation and critical to helping other sexual minority



Disclosure of Confidential Information in Non-Therapeutic Research

The Scientist-Citizen Dilemma

Do scientists with expertise in problems of adolescent health risk have a special obligation to help those they know are in jeopardy?



Maintaining Confidentiality: Parent & Teen Perspectives

Fisher, 2002, 2003

- Avoids feelings of betrayal
- Vent feelings
- Encourages teenagers to take responsibility
- Avoids granting undue authority to investigators to make reporting decisions
- Prevents giving credibility to false or inaccurate responses
- Avoids involvement with child protection agencies



Reasons to Refer or Disclose: Parent & Teen Perspectives

Fisher (2002, 2003)

- Teens may not know they need help
- Teens may be asking for help
- Others may be in harm's way
- Scientists have an obligation to help & would be "accomplices" if problem worsens



GFE: Teen & Parent Preferences: Drugs & Suicide Research

Fisher, 2003

Policy Preferred?

- Not tell anyone
Teens 10% Parents 6%
- Discuss w/ Teen
Teens 65% Parents 61%
- Tell another adult who can help
Teens 25% Parents

Who Should be Told?

- Parent
 - School Counselor
 - Doctor Outside School
- Teens 37% Parents 17%**



Confidentiality Policies & Consent

O'Sullivan & Fisher, 1997

	Parent Teen		Parent Teen		Parent Teen	
	DRUGS		SEXUAL ABUSE		STD	
Confidentiality	32%	76%	14%	64%	28%	66%
Referral	66%	84%	48%	66%	60%	82%
Disclose to Parent	100%	32%	92%	70%	100%	36%



GFE: Referral & Disclosure Practices

- Step 1: Identify population + research risk related disclosure concerns
- Step 2: Evaluate validity of risk Relevant laws
- Step 3: Review relevant laws and professional guidelines
- Step 4: Identify community resources
- Step 5: Consider disclosure risks
- Step 6: Determine best fitted policy



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Waiver of Guardian Permission for Adolescent Health Research



Federal Regulations & Mature Minor Laws

- Permitted for minimal risk research if research is not “feasible” or “reasonable” if guardian permission is required (§ 46.116 & 408)
- § 46.402 “Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research is conducted”
- State *mature minor laws* permit teens access to sexual health, mental health and substance use treatment *without guardian permission*
- Guardian permission waiver recommended by SACRHP, 2005; SADM, 2003, SRCDC, 2014



Justice

Failure to waive guardian permission deprives adolescents of their full rights and protections as “adult” participants under the Common Rule and fair access to potential benefits of research participation.



Parent & Teen Perspectives

Fisher, 2002, 2003

Reasons to Require Parental Permission

- Respect for Parents
- Protection Against Coercion & Deception
- Power Differentials
- Post-Experimental Stress

Reasons to Waive Parental Permission

- Cognitive Maturity
- Teen Autonomy & Privacy
- Parents' Reactions
- Honesty of Disclosures
- Parents are Cause of Problem



GFE: Waiver of Guardian Permission

- Evaluate the age groups' understanding of their rights and research procedures (by age 14 teens reach adult levels IOM, 2004)
- Include educational procedures for enhancing consent
- Ensure language is age-appropriate
- Assess (when appropriate) individual minors' consent readiness
- Appoint a participant consent advocate



Research Participant's Bill of Rights

Bruzzese & Fisher, 1999

- To be fully informed
- To have all questions answered
- To freely choose to participate or to refuse participation
- To withdraw or not answer questions
- To privacy and confidentiality
- To be protected from harm
- To know the results of the study
- To understand these rights



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Consent for therapeutic research involving adolescents with health disorders



§ 46.408 Waiver of Child Assent Permitted If...

- Capability... is so limited that they cannot reasonably be consulted or
- Intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children *and*
- Is available only in the context of the research



Parent-Teen Perspectives: Pediatric Cancer Trials

(Masty & Fisher, 2006)

- While important to respect a child's decision-making abilities
- Parents had responsibility to shield children from anxiety-provoking information and feelings of self-blame or guilt if participation did not produce results



GFE: Recommendations

Masty & Fisher 2006

- Child's Cognitive and Emotional Maturity, Nature of Disorder and Possible Reactions to Information
- Parent's Medical and Research Knowledge & Experience, Cultural Styles, Economic concerns and Level of Anxiety
- Family's Decision-Making History and Negotiation Process
- Never ask a child to make a participation choice if that choice will not be respected



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Informational Risk and Research Involving Genetic Testing



Stigma & Privacy

- Gene-environment interactions are probabilistic, yet results may influence parenting practices
- Parents have access to child's private information
- Child's privacy needs change over time
- Genetic literacy & family privacy risks



GFE: Disclosing Results of Genetic Research

(Fisher & McCarthy, 2013)

- Is design sufficient to identify relative contribution of genes and environment?
- How high is the predictive validity?
- Does the disease present a major risk to the child's immediate health?
Are remedies possible?
- Is this an adult onset disease? Are there preventive interventions available prior to the child's age of majority
- What is the risk of personal stigmatization or financial burden of increased health costs?
- Informational risk & disclosure policy must be included in



Social Justice and Research Involving Genetic Testing

- Gene-context risk influences societal definitions of normal and abnormal and health and disease.
- New “genetized” diseases may be created
- Public tendency toward genetic essentialism
- Potential for group genetic stereotyping
- Genetic versus social definitions of race and gender



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Social Justice & Genetic Research Involving Social Minorities



Parent-Teen Perspectives

(Fisher & Wallace 2000)

Genetic studies on teen violence:

“They know the reason why [there is violence]...ghettos...racism...and prejudices may still exist, but they don’t want to say that. They want to say it’s in their genes...to make a cover story.”



Parent-Teen Perspectives

(Fisher & Wallace 2000)

My Moms and Pops spoil me...and...I'll still be a bitch...I will still fight. Why? Because it's already in me. I guess it probably is genetic. Hey, I'm Puerto Rican, Black Dominican, Italian, and Cuban. You pick a race where it came from."



The Rights of “Genetic Citizenship”

- Federal funding for genomic research is often driven by economic and political concerns (e.g., urban crime, educational costs, mental health disorders, health care costs)
- These may have little to do with or are antithetical to the concerns and social circumstances of participant groups
- Ethical decision-making cannot be isolated from knowledge of how participant’s view the informational goods and harms of genomic research



Parent-Teen Perspectives

(Fisher & Wallace 2000)

"The key is Dr. Fisher, that when you...talk to your counterparts...ask yourselves what will others do with this research? No matter what role that you have played to make this happen, you could have the purist intention, but if it gets into the wrong hands then it becomes a weapon"



Doing Good Well

Inclusion of participant perspectives to create goodness-of-fit ethical practices will

- Minimize Participant & Population Risk
- Maximize Public Health Benefits
- Optimize informed choice
- Ensure fair access to research benefits



Questions/further discussion





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Fordham University HIV & Drug Abuse Research Ethics Training Institute

- Initiated in 2011 NIDA #1R25DA031608-1
- Provides early-career investigators in the social, behavioral, medical & public health fields with research ethics training
- Celia B. Fisher, Ph.D., Program Director & Principal Investigator
- Elizabeth Yuko, Ph.D., Program Administrator
- 32 faculty members
- 29 trainees admitted



AIM 1: To increase early-career prevention scientists' knowledge of and competencies to address key ethical issues in HIV and drug abuse prevention research

Major Curriculum Areas

- HIV/Drug Abuse Research Ethics: History, Theory & Basic Concepts
- IRB/REC Review of HIV/Drug Abuse Research
- Informed Consent to HIV/Drug Abuse Research
- Protecting Confidentiality & Privacy in HIV/Drug Abuse Research
- Standards of Care & Standards of Prevention in HIV/Drug Abuse Research
- Ethical Engagement of Communities in HIV/Drug Abuse Research
- Empirical Research on Research Ethics (ERRE): Theoretical Frameworks & Methods for HIV/Drug Abuse Research



AIM 2: To enhance investigators' capacity to ethically engage participants and communities in the construction of participant protections

- All trainees convene community advisory boards (CABs) to assist in their developing participant & population-sensitive research designs & implementation
- CABs also advise on the interpretation & dissemination of research
- Illuminates the moral lens through which HIV/drug abuse research is viewed by participant populations
- All trainees have included or plan to include CABs in their future research
- Many trainees have continued to work with their CABs for additional work with that community



AIM 3: To provide training, mentorship and funding to generate empirical data to inform HIV prevention research practices and policies





AIM 4: To create and sustain a global online information network with continuously updated resources on HIV/drug abuse research ethical issues, empirical tools and evidence-based practices

RETI Web Resources & Global Reach			
Website	Total Views	Total Visitors	Number of Countries
RETI Website www.fordham.edu/ethicsinstitute	38,162	9,277	145
Ethics & Society blog ethicsandsociety.org	40,937	23,000	157
Research Ethics Scales & Measures researchethicsmeasures.org	2,015	1,130	86



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