



# Goodness-of-Fit Ethics

## Theory and Methods for Enhancing the Responsible Conduct of HIV and Drug Abuse Research

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# Why We Are Here

(Fisher, 2014; Fisher & Yuko, 2016)

- The global HIV/AIDS and drug abuse pandemics → critical need for empirically informed interventions
- Population Characteristics → Ethical challenges
- Moral reflections of Investigators and IRBs insufficient
- **Needed: An empirical basis for research ethics policies and practices reflecting participant values and lived experiences.**

# Goodness of Fit Ethics (GFE)

Fisher 1999, 2002, 2004, 2014; Fisher, Brunnquell et al., 2013; Fisher & Goodman, 2009; Fisher & Ragsdale, 2006; Masty & Fisher, 2008)



Vulnerability in life  $\neq$  Research  
Vulnerability

Research vulnerability = failure to fit  
research procedures to participant  
research assets and susceptibility to  
research harms

GFE shifts the burden of research  
vulnerability from participant to the  
research context

# GFE Questions

There are no cookie cutter solutions to fitting research ethics practices and policies to all populations and all research designs.

- *What special life circumstances may render participants more or less vulnerable to research harms?*
- *Which aspects of the research design may create or exacerbate research vulnerabilities?*
- *How can procedures be modified to best fit participants' abilities, values and lived experiences?*



# Minimizing Research Vulnerability Through Co-Learning

## ***INVESTIGATOR***

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

## ***PARTICIPANT COMMUNITIES***

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

Fisher, 1999, 2000, 2002

# Methodology of Co-Learning

- **Ensure that participants are familiar with the research methods and context for which their opinions are sought**
- **Questions should explicitly communicate or clearly address the ethical issue**
- **Avoid procedures that discourage non-contemplative responses**



# Do Researchers Have a Duty to Warn Third Parties at Risk for HIV Transmission?

Fisher, C. B. et al (2009). Do drug abuse researchers have a duty to protect third parties from HIV transmission? Moral perspectives of street drug users. In D. Buchanan, C. B. Fisher, & L. Gable (Eds.), *Research with high-risk populations: Balancing science, ethics, and law* (pp. 189–206). Washington, DC: APA Books.

Funding: National Institute on Drug Abuse (NIDA) (grant # RO1-DAO15649)  
PIs C.B. Fisher & M. Singer



# Key GFE Questions

- When, if ever, does an ethnographer have a moral obligation to break participant confidentiality to warn 3<sup>rd</sup> parties they are at HIV risk?
- How is ethical justification for confidentiality and disclosure decisions related to informed consent?

# Video Ethics Vignettes

- 11 focus groups: 100 economically/educationally marginalized PWUDs, ethnically diverse, 39% HIV+
- Video scripts drew on investigator dilemmas and were modified by CAB
- Videos in English & Spanish; Male & Female versions; eliminated heterosexist bias with gender neutral name
- Narrator encourages focus group members to think about case-specific ethical issues

# Field Research/Ethnography

- Participant Perspectives on HIV/Drug Research Ethics
- [Field Research/Ethnography Video](#)



# Participant Perspectives

Theme	Exemplars
Researcher as moral agent	Obligation to say something: Personal conscience & professional responsibility
Researcher community obligation	Must limit community harm or lose credibility
Participant as moral agent	Steve has a responsible to tell Chris; not telling is a crime—like killing them—gives up right to confidentiality
Community members' personal responsibility	Everyone should know about AIDs and Chris should protect him/herself
Informed consent is a contractual obligation	<p>If IC explained disclosure it is OK; <i>But not if he was high at the time</i></p> <p>If IC promised confidentiality its “illegal” to disclose without a signed release</p> <p>If Steve agreed in the beginning he has to accept that researcher will tell</p>
Pragmatism	<p>He could have killed her</p> <p>Don't reveal, but encourage Chris to be tested</p>

# GFE Guidance for Confidentiality Procedures

- Prior to study draw on community expertise to determine limits of confidentiality based on potential harms, community resources & values
- Clearly specify and ensure participants understand extent and limits of disclosure during IC
- Revisit confidentiality/disclosure obligations during multiple meetings
- Assuming a protective stance over participants without considering their own definitions of autonomy and responsibility may lead to poorly fitted confidentiality procedures.



# Assessing and Enhancing HIV Vaccine Trial (HVT) Consent Preparedness Among Street Drug Users

- **Fisher, C. B.** (2010). Enhancing HIV vaccine trial consent preparedness among street drug users. *Journal of Empirical Research on Human Research Ethics*, 5, 65-80. PMID: 20569151, PMCID: PMC3133928

Funding: National Institute on Drug Abuse (NIDA) (grant # RO1-DA015649)  
PIs C.B. Fisher & M. Singer



# GFE Research Questions

What are informational barriers to HVT consent among marginalized persons who use street drugs?

- Knowledge: HIV transmission, vaccines, research
- Research & medical trust/distrust

Can a brief lesson fitted to this population's needs correct misconceptions and increase HVT relevant knowledge?

Can a brief lesson reduce research mistrust?

# Procedures

- Piloting to determine participant misconceptions and informational needs
- Street recruitment
- Pretest, lesson and post-test conducted in community storefronts and read to participants
- Participants: N = 30; HIV-negative impoverished active drug users; 44% less than high school degree

# HIV Vaccine Research

- Researchers are testing whether new medications can prevent HIV
- These research studies are called **Experimental HIV Vaccine Studies** or HIV Vaccine Clinical Trials
- For each study, researchers do not know if the vaccine works until the study is over



# What is a Vaccine?

- A vaccine is a drug that prevents people from getting a disease, like hepatitis or polio.



There is **NO** vaccine for HIV

# Researchers test whether the new vaccine works by comparing its effects to a placebo

- Half the people who agree to participate receive the experimental vaccine

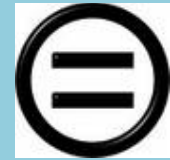


- Half receive a placebo (a sugar pill or an injection that does not contain any medicine)



# Randomization

- Everyone who volunteers has an equal chance of being in the experimental vaccine or placebo group.
- This is called randomization and it is like a coin toss. Neither volunteers nor researchers can choose which group people will be in.
- Neither the volunteer or the researchers know who is getting the vaccine or placebo until the study is over.



# Side Effects of the Vaccine

- Side effects from the experimental vaccine are usually short-term and mild such as arm soreness, fever, headache or tiredness.





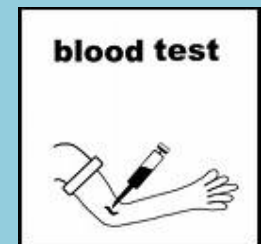
# Who Can Participate?

- Because the purpose of a experimental vaccine is to prevent people from getting HIV,
- Only people who are HIV negative can participate.
- Therefore, to qualify to be in the study everyone must take an HIV test.



# What Can I Expect if I Participate?

- Experimental vaccine studies usually last for 1 or 2 years and requires about 6 – 20 visits.
- Most visits require participants to take a blood test and visits last anywhere from 30 minutes to 3 hours.
- Participants are paid between \$50 - \$150 or more a visit depending on how long the visit lasts.



# How Will Researchers Know Whether the Vaccine Works?

Blood tests will tell whether people getting the vaccine build up antibodies that can fight the HIV virus



At the end of the study researchers will see whether people who received the vaccine were less likely to get HIV than those who received the placebo.



# The Vaccine DOES NOT Contain the HIV Virus

- The vaccine is made from artificial material and does not contain the HIV virus. The vaccine is designed to make the body build up its own defenses against the HIV virus.



YOU CANNOT GET HIV FROM THE VACCINE

YOU CANNOT TRANSMIT HIV TO OTHERS IF  
YOU TAKE THE VACCINE



# False Positive HIV Tests

- Since one way doctors usually diagnosis HIV is to test the body defenses to the virus, people who participate in an HIV vaccine study may test positive for HIV even though they do not have HIV
- Researchers will use special tests during the study that will provide correct test results.



# Participation is Voluntary & Confidential

- Participation in these studies is always voluntary and all the facts about the study are explained to each person before they are asked if they want to participate.



- All information is given the same confidentiality protection as other medical records



# Results: Lesson Significantly Decreased Research & Vaccine Misconceptions

True-False Question	Pre-Post
Participants will know whether they are given vaccine or placebo	63% → 13%
Trial Doctor will know if I was given vaccine or placebo	93% → 27%
Individuals with HIV can participate in an HVT	60% → 13%
The vaccine contains the HIV virus	33% → 10%
The vaccine will increase probably of transmitting HIV	43% → 3%



# Results: Lesson Less Effective in Reducing Distrust

True-False Questions	Pre-Post Test
Gov' t does NOT test the safety of a vaccine before giving it to participants	70% ➔ 57%
Scientist will NOT be honest about HVT risks	73% ➔ 53%
Vaccine studies sponsored by the gov' t will not report results honestly	81% ➔ 60%
Scientists use addicts as guinea pigs for vaccine for “better offs”	73% ➔ 73%

# GFE: Implications for RCR

- Without educational lessons this population may be unprepared for IC
- Pre-study lessons fitted to participant informational needs can significantly improve informed consent
- Enhanced understanding is not the same as believing in the honesty and good intentions of the investigators
- Research distrust is linked to participant and group histories of health disparities and research exploitation → low participation rates
- Investigators need to work with community groups to develop relationships and procedures that engender trust.



# ***Ethics & Social Justice in Sexual Health Research Involving Sexual and Gender Minority Youth***

**Fisher, C. B.**, Arbeit, M. Dumont, M., Macapagal, & Mustanski, B. (2016). Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Research on Human Research Ethics*. 11, 3-14. PMID [26956988](#) and PMCID [PMC4842126](#)

Funding: National Institute on Minority Health and Health Disparities (# 1 R01 MD009561) PIs C. B. Fisher & Brian Mustanski



National Institute  
on Minority Health  
and Health Disparities

# The Ethical Challenge

Fisher et al., 2016; Fisher & Mustanski, 2014; Mustanski & Fisher, 2016

- CDC recommends pre-exposure prophylaxis (PrEP) for high-risk populations to prevent HIV infection
- YMSM, bisexual women and transgender youth 13 - 24 comprise majority of new HIV diagnoses
- There are currently no evidenced-based PrEP prevention programs for SGMY under 18 years
- IRBs refuse to waive guardian permission for HIV prevention studies  
➔ low recruitment

# Waiver of Guardian Consent Permitted Under §45CFR46 Subpart D

- When minors have attained their state's defined legal age for consent to treatment or procedures involved in a research they are considered adults §46.401
- “When guardian permission is not a reasonable requirement to protect the subjects (e.g. neglected or abused children)” §46.408
- An appropriate substitute mechanism to protect the participant is provided

# Goodness of Fit

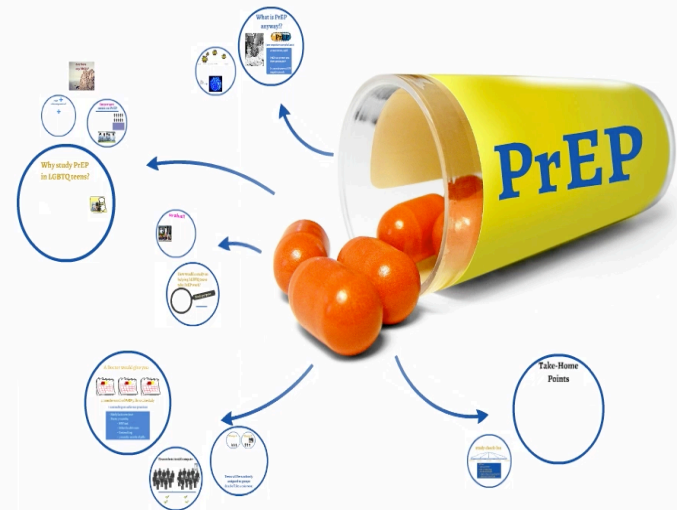
## Research Questions directed at Federal Regulations

- Is guardian permission a “reasonable protection” for SGMY participation in PrEP research?
- Is adolescent self-consent an adequate protection?

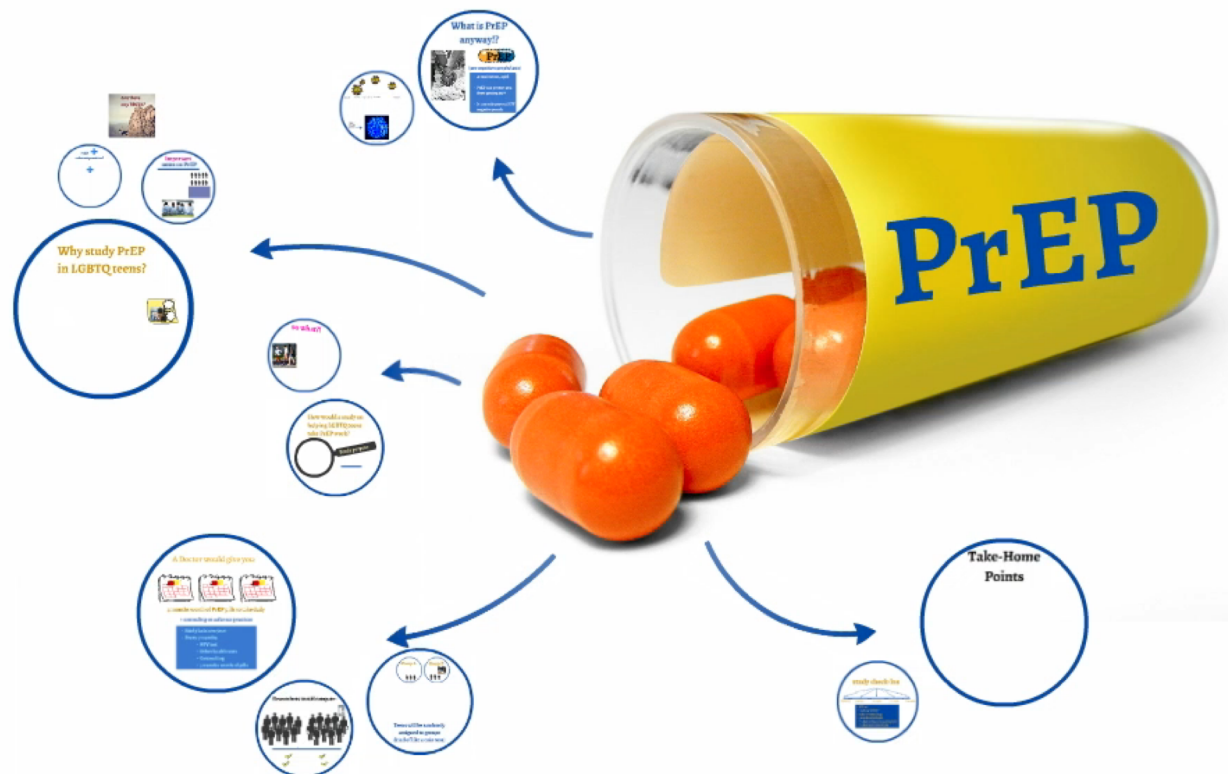
# Guardian Waiver & Youth Self-Consent

**Participants:** 74 sexually active 14 – 17 yr old SGMY

**Method:** viewed animated descriptions of a PrEP HIV prevention study and responded to online survey questions and asynchronous focus group discussions



# video





# Would you Participate in a PrEP Study if Guardian Permission is Required?

61% of youth not “out” and 21% who were out to parents would refuse to participate if GP required



*GP would “out me to parents”*

*“I’m out, but parents unsupportive”*

*“They would punish me or kick me out of house”*

*Parents would ask questions about sex*

# CAN SGMY MAKE A “REASONED” PARTICIPATION DECISION



# Understanding & Appreciation

## Understanding

- Study requirements (HIV testing, 3 month visits)
- Random assignment,
- Risks(not protected against STIs; bone risks, informational risks)
- Benefits (prevent HIV; counseling, free PrEP)

## Appreciation

- Outed if someone saw me taking pills
- I'm too forgetful to take pills
- I have other health conditions that might make me more susceptible to bone risk
- I am monogamous and use condoms

# Implications for Guardian Permission Waivers

- IRBs should first consider whether adolescents recruited for HIV prevention research are “children” under Subpart D
- If “children” there is sufficient empirical data suggesting that for a significant percentage of SGMY guardian permission is not a “reasonable protection”
- SGMY can make a reasoned consent decision when investigators take an age appropriate educative approach
- As IRBs seek to protect the rights and welfare of SGMY – we need to re-conceptualize access to HIV prevention trials as a critical health care right that requires protections against research exclusion.

# Why We are Here

- GFE is integral to good research design—it enhances participant participation, trust, and response validity
- There are no cookie cutter solutions to fitting research ethics practices and policies to all populations and all research designs.
- Participants, investigators, and IRBs may have different perspectives on the value, validity, risks and potential benefits of research.
- Empirical studies are an essential means of insuring the RCR is informed by these different perspectives.



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