

Fordham HIV & Drug Abuse Prevention Research Ethics Training Institute

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Empirical Assessment of Informed Consent, Voluntariness, and Social Harms in Research involving Individuals with Substance Use Disorders

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Introduction

- Informed consent is a key component in ethical research that seeks to ensure:
 - Understanding of rights and protections
 - Autonomous decisions regarding participation
- Research has demonstrated generally poor rates of comprehension and retention of consent information
- Particularly true with vulnerable populations such as substance abusers

Overview

- This presentation will:
 - Review the primary tenets of informed consent
 - Discuss ways in which the informed consent process could be compromised among individuals with substance use disorders (SUDs)
 - Discuss the potential for undetected social harms that may be experienced by this vulnerable population
 - Provide practical evidence-based methods to address these issues

Basic Principles of Informed Consent

- Intelligent
 - Must be capable of understanding
- Knowing
 - Must be understood and retained
- Voluntary
 - Must be autonomous

Intelligence

- Refers to one's intrinsic capacity to understand, appreciate, and express a choice
- May be compromised in substance abusers due to a host of factors
 - Severe neurological effects of chronic drug use
- Primary strategy to address intelligence is the use of legal surrogates
- Largely immutable and not amenable to interventions

Knowingness

- Refers to one's accurate understanding and appreciation of the study and their involvement
- Individuals with SUDs may experience impaired attention, cognition, or recall as a result of:
 - Acute intoxication or withdrawal
 - Long term effects of drug use on the brain
 - Developmental and environmental factors
 - Limited education, poor nutrition, and comorbid health and mental health problems

Knowingness: Remedial Strategies

- Generally aim to overcome these cognitive limitations and simplify the cognitive task
- Structure of form
 - Reading level
 - Font size
 - Supplementary materials
- Quizzes with corrected feedback (alternatively called test/retest, teach back method)

Corrected Feedback

(Festinger, Dugosh, Croft, Arabia, & Marlowe, 2010)

- Administered a consent quiz at the time of consent and then monthly for three months
- Consent quiz evaluated understanding of
 - Study protocol and procedures
 - Risks and benefits of participation
 - Human subject protections
- Half of participants received corrected feedback on incorrect answers on the quiz
- Compared the consent quiz scores of those who did and did not receive corrected feedback over time

Client ID _____ Interviewer ID _____

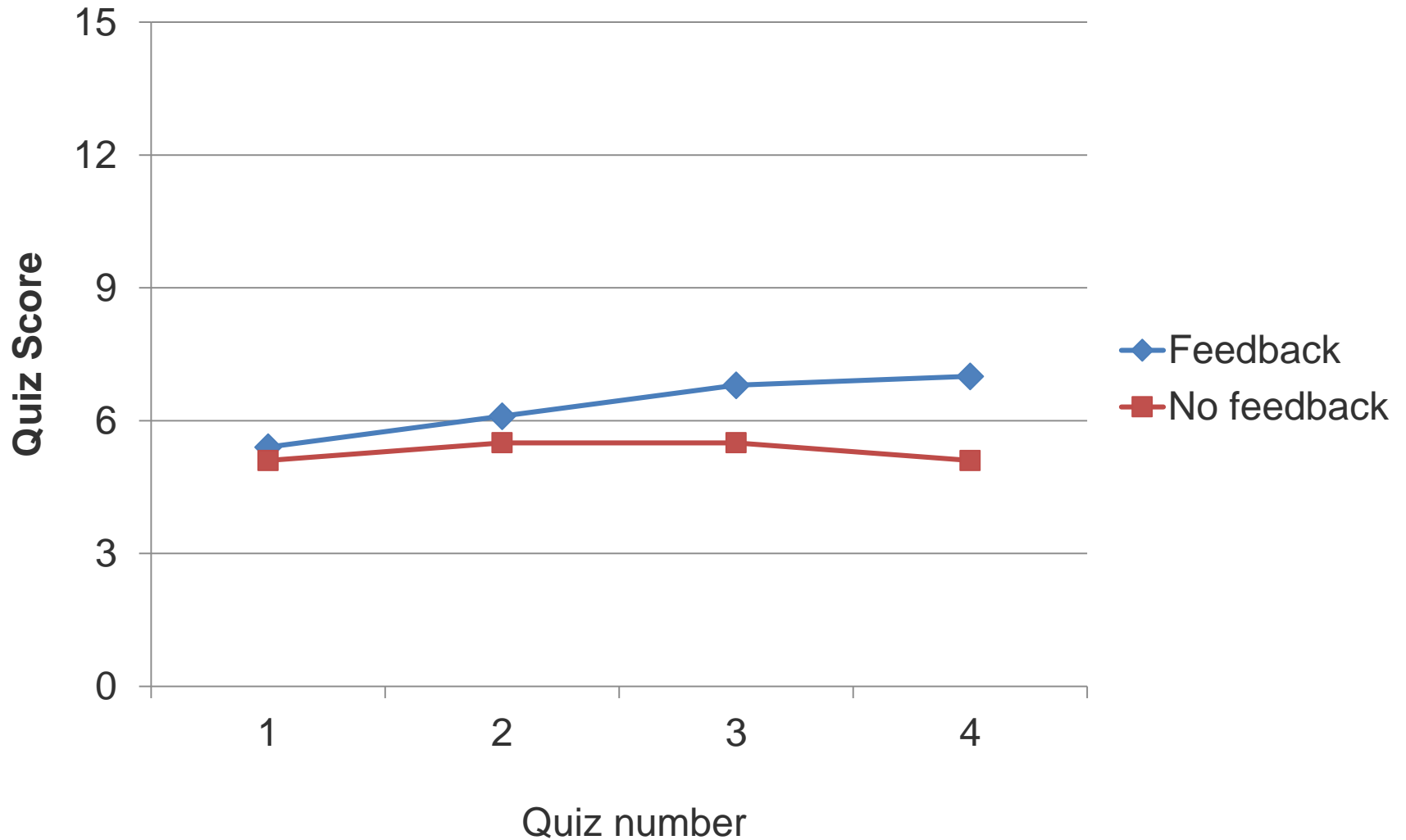
Date _____

Consent Quiz

Category	Question
Protocol/Procedures	1. What is the purpose of this study?
	2. How many study groups are there?
	3. How do the study groups differ?
	4. How did we decide what group you were assigned to?
	5. How many months will you be in the study last?
	6. When will you be asked to meet with us?
	7. What will you be asked to do during these meetings?
	8. How will you be compensated for each of these meetings?
	9. For what reasons could you be removed from the study?
Risks & Benefits	10. What good things or advantages may come from you being in this study?
	11. What risks or discomforts may you face by participating in this study?
	12. Under what circumstances may we disclose your information?
	13. Aside from TRI's research team, who has access to the information that you give as part of the study?
Human Subject Protections	14. Who should you ask if you have a question about this study?
	15. Who should you contact if you believe you have been harmed by the study or have questions about your safety or rights as a research participant?

Corrected Feedback

(Festinger, Dugosh, Croft, Arabia, & Marlowe 2010)



Knowingness: A Motivational Strategy

- Individuals may not be *interested* or *motivated* to learn the information provided during the consent process
- May result in decreased attention, understanding, and recall
- Examined the role of motivation through the use of incentives

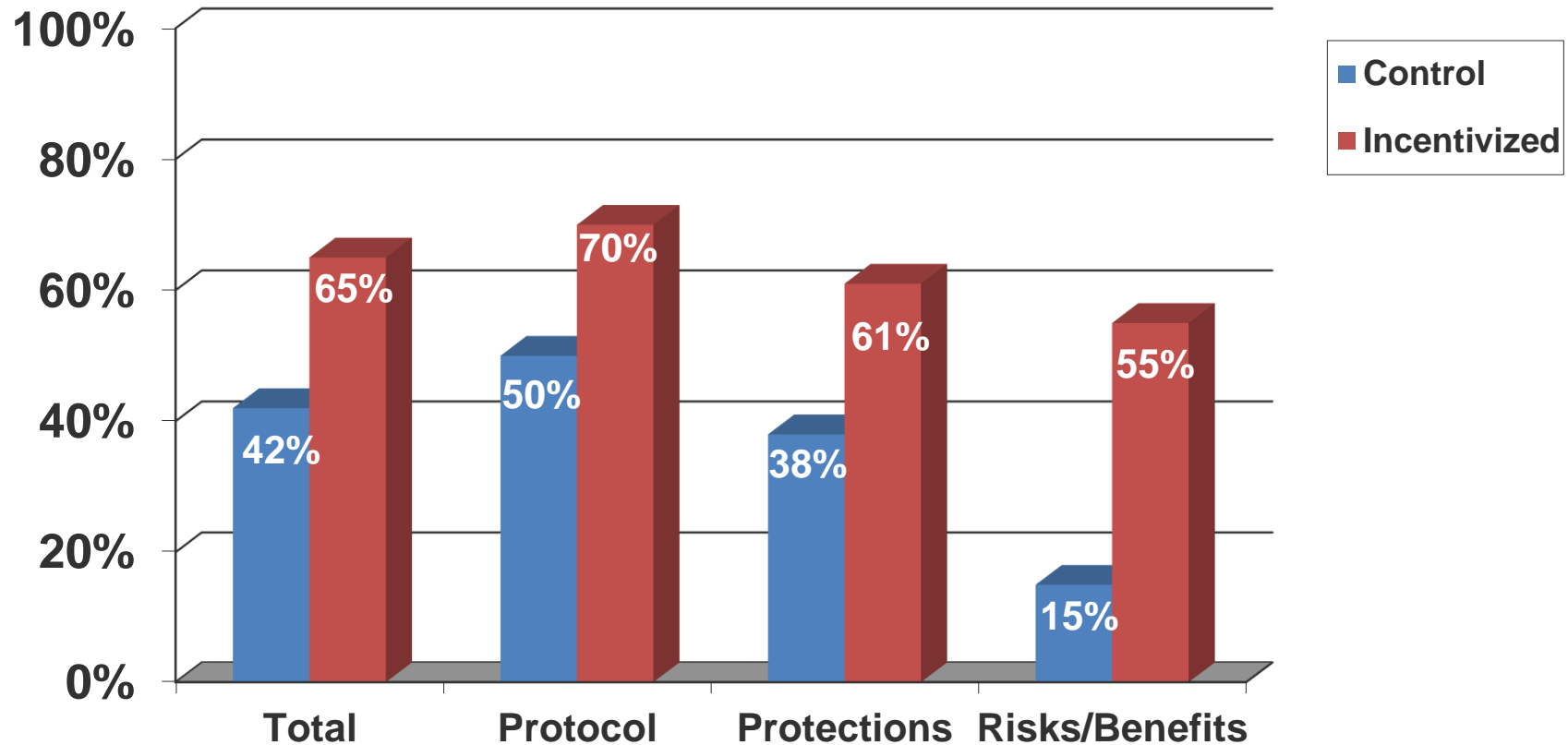
Incentivized Consent Procedure

(Festinger, Marlowe, Croft, Dugosh, et al. 2009)

- Participants completed a standard consent quiz
- Prior to initiating the consent process, all participants were informed that they would be completing a consent quiz
- Half of participants were also informed that they would receive \$5 for every correct answer they provided on the quiz
- Hypothesized that the monetary incentive would increase motivation to attend to and remember consent information

Incentivized Consent

(Festinger, Marlowe, Croft, Dugosh, et al. 2009)



Knowingness: A Combined Strategy

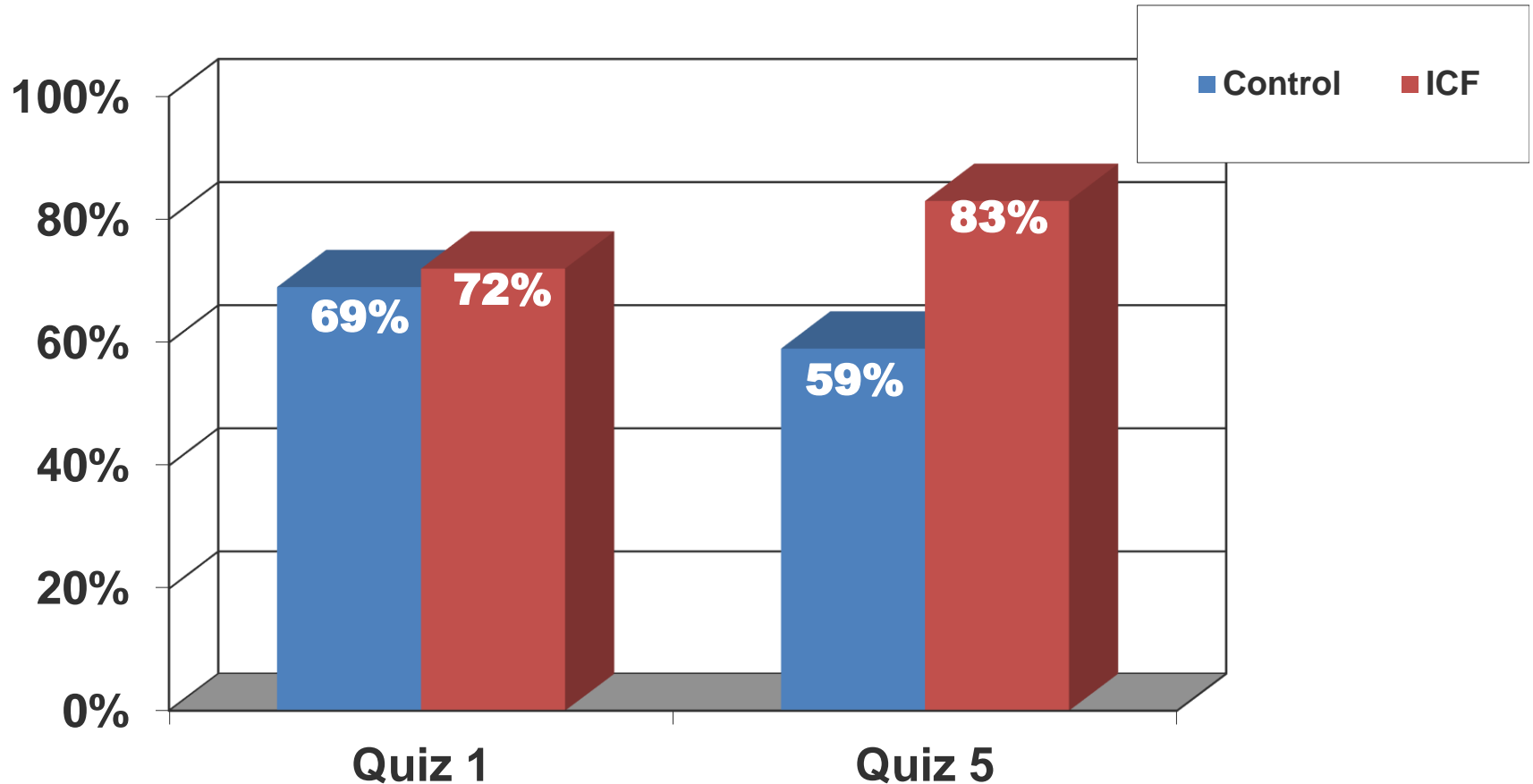
(Festinger, Dugosh, Marlowe, & Kirby, 2013)

- Evaluated the efficacy of a combined remedial and motivational procedure
- Participants received either:
 - Monthly consent quizzes with corrected feedback and incentives or
 - Monthly consent quizzes only (no corrected feedback, no incentives)
- Hypothesized that the incentivized corrected feedback procedure would improve understanding and recall of consent information over and above either intervention alone

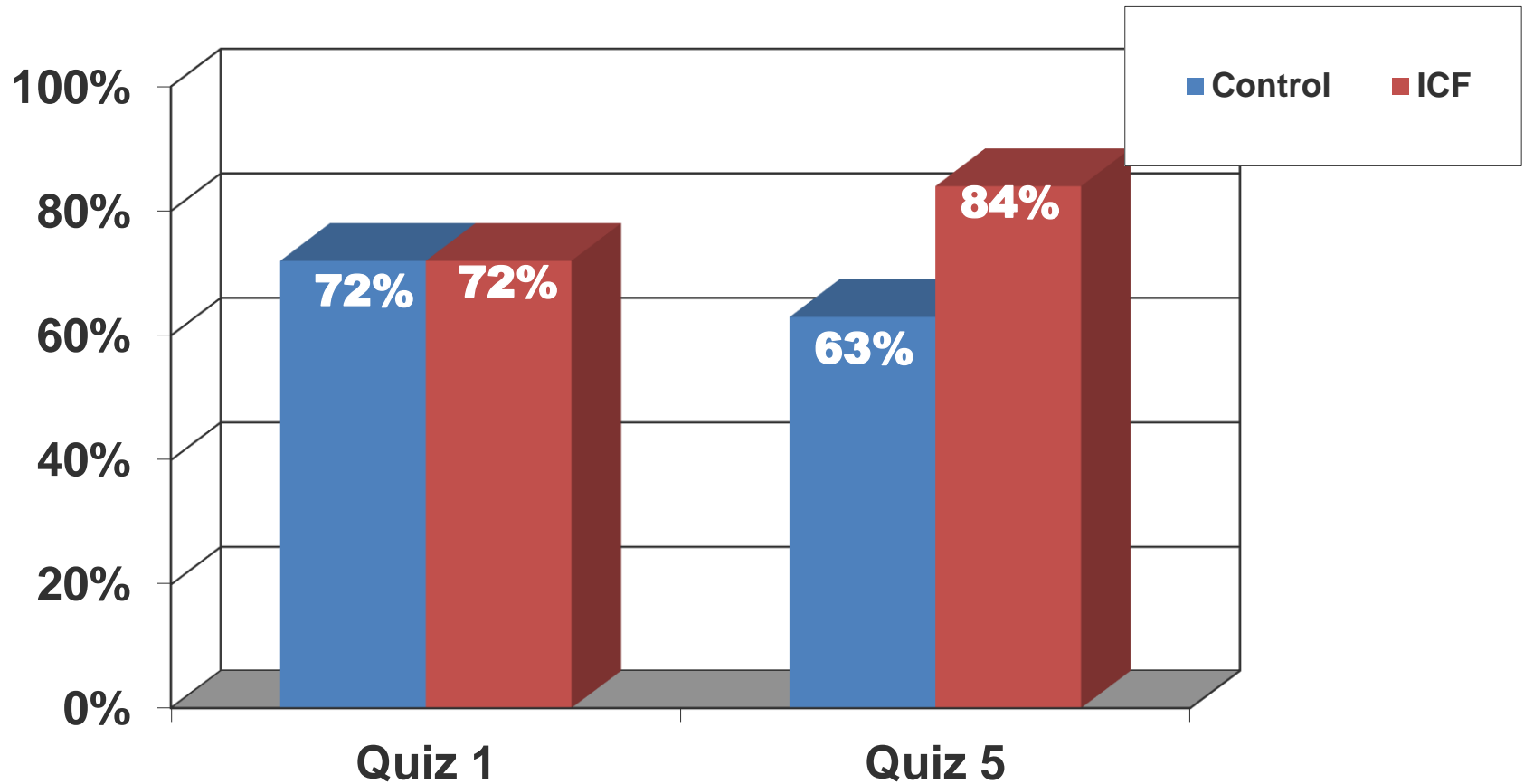
Incentivized Corrected Feedback

Total Score

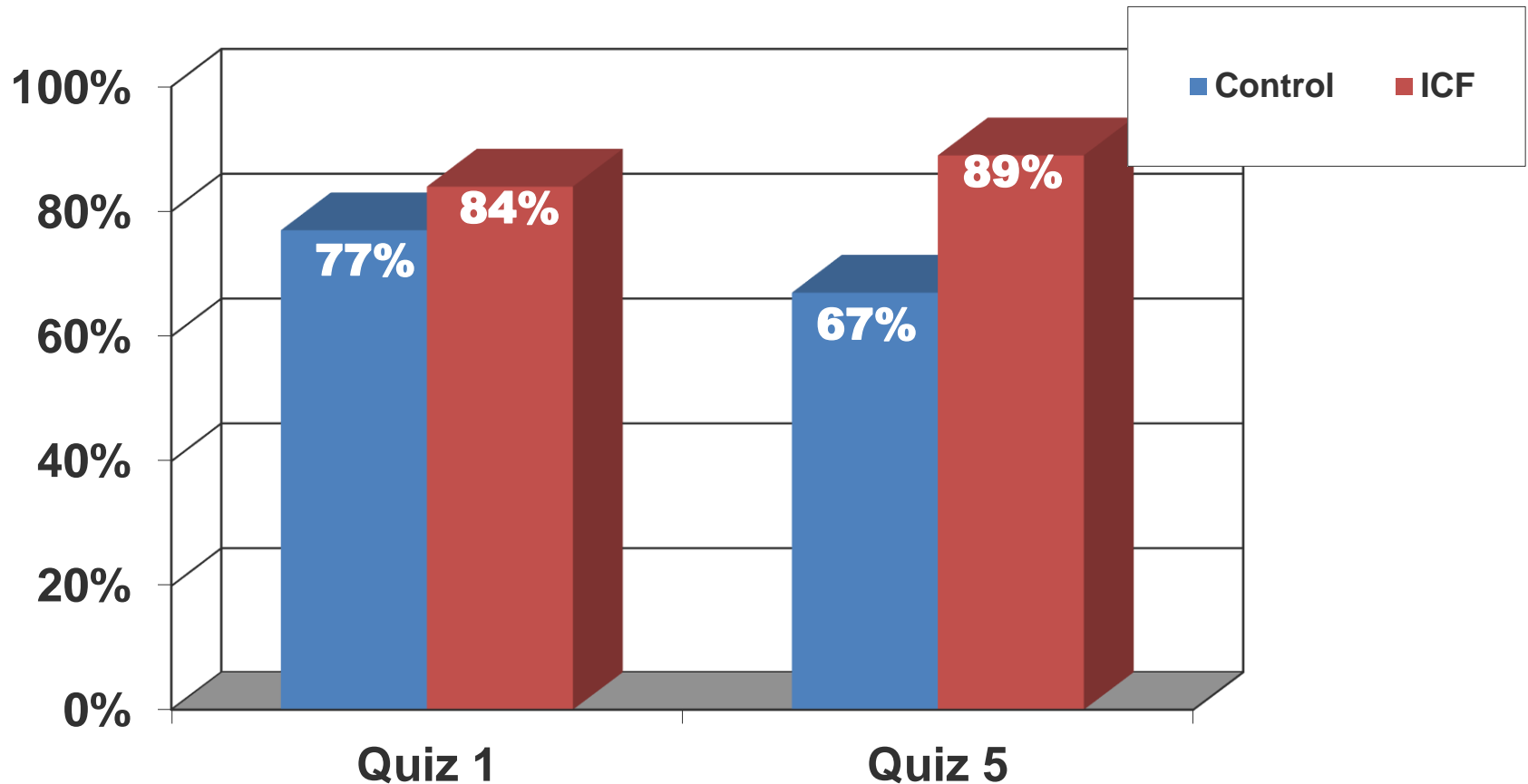
(Festinger, Dugosh, Marlowe, & Kirby, 2013)



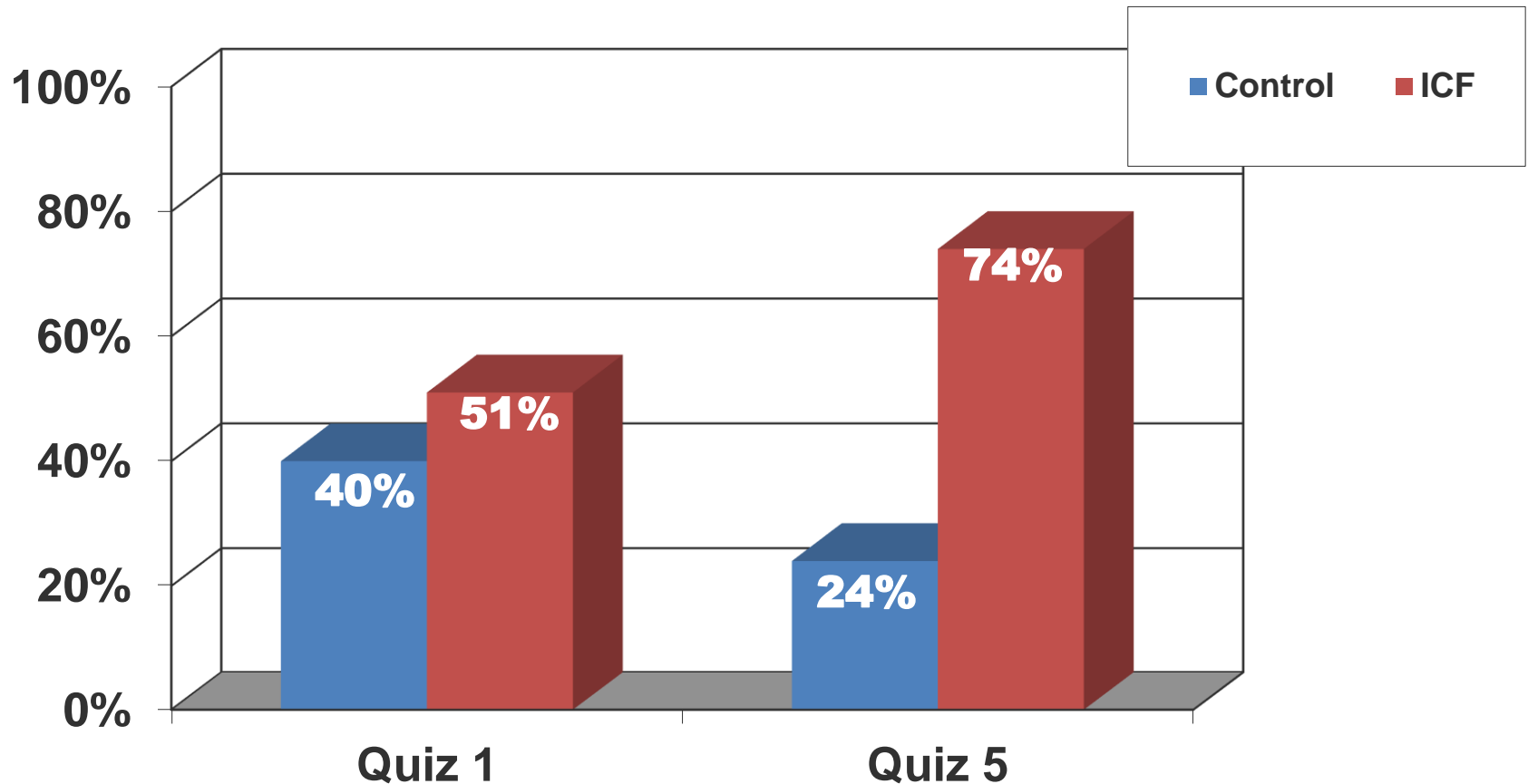
Incentivized Corrected Feedback Protocol



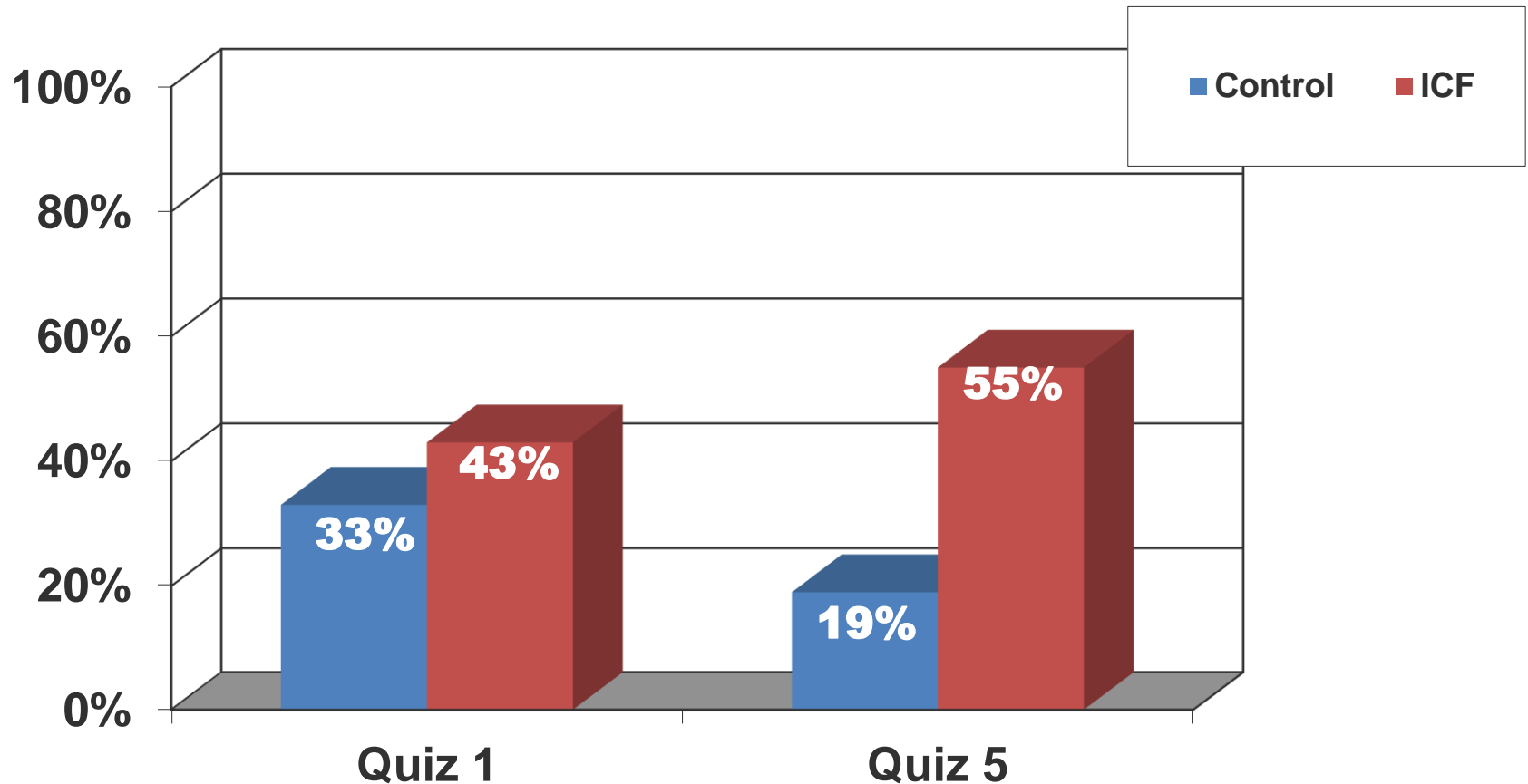
Incentivized Corrected Feedback Protections



Incentivized Corrected Feedback Risks



Incentivized Corrected Feedback Benefits



Summary

- Can improve knowingness among substance abusers who enter research studies
- Most effective strategies are likely to address both remedial and motivational issues

Voluntariness

- Participation free from coercion and undue influence
- Individuals with SUDs often have certain situational factors that may interfere with their ability to make autonomous decisions
 - Often recruited from settings that are implicitly coercive (e.g., inpatient units, detoxification facilities, prisons)
 - May perceive correctly or incorrectly, that cooperation is essential for their well being

Strategy: Assessment

- Measure perceptions of coercive pressures
- By identifying real or perceived sources of coercion, researchers can:
 - Correct misperceptions
 - Address real and existing issues
 - More accurately assess eligibility for research participation
- Could be built into existing consent quizzes and procedures

Coercion Assessment Scale (CAS)

(Dugosh, Festinger, et al., 2010, 2014)

- Brief 13-item measure of coercive pressures that criminal justice-involved substance users may experience when asked to participate in research
- Can be used to identify individuals who may need enhanced consent procedures or who may not be suitable for research participation as their autonomy may be compromised by real or perceived pressures

Coercion Assessment Scale

(Dugosh, Festinger, Marlowe & Clements, 2014)

	1 Not at all	2 A little	3 More than a little	4 A lot
I felt like I was talked into entering the study.				
It was entirely my choice to enter the study.				
I thought it would look bad to my case manager if I did not enter the study.				
I felt the judge would like it if I entered the study.				
I entered the study even though I did not want to.				
I felt that I could not say no to entering the study.				
I felt that entering the study would help my criminal case.				
I felt that my probation officer would like it if I entered the study.				
I thought it would look bad to my counselor if I did not enter the study.				
I felt that I could not say no to being in the study because of the money.				
I entered the study because I thought it would please my attorney.				
It would have created problems between me and my family if I chose not to participate.				
It would have created problems between me and other people (i.e. peers) in the program/facility if I chose not to participate.				

Coercion Assessment Scale

(Dugosh, Festinger, Marlowe & Clements, 2014)

- Test-retest reliability (3-5 days)
 - Average exact agreement of 87%
- Convergent validity
 - Individuals who endorsed at least one item the Iowa Coercion Questionnaire (Moser, 2010), a more general measure of coercion, had higher CAS scores than those who did not ($p < .0001$)
- Discriminative validity
 - CAS scores were significantly related to Locus of Control (Rotter, 1969) with externals endorsing more items and internals endorsing fewer items ($p = .025$)

Strategy: Intermediary

- Research intermediaries can be used to interact with potential participants prior to providing informed consent
- Must be perceived as independent from research, treatment, and other involved agencies
- Research supports the utility of intermediaries in reducing perceived coercion among criminal justice-involved individuals with SUDs who are recruited for research

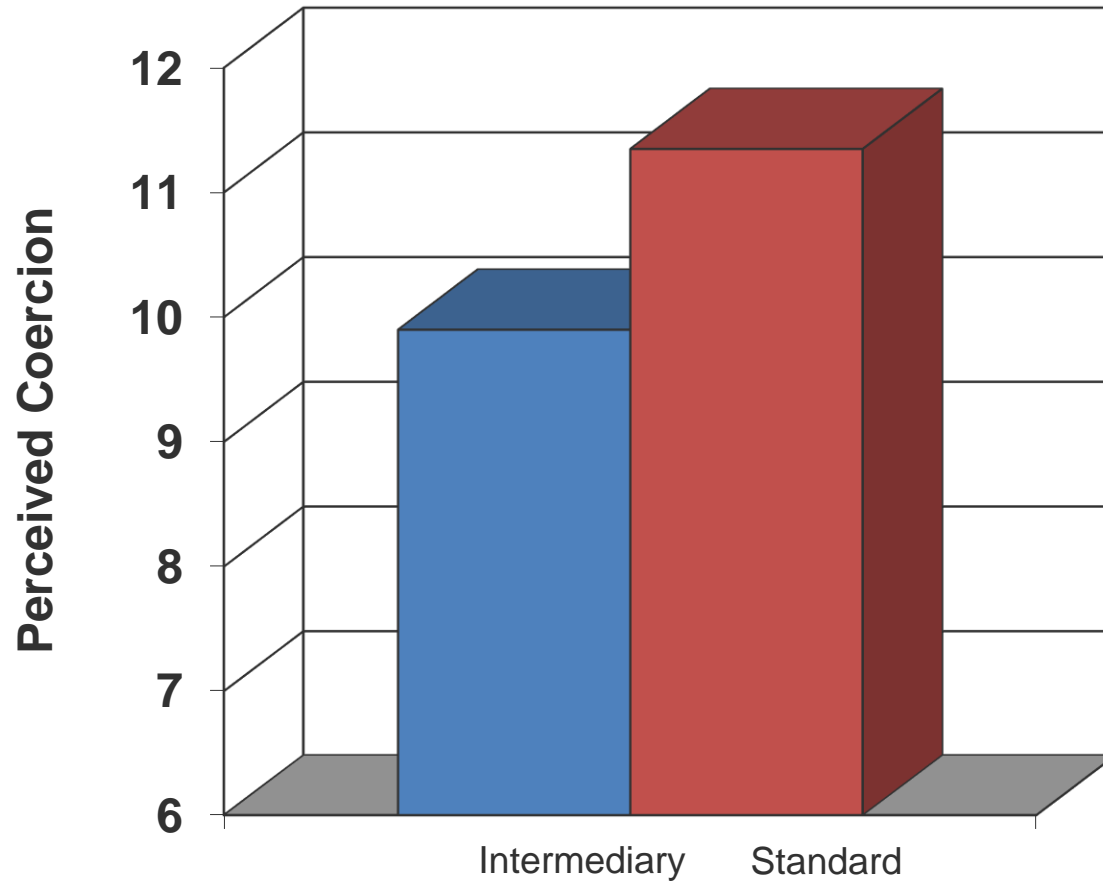
Research Intermediary

(Festinger, Dugosh, Croft, Arabia, & Marlowe, 2011)

- Evaluated the efficacy of including a research intermediary in reducing perceptions of coercion
- PsyD students from a local university who were not employed by the research team, treatment program, or court served as intermediaries
- Intermediaries were present during the consent process and met individually with potential participants to discuss any questions, issues, or concerns prior to providing written informed consent
- Provided their contact information so that participant could reach them if any issues arose
- Measured perceived coercion using the CAS

Research Intermediary

(Festinger, Dugosh, Croft, Arabia, & Marlowe, 2011)



Voluntariness and Payment

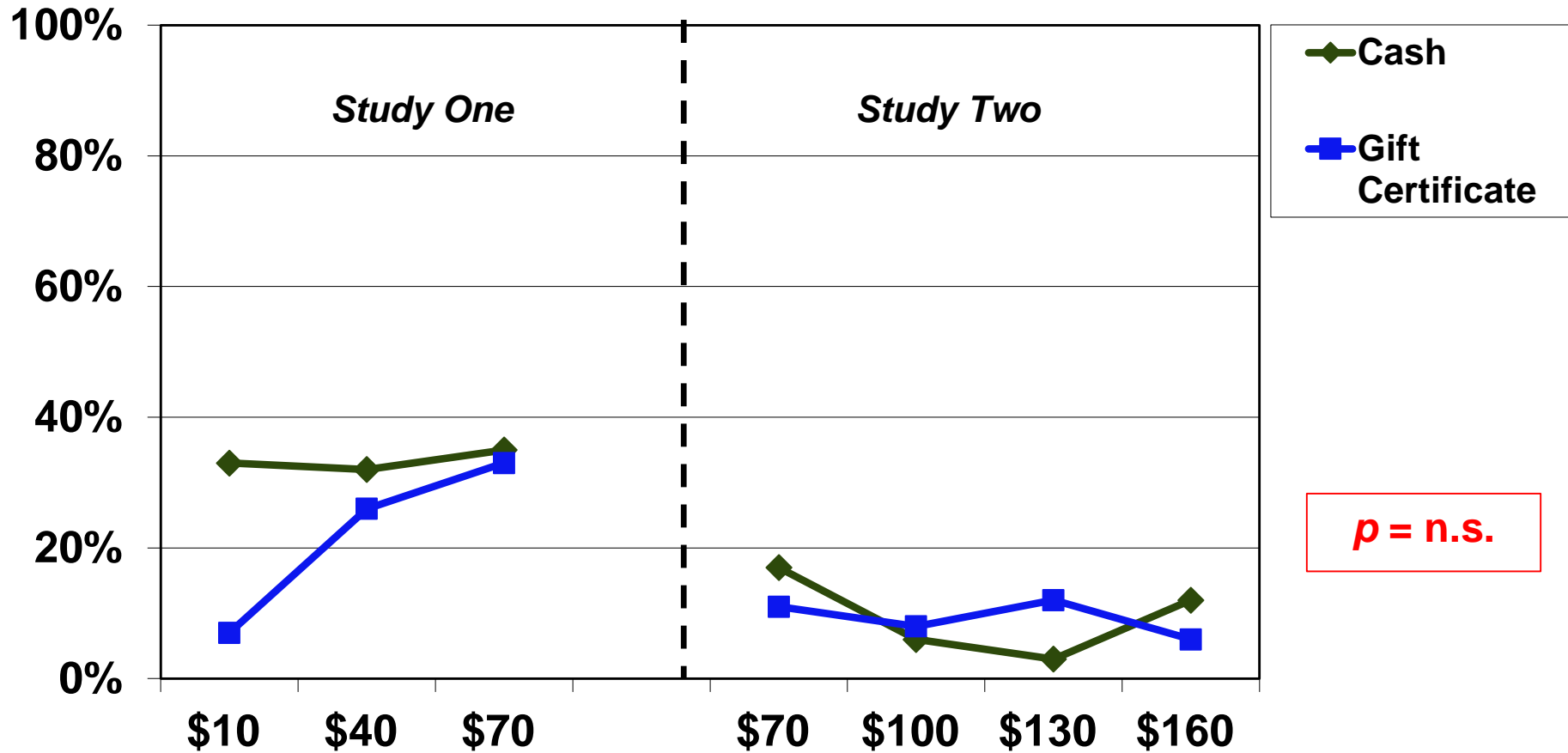
- Widely held belief that providing monetary incentives to individuals with SUDs is an undue influence
 - Lower SES, lower educational attainment
- Address this by providing gift card payments, non-monetary goods and services
- Research suggests that higher magnitude cash payments are *not* perceived as coercive and do *not* precipitate new drug use

Voluntariness and Payment

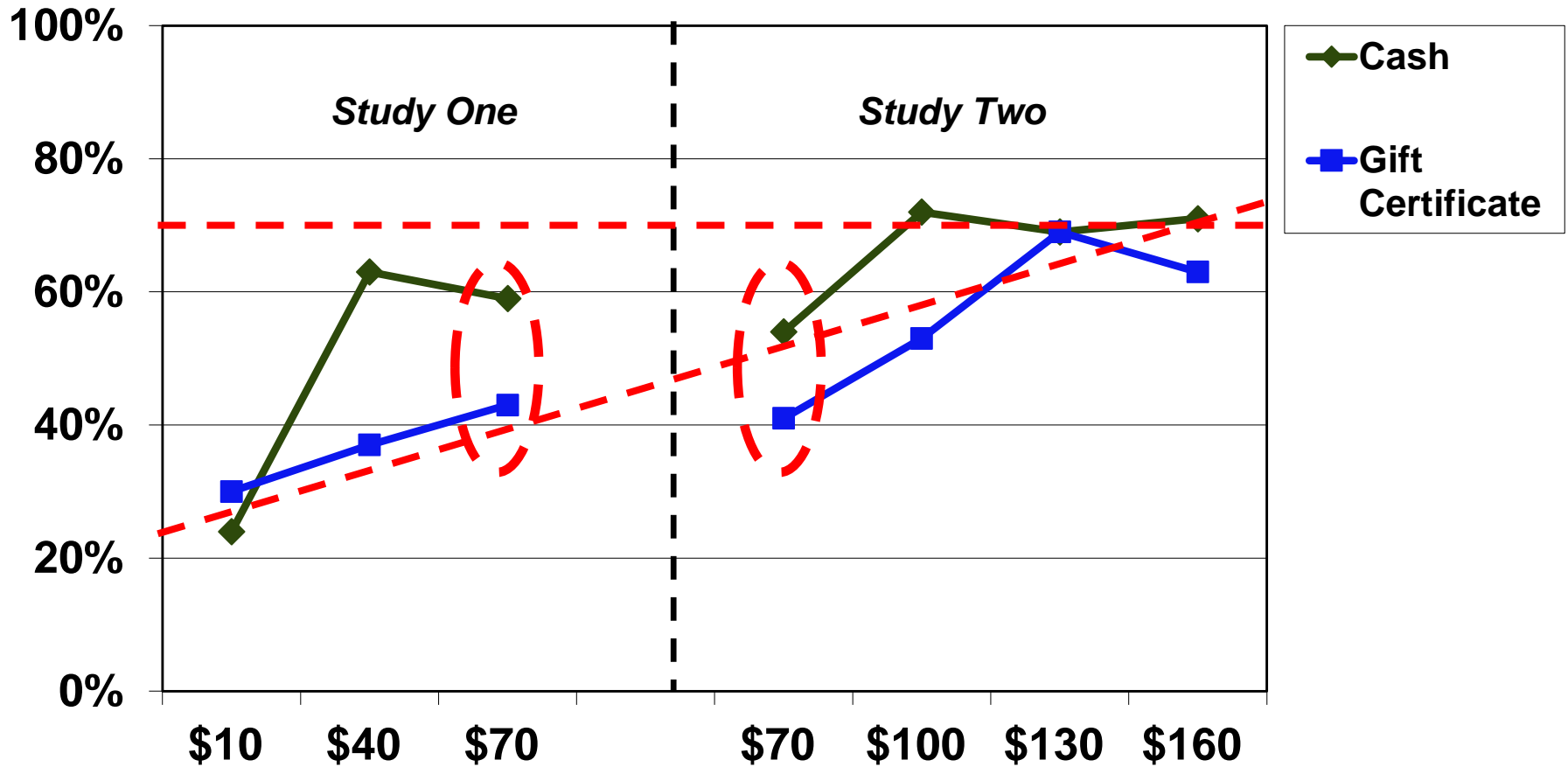
(Festinger, et al., 2005, 2008)

- Randomly assigned consenting SUD treatment clients to attend a 6-month follow-up appointment where they would receive one of several modes and magnitudes of payment
 - **Study 1:** \$10, \$40 or \$70 in cash or gift card
 - **Study 2:** \$70, \$100, \$130, and \$160 in cash or gift card
- At follow-up, participants provided a urine sample before receiving predetermined payment and were re-consented to return in 3 days for another interview and to provide a second urine sample

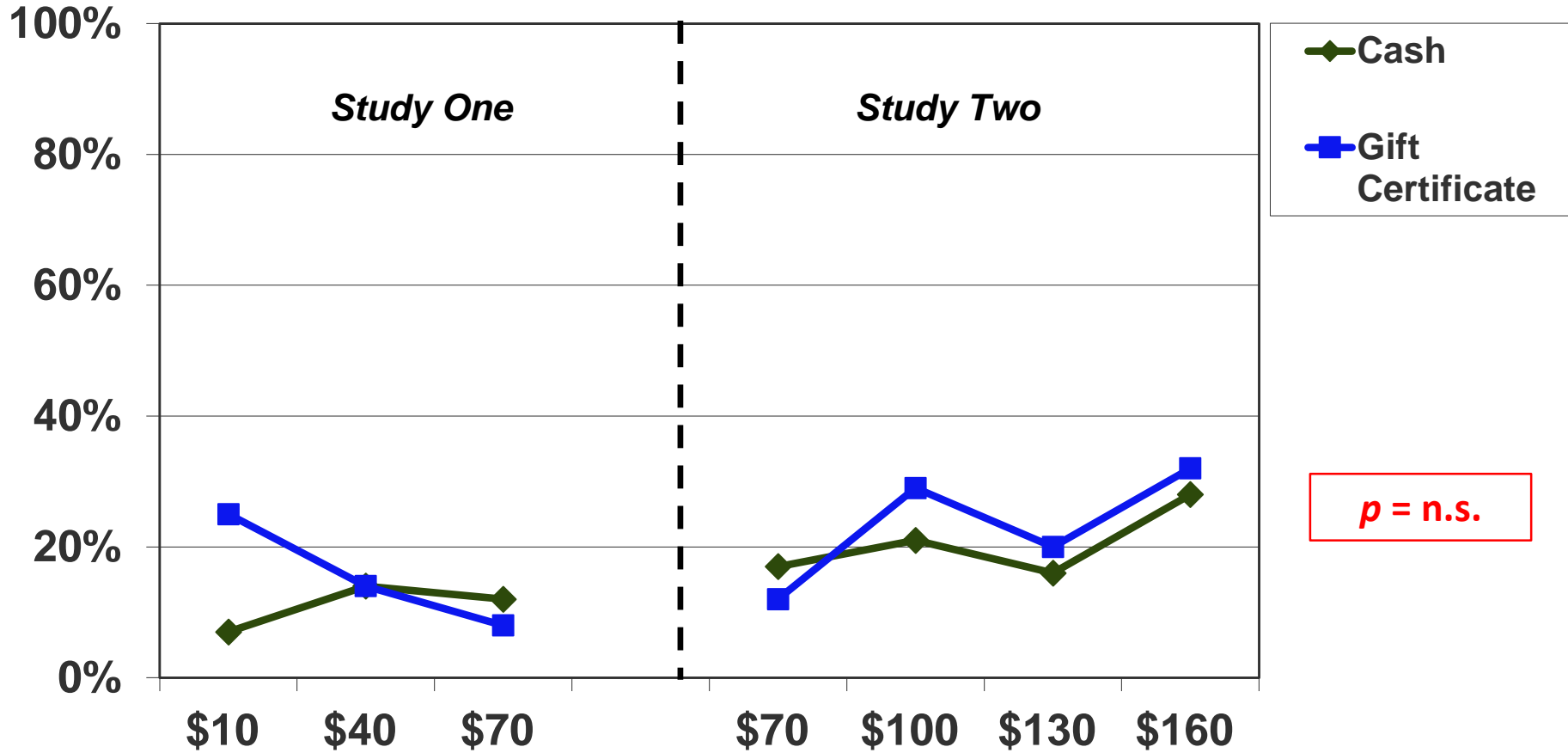
Perceived Coercion



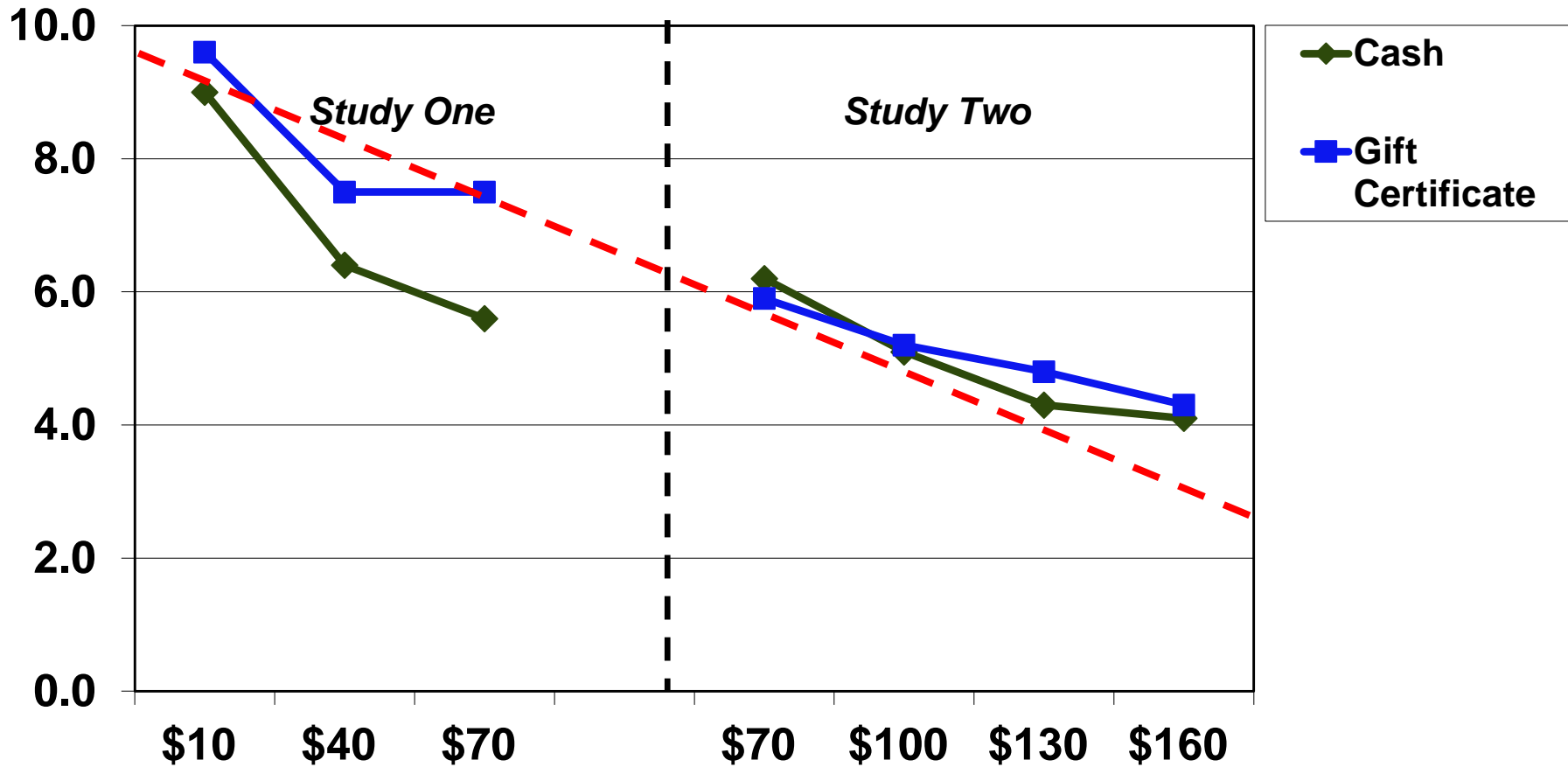
Follow-Up Rates



New Drug Use



Number of Tracking Calls



Identifying Social Harms

- Individuals with SUDs who participate in HIV-related trials often experience a greater risk of oppression, discrimination, and victimization.
- Many social harms are unforeseen and, consequently, are not systematically monitored.
- Few instruments exist to monitor the occurrence of negative social harms, and those that do (e.g., HIV Vaccine Trials Network Social Impact Assessment; SIA) lack item specificity.
- This project sought to develop a comprehensive, self-administered interview for researchers to more easily identify and monitor social harms that participants may experience throughout the research process.

Phase I: ACASI-SHQ Development

- Potential items were developed by
 - surveying researchers conducting HIV-related trials
 - holding a focus group with former HIV-related trial research participants who had SUDs
 - convening a multidisciplinary expert panel to guide item generation.
- Items were evaluated for clarity and intent by conducting a protocol analysis with 20 substance users participating in an HIV-related study.
- This iterative process resulted in a 12-item scale that measured
 - (1) whether or not the participant experienced the specific social harm
 - (2) the frequency with which the social harm was experienced
 - (3) the seriousness of the harm
 - (4) the way in which it was study-related.

ACASI-SHQ Items

Since we last met have you...

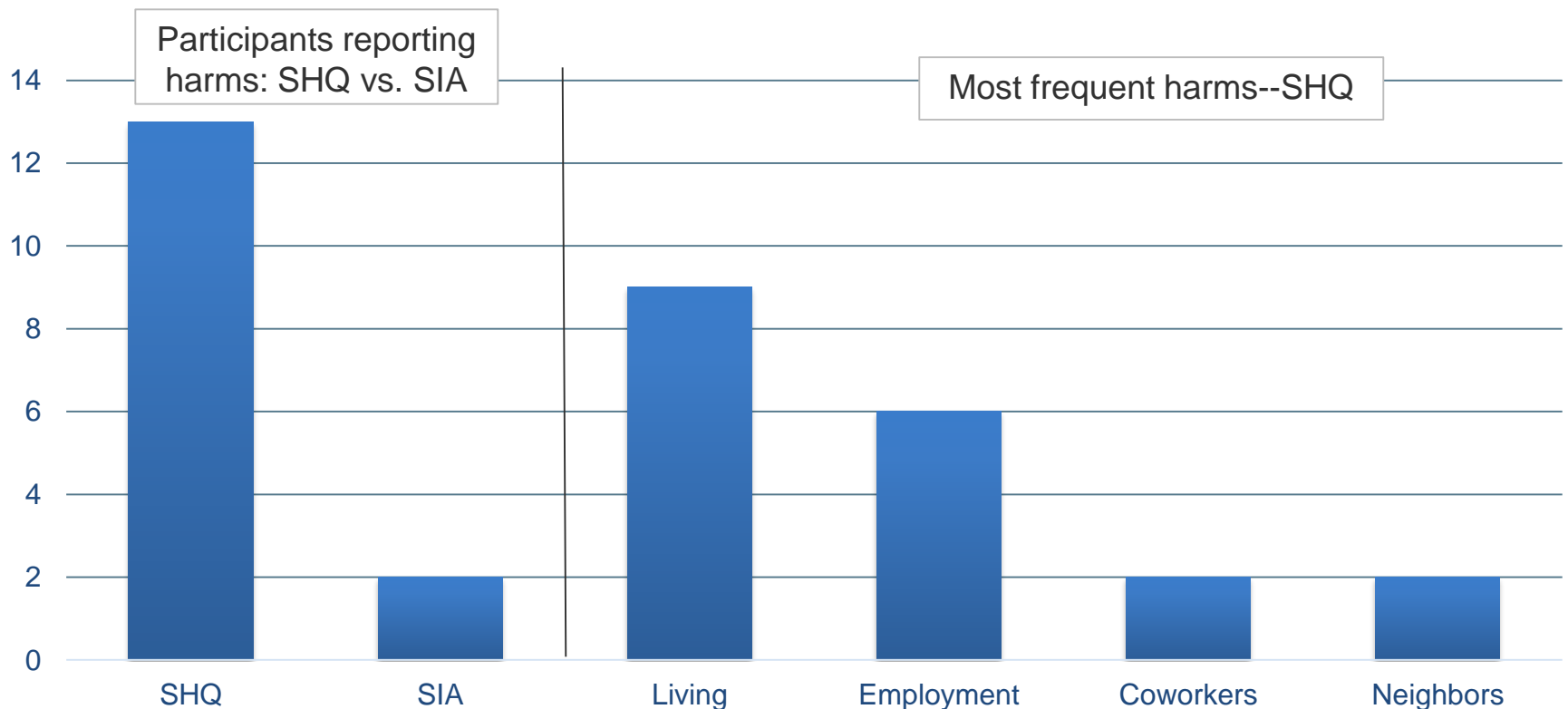
- (1) experienced any problems with having a place to live because you are in this study?
- (2) experienced any financial problems, like with your child support, welfare, or food stamps, because you are in this study?
- (3) experienced any problems getting a job or with your current job because you are in this study?
- (4) had problems with or lost your health insurance because you are in this study?
- (5) experienced problems getting medical treatment at a clinic, doctor's office, or hospital because you are in this study?
- (6) had any problems with the police, probation officers, or parole officers because you are in this study?
- (7) experienced other legal problems because you are in this study?
- (8) experienced problems with family or friends because you are in this study?
- (9) experienced problems with coworkers because you are in this study?
- (10) experienced problems with people in your neighborhood because you are in this study?
- (11) experienced problems with members of your church, synagogue, mosque, or other religious organization because you are in this study?
- (12) been attacked or victimized because you are in this study?

Phase II: Acceptability, Feasibility, and Utility of the ACASI-SHQ

- Participants were 79 individuals with SUDs participating in one of two HIV-related trials.
- Participants completed the ACASI-SHQ and HVTN SIA interview at months 1, 2, and 3 post-host study consent.
- The order in which the instruments were delivered was counterbalanced to control for carryover effects at each appointment.
- Survey data about perceptions of feasibility and acceptability of the SHQ were collected from study participants and the research team.

Results

- **Acceptability to participants:** Of the 64 clients that completed the satisfaction assessment, 92.2% (n = 59) found the ACASI-SHQ to be acceptable.
- **Acceptability to research staff:** Of the 4 members of the research team that completed the feasibility survey, no respondents indicated disagreement to the statement “the ACASI-SHQ was clear and easy to understand” nor “The ACASI-SHQ will improve client protections.”



Conclusions

- Substance abusers present unique challenges related to informed consent to research
- Research has provided useful strategies to help improve the consent process and the identification of social harms in studies with this population
- Future efforts should focus on further development of such novel strategies and ways to facilitate their broader use