Perceptions, Delivery, and Understanding of the Informed Consent Process Among Women Participating in a CBPR Study of Welfare Policy and Health

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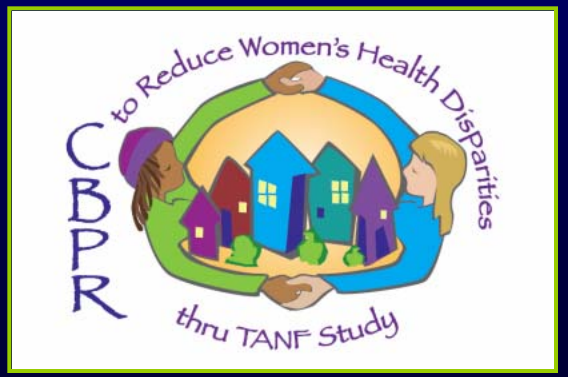

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Study Purpose

The purpose of this study was to better understand the following from a sample of low-income women that recently participated in a study using a "community-based participatory research" (CBPR) approach:

a) why they chose to enroll in the study,
b) what they recall from the informed consent process,
c) what they learned about research during participation in the study, and
d) what aspects of the focus group studies are most likely to engage them in future studies.

Study Sample/Context

- Women receiving TANF/public assistance benefits in Welfare Transition Program (WTP)
- Participated in focus groups for larger study
- Focus groups held on-site at WTP
- High potential for coercion / not understanding participation is voluntary
- Lack of trust in agents working on behalf of WTP

Study Sample/Design

- n=61 women who participated in 10 CBPR Focus Groups from Jan.2006 – May 2006
- Exempt IRB approval May 2006
- Mailed survey/questionnaire
- 1st Mailing: June 2006 (n=60)
- 2nd Mailing/Reminder: July 2006(with <75% response rate from 1st mail out)
- Questionnaire: Brief – 3 pages
- $5.00 Gift certificate included w/ 1st mail out

Response Rate

- n=29 responded w/ 1st mail out
  - 48% response rate
- Additional n=6 responded w/ 2nd reminder mail out
  - Additional 10% response rate
- Total of n=35 out of 60 responded
  - 58% of sample responded

Sample Demographics

Sample Demographics

Characteristic	%	Mean	SD	Min - Max
Age		31.8	8.3	19 – 52
Race				
AA/Black	57%			
White	40%			
Ethnicity				
Hispanic	21%			
# of Children		2.4	1.2	1 - 6

Sample Demographics (2)

Characteristic	%	Mean	SD	Min - Max
Education Level				
‹ 12th Grade	9%			
HS Dip/GED	57%			
Some College	31%			
Marital Status				
Single/Div/Wid	89%			
Married	11%			

Sample Representation

	Focus Grp Sample (61)		FG Views Sample (35)	
Characteristic	%	Mean	%	Mean
Race: AA/Black	69%		57%	
White	25%		40%	
Ethnicity: Hispanic	7%		21%	
Educ: <12th Grade	25%		9%	
HS Dip/GED	25%		57%	
Some Coll.	39%		31%	
Coll Degree	10%		3%	

Wilcoxen rank-sum of factors describing why participated in FG study = no significant differences by race except for: 'Way the RA talked to me.' White women ranked as more important than AA women (p=.047)

Informed Consent Process Questions

- Anecdotal observations in prior studies and CBPR focus groups suggested informed consent played small role in decision-making to participate in study.
- Unclear whether content of consent well understood.
- Absence of literature regarding preferences for, perceptions of, and/or understanding of consent by lower SES women who participate in research.

Questions About Informed Consent

Focused on:

- Knowledge/understanding/retention of IC content
- Weight in decision-making about whether to enroll
- Interest in/review of consent after participation
- Prior knowledge of past research participant abuses
- Trust in researchers to follow what was outlined in the consent
- Preferences for consent process.

Understanding of Informed Consent

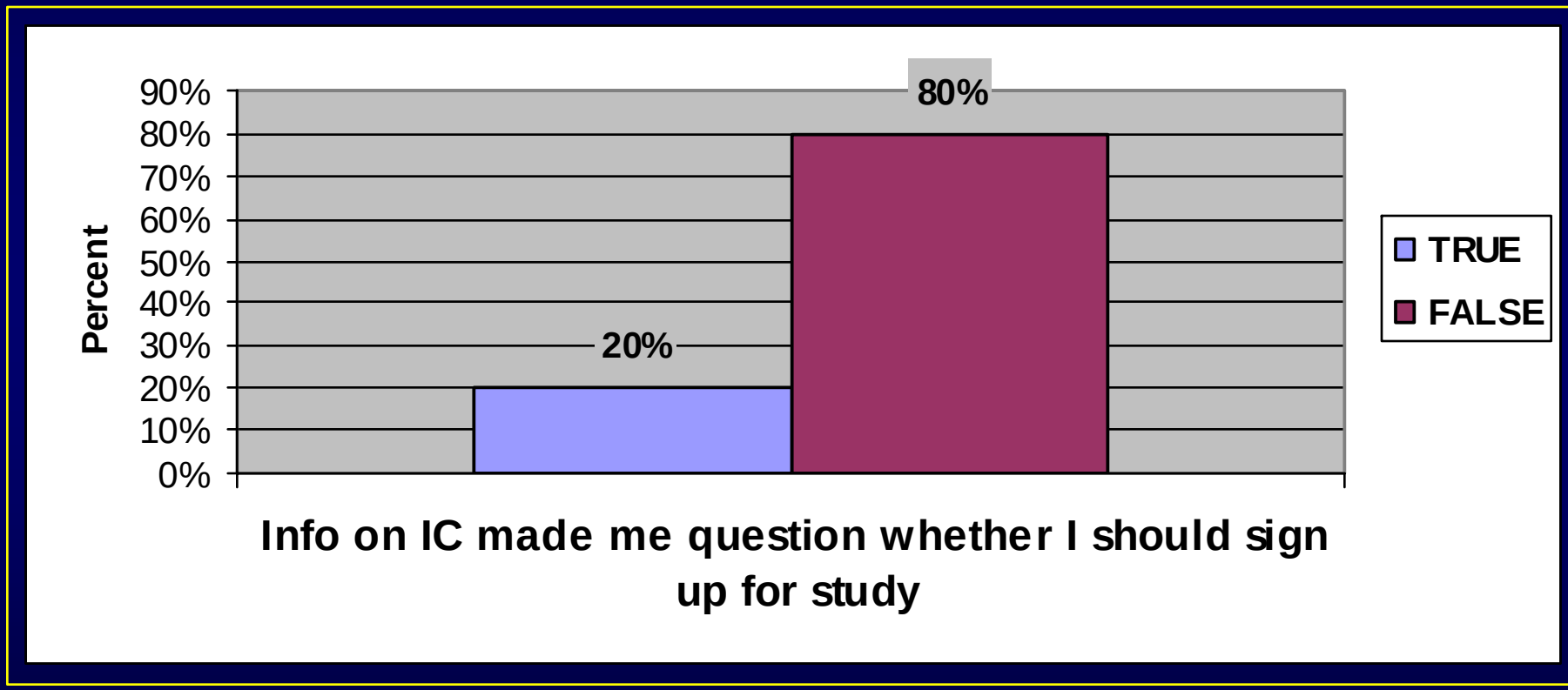
100% correctly selected "True" to the following:

a. The informed consent tells you about how the researchers will protect your confidentiality and personal information.

b. The informed consent stated being in the study was completely my choice, or voluntary.

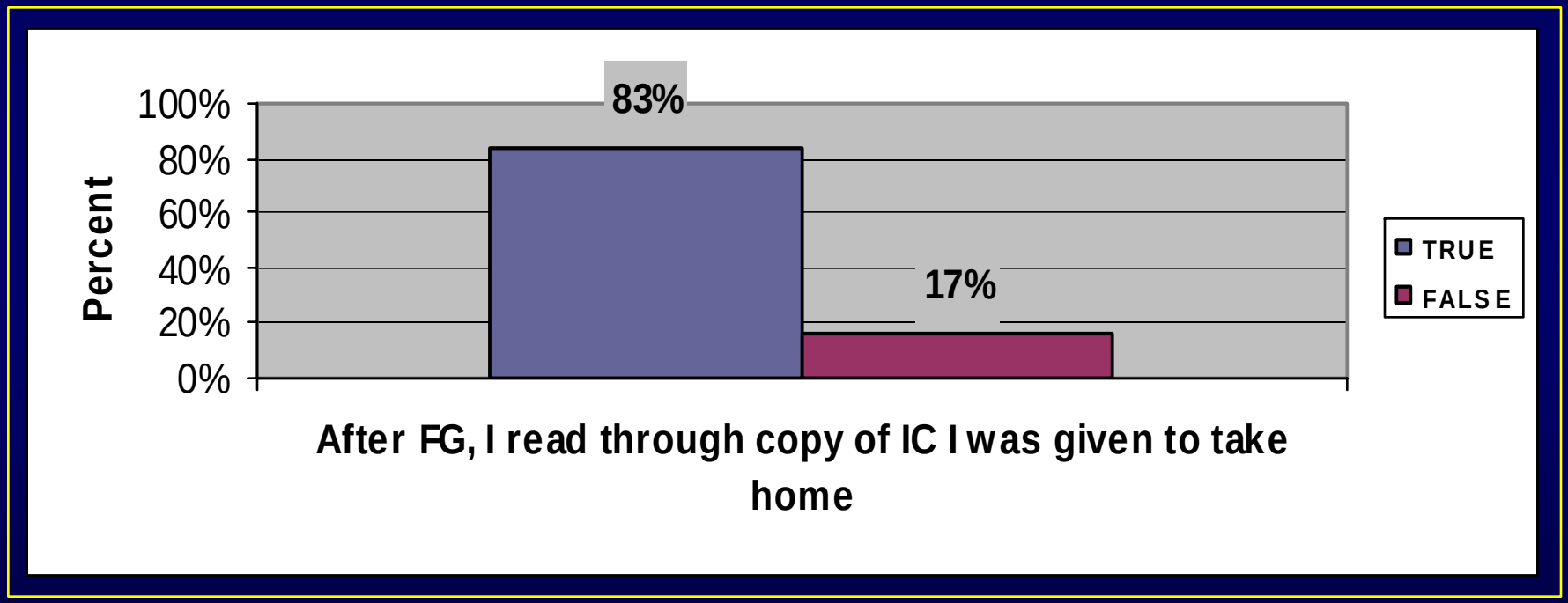
c. Being in the focus group was not part of the Welfare Transition Program.

Weight of Decision-Making About Whether to Enroll in Study

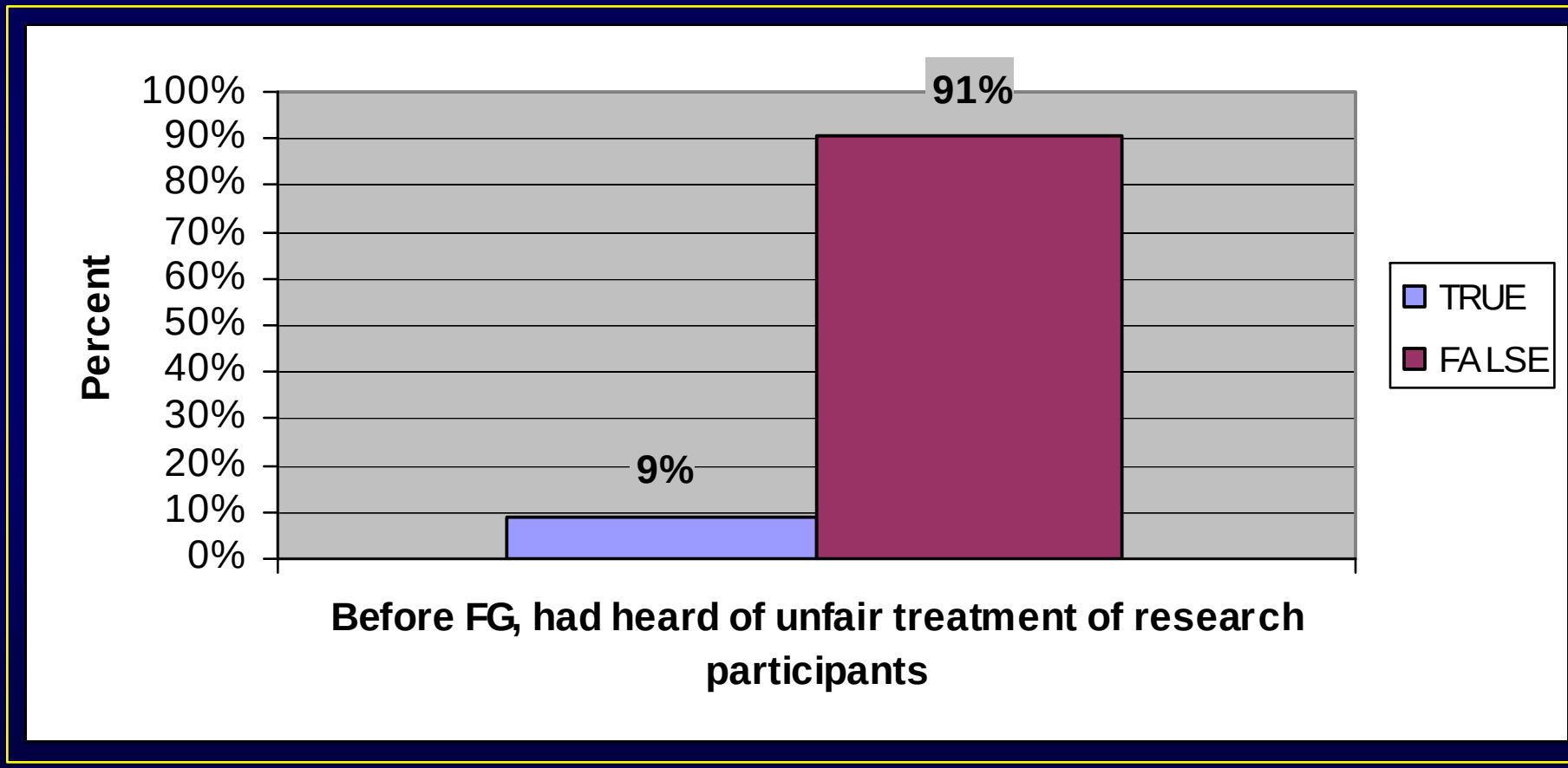


100% of women enrolled in the study following review of IC

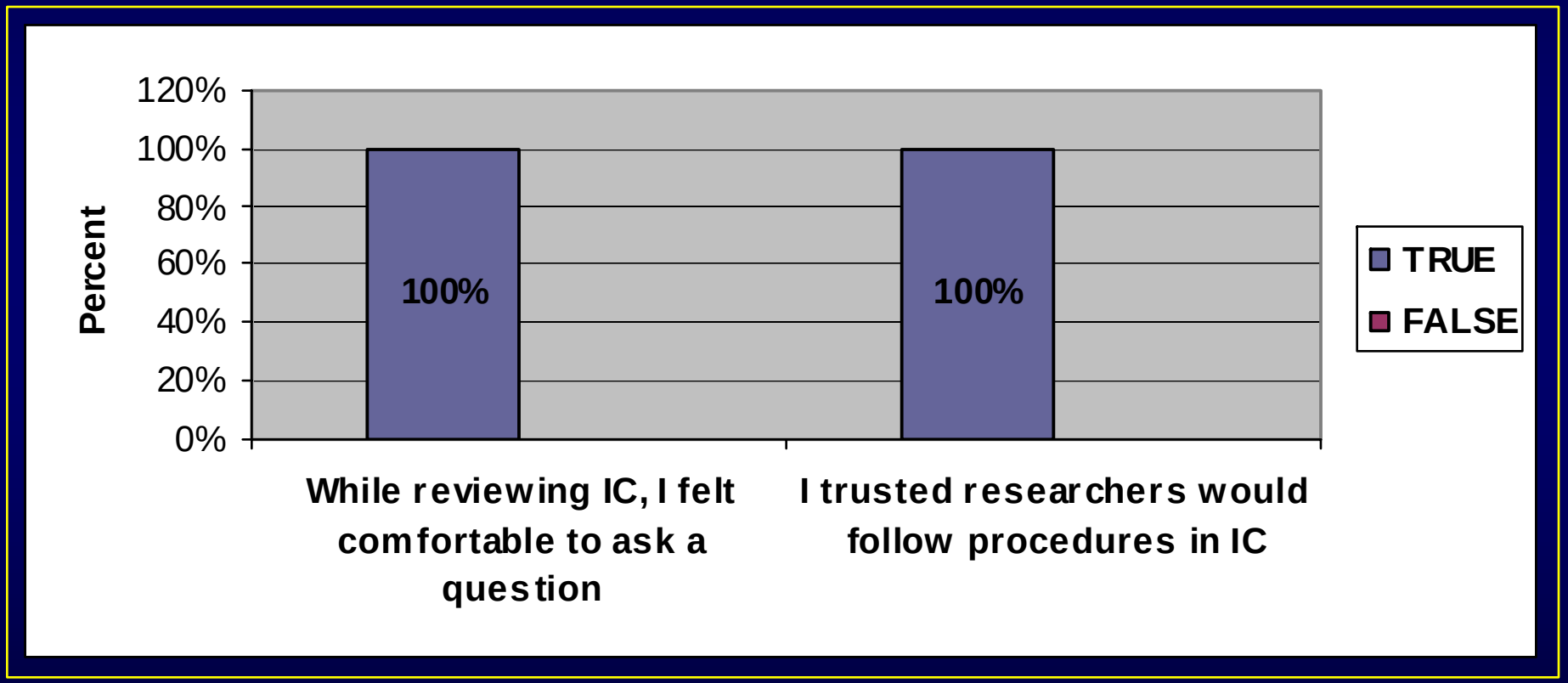
Review of Informed Consent After Focus Group Completed



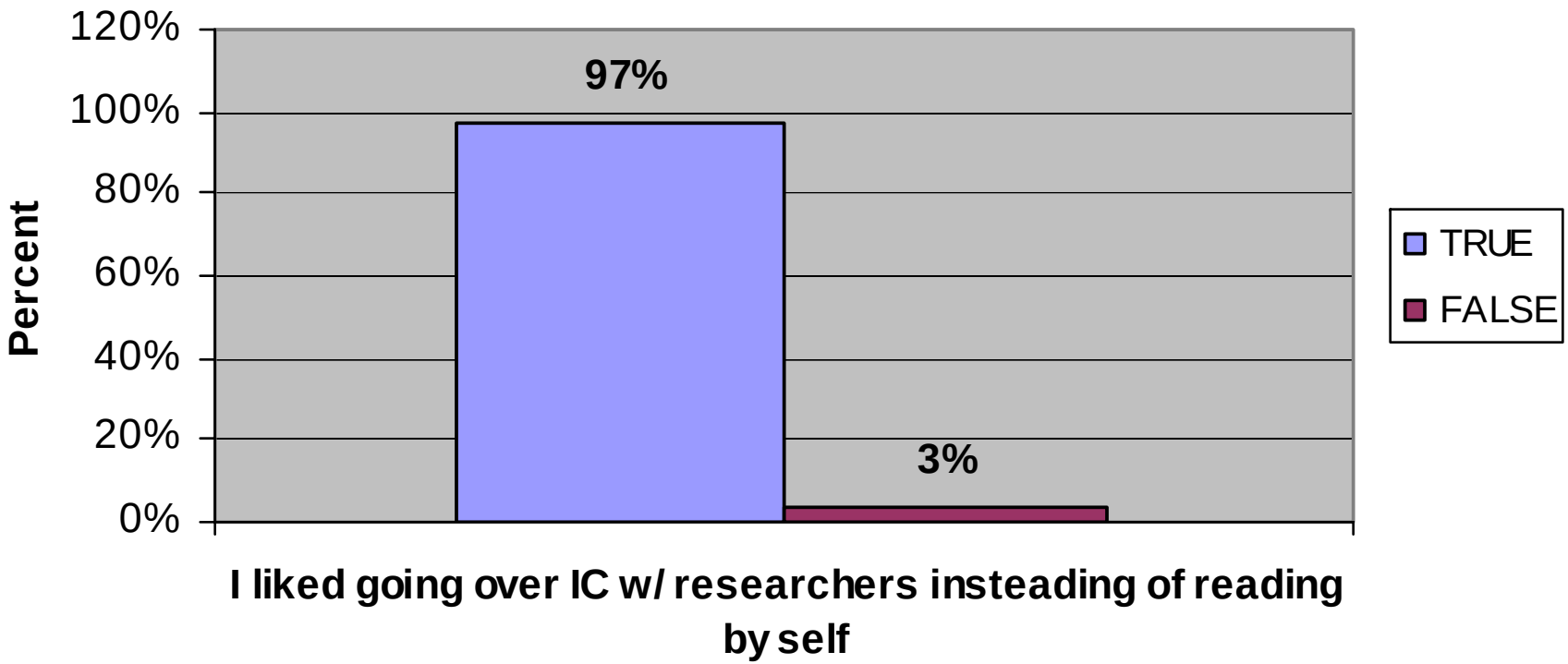
Prior Knowledge of Research Participant Abuses



Comfort With / Trust in Researchers Regarding Informed Consent



Preferences for Consent Process

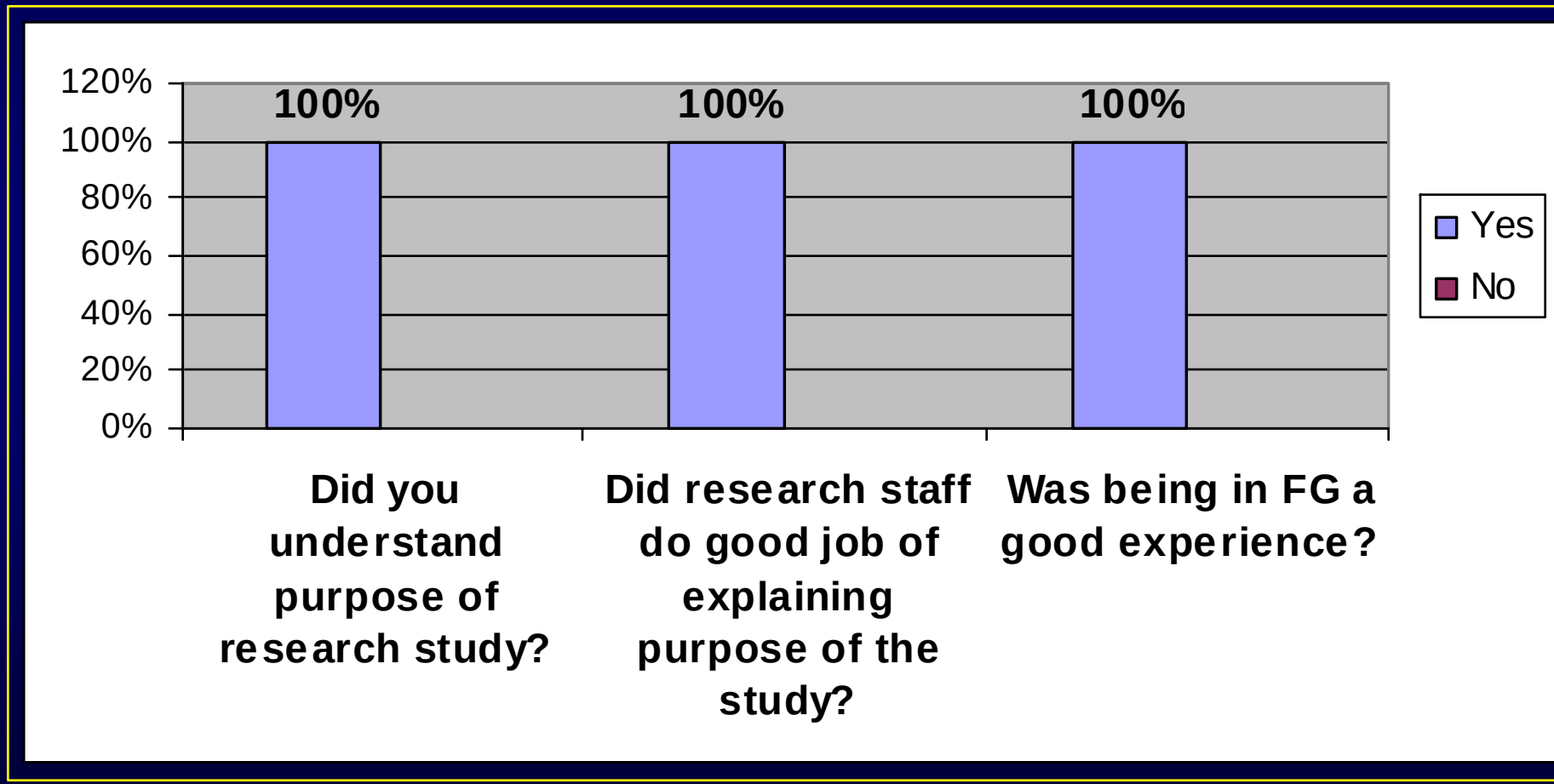


Open-Ended Questions & Narratives

"Please tell us what you learned *about research* by participating in our CBPR focus group study" . . .

- "I learned that research does deal with realistic concerns with everyday people such as myself."
- "That this is a good thing, research isn't at all that bad."
- "[It] takes a long time to study stuff-its better the way you did it. I hate it when people walking around on the street or a phone call to you to ask questions, you don't even want to talk to them, you all did it right."
- "Very long / too long . . . Very complicated."

Explaining/Understanding of FG Purpose, General Experience



Summary

- CBPR FGs were a good experience.
- Women understood informed consent purpose, trusted researchers, and demonstrated interest in consent by reading copy given to them at home.
- Most important reasons women participated related to identified need/problem, forum to communicate w/ other women in WTP, to help others, and nurse involvement.
- Narratives suggest understanding of study complexities, and positive perceptions of research participation.

Future Directions

- Consider similar set of questions for women who participate in the RCT portion of the study for comparison – FG design vs. RCT design.
- Consider submission for PA-06-368: *Research on Ethical Issues in Human Subjects Research.*

Appendices

Questions About Informed Consent

a. The informed consent tells you about how the researchers will protect your confidentiality and personal information.

b. The informed consent stated being in the study was completely my choice, or voluntary.

c. The information in the informed consent made me question whether I should actually sign up to be in the study.

d. While reviewing the informed consent with the study investigator, I felt comfortable enough to ask a question if I wanted to.

e. After the focus group, I read through the copy of the informed consent I was given to take home.

f. I liked going over the informed consent with the study investigator instead of having to read it all by myself.

g. I trusted the researchers would follow all of the procedures outlined in the informed consent.

h. Before participating in the focus group, I had previously heard about research participants being treated unfairly in the past.