

Ethical tensions in IRB review of community participatory research:

Who is being protected?

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Case Study: The PHAT Project

Protecting the Hood Against Tobacco
San Francisco Bayview Hunters Point Community project

Background

- ◆ African Americans disproportionately affected by tobacco-related diseases
- ◆ 55% AfAm residents in community believed health and illness beyond their control
(compared to 15% white residents)
- ◆ CBPR approach emphasizing empowerment

PHAT Community Research Partners

- Participated in all phases of research
- Identified community leaders and groups
- Conducted community survey on obstacles to cessation

Smoking cessation and single cigarette (“loosie”) sales

“Loosies” identified by community residents as a major obstacle to cessation

- ◆ Readily available
- ◆ Cheaper unit than pack
- ◆ No warnings

CRPs did not realize single cigarette sales are illegal

Community research: Prevalence of single cigarette sales

- CRPs mapped all convenience and liquor stores in community
- University Institutional Review Board (IRB) approved observational study
 - ◆ tobacco advertising density
 - ◆ smoking activity
 - ◆ store sales practices, including single cigarette sales

CRPs: “Observational study inadequate”

- Loitering discouraged



- Long waiting times impractical
- CRPs wanted 1 purchase attempt at each store
- Returned to IRB: modified protocol



Seeking IRB Approval

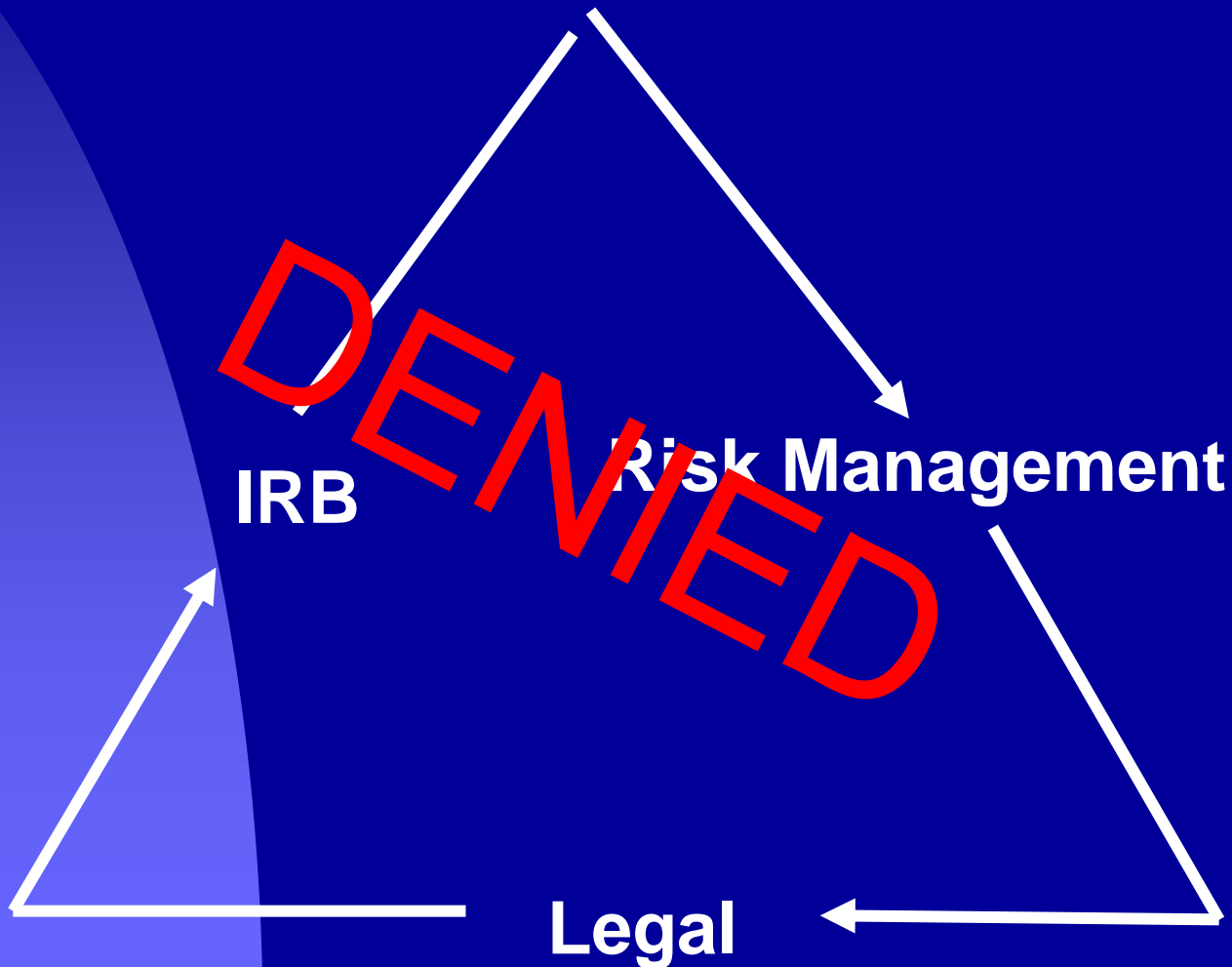
No individual store, sales clerk, or owner could be identified from data

- ◆ No identifying of individuals or stores by name in any report
- ◆ Report findings in aggregate only

IRB Refused Modification

- Did not understand CRPs were paid researchers on the team
- Soliciting CRPs *“to commit an illegal act”*
- Trying to buy single cigarette would constitute “entrapment” of store personnel

Appeal and Referrals



New Appeal to IRB with ...

- District attorney's signed grant of immunity
- California Penal Code:
Buying a single cigarette not illegal
- Written opinion from state attorney general:
Not "entrapment"
- Documentation from other studies using identical procedures
- Letter of support from state tobacco research program

We Also Argued...

- Important for the university to respect the community's knowledge and skills
- Unit of analysis was *store*: No data to be collected on *individuals* working in store

IRB's Final Decision?

NO!

IRB :

- Anticipated benefits of study did not justify the risk (though precise nature of risk never specified)
- PHAT should do different type of study

CRP response to IRB decision

- ◆ *CRPs experienced IRB rejection as betrayal: “protecting community predators”*
- ◆ *CRPS broke off from PHAT project to carry out study independently*
 - As interested citizens, needed no IRB approval*
- ◆ *Gained knowledge about single cigarette sales could not be published or reported as finding of the PHAT project*

Analysis

Biomedical ethics perspective:

- ◆ Focus on individuals as “subjects”
 - ★ Store personnel are research subjects who must provide consent
 - ★ Principle-based: non-maleficence
 - Unethical consequences of deception
 - Putting community members at risk

Analysis

Critical/communitarian ethics perspective:*

- ◆ Human beings viewed as social, not isolated individuals
- ◆ Social ecological perspective on risks/benefits
- ◆ “Problematizing” assumptions

Analysis

- Did the proposed study actually constitute human subjects research?
- What were the risks involved, and who was at risk ?
- Did institutional conflicts of interest influence decision-making?

Did the proposed study constitute human subjects research?

Human subjects are “individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project.”

(Department of Health and Human Services’ Institutional Review Guidebook)

- Our study was to assess *institutional practices* within a community – not the responses of individuals within those institutions

What were the risks involved, and who was at risk ?

Biomedical view: Risks for store clerks

- ◆ exposing illegal behavior
- ◆ psychological risk of feeling deceived
- ◆ being lured into acting illegally

Communitarian view: Risks for stores

- ◆ negligible risk for stores (given protections) compared to potential benefits to community from knowledge generated

Did institutional conflicts of interest influence decision-making?

- Hot potato referrals
- Protecting the *university* or the “*subjects*” ?
- Risk more inherent to lower income communities?

Conclusions

- IRBs are critically important for evaluating and managing risks in research
- Power dynamics are embedded in all ethical decision-making
- However, if CBPR encouraged, IRBs may need to expand ethical horizons
- Protecting institutional power vs. community empowerment