

Standard of Care: A Case Study



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You will soon begin implementation of a multi site, randomized controlled trial in your country to examine the effectiveness of a vaginal microbicide against acquisition of HIV infection in women. The trial is sponsored by the National Institutes of Health of the US government. The populations from whom participants will be recruited generally have poor access to health care services. They attend public family planning, maternity and STD clinics where care is provided free of charge except for medicines; prescriptions are written for drugs which women are often unable to afford. In the family planning clinic, Pap smears are not done because there is no national cervical cancer screening program, nor the equipment or personnel to do them. As part of your study, women will be routinely tested and treated for viral and bacterial STDs, they will get yearly Pap smears, and treatment will be provided free of charge for most abnormal conditions diagnosed. Such diagnosis and treatment are only available at considerable expense in the community, if at all.

As well, women who present with other problems unrelated to the study such as fever, diarrhea and malaria, can be seen by a study clinician and will be treated free of charge. Your site has provided such care in past trials on this informal basis, as a service to participants.

Despite a lengthy informed consent process explaining the risks and benefits of the study, you are concerned that women may be joining the study because they will get health services not otherwise available to them. Perhaps for them, the benefits of enhanced access to free care may so outweigh the risks of the trial, that an unfair inducement to participate in the trial could exist. In addition, your Community Advisory Board has told you that women in the community who are not eligible to join your studies have voiced frustration that they do not have access to the same services. There also is nothing in the study protocol which discusses continued access to this level of care when the trial is over.



Question: What is unfair inducement to participate in a research study?

NBAC Report (2001):

- undue inducement = “an excessive, unwarranted, inappropriate, or improper reward.”

However,

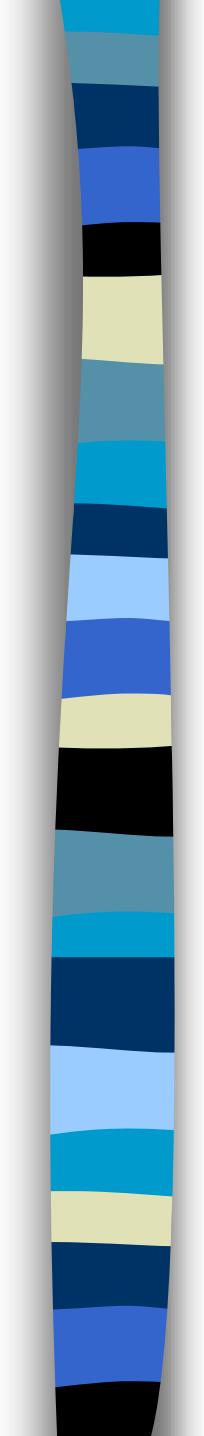
- “...it is reasonable to conclude that providing medical care to research participants is warranted, appropriate, and proper” (p. 47).



CIOMS Guidelines Draft, Jan. 2002

Guideline 7: Inducement to participate

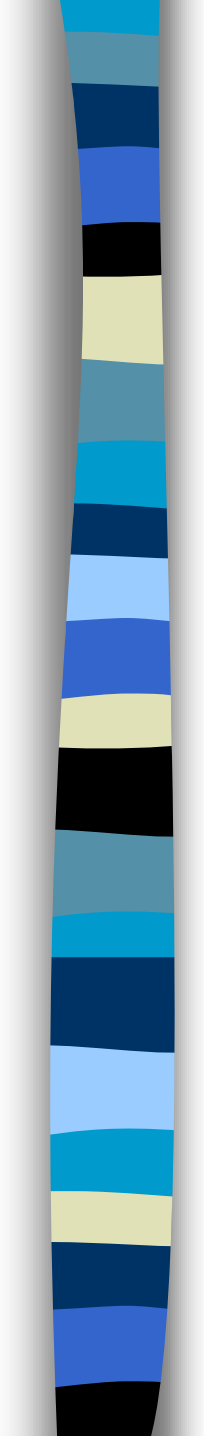
- “The payments should not be so large...or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment (‘undue inducement’).”

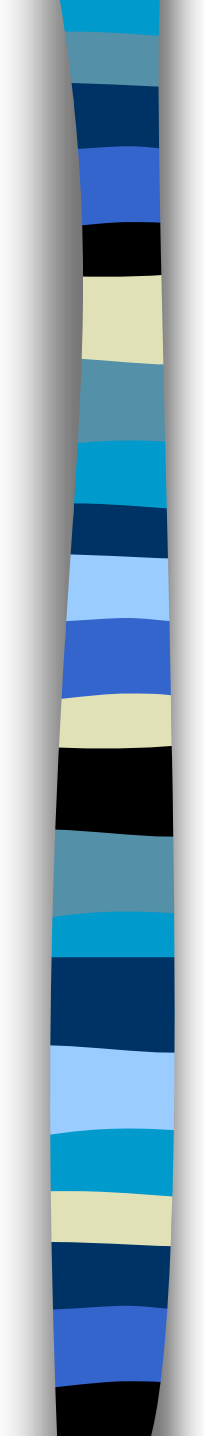


UNAIDS Guidance Document, Ethical Considerations in HIV Vaccine Research, May 2000:

- Guidance Point 10

The research protocol should outline the benefits that persons participating in HIV preventive vaccine trials should experience as a result of their participation. Care should be taken so that these are not presented in a way that unduly influences freedom of choice in participation.

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- As an investigator, what steps would you take to resolve this issue? Who would you work with? Who has the authoritative voice?

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- As a Community Advisory Board member...
 - As a staff nurse...
 - As an IRB member...
 - As the study sponsor...



HPTN ethics strategies:

- ⑩ CAB development and support to insure a community voice early in study design and implementation.
- ⑩ Developing science and ethics training with and for CABs/community to enhance community decision making.
- ⑩ Development of an ethics training strategy, including use of the FHI Research Ethics Training Curriculum, for all site staff.



HPTN ethics strategies (*cont.*)

- ⑩ Empiric ethics research to determine what different standards of care really exist in the community and the effect of the difference.
- ⑩ Writing an ethics guidance document to guide network research.
- ⑩ Writing ethics position papers to put forth proposed strategies for peer review and discussion.
- ⑩ Developing an IC process which to improve understanding of the issues so that potential participants can make a more truly informed choice, weighing risks and benefits.