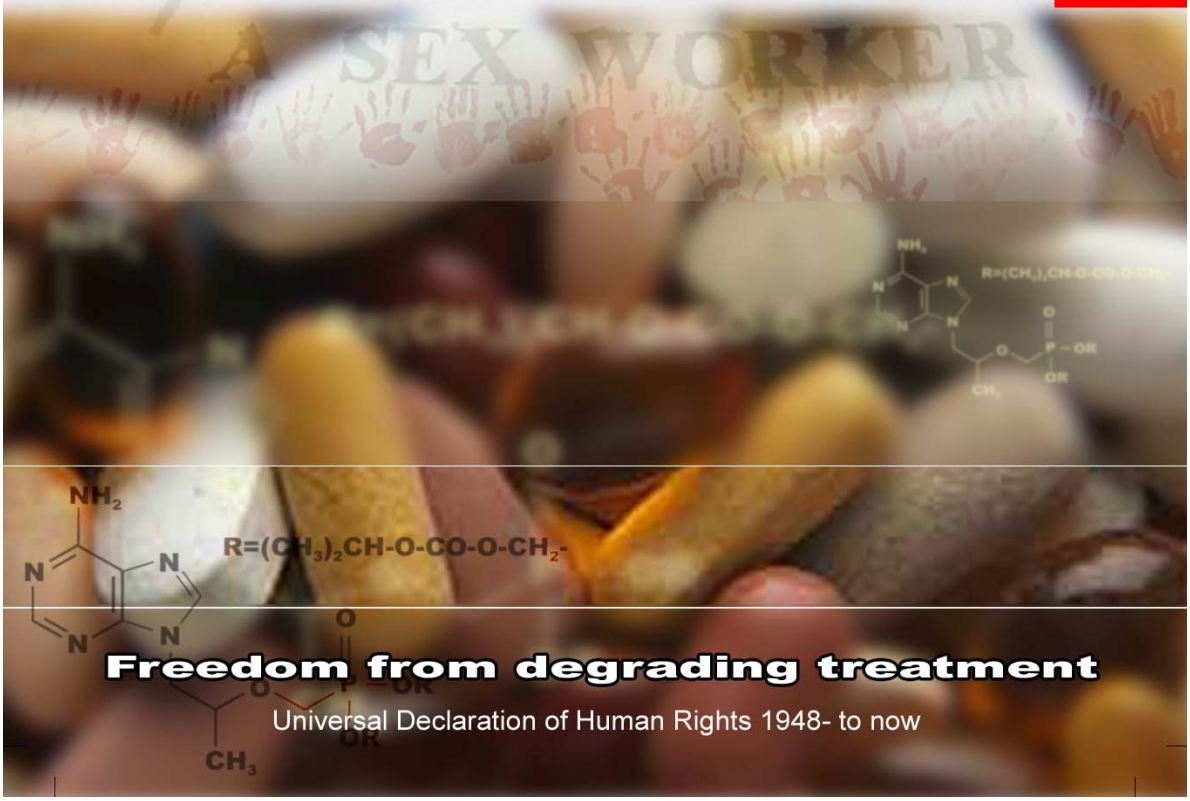
SEX WORKERS HAVE RIGHT IN DRUG TRIALS

YOU HAVE RIGHTS, SO DEMAND THEM
some of them are:
Dignity - Freedom - Equality



Freedom from degrading treatment

Universal Declaration of Human Rights 1948- to now

SEX WORKER HAVE RIGHTS IN DRUG TRIALS

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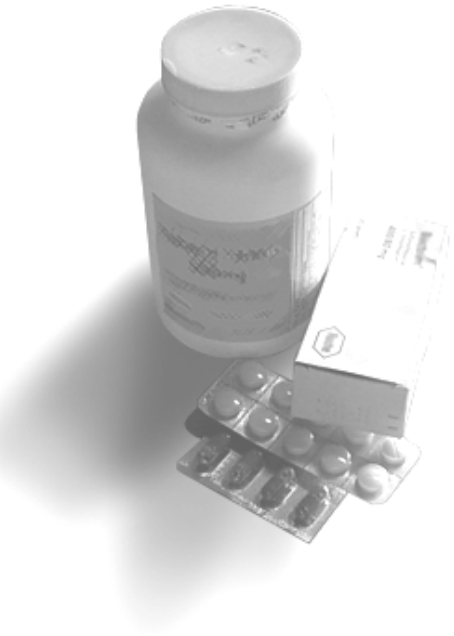
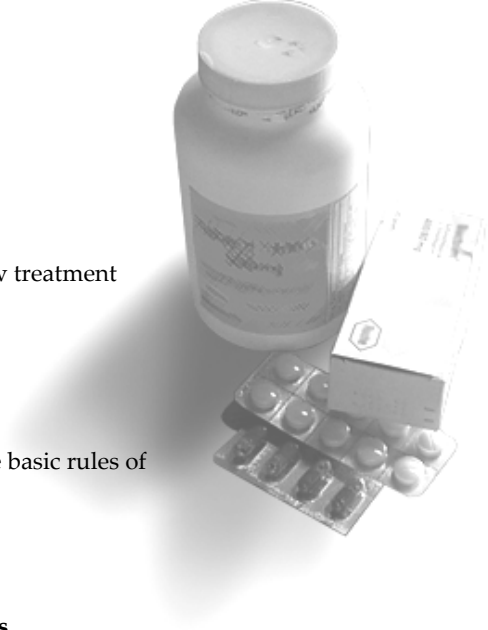




What are Ethical Trials?

Ethical Trials respect people participating in the trial by:[1]

- Making sure the trial respects the dignity of participants
- Doing the work "with (not on) communities" to discover new treatment options

Who decides what is an Ethical Trial?

The participants and drug companies decide together.
There are several international organizations and documents that give basic rules of ethics that are supposed to be followed all the time. They are:

The Declaration of Helsinki
The International Conference on Harmonization
The WHO (World Health Organization) Guidelines
The Medical Research Council Guidelines

Are Trials the same around the world?

No, depending on the country a trial takes place in, it will vary. Trials are supposed to respect international and local rules of ethics.

This DOES NOT mean that if a country hosting a foreign trial allows more to be done to its citizens than the companies home country that Drug Companies only have to follow local guidelines.

This means that if a drug country operates in a country different than its own, it is supposed to follow all the human rights rules from both countries and international standards.

Are there good Drug Trials?

YES. Drug Trials are responsible for a lot of the medicine we have today, including life saving ARVs. Overall they have helped improve health world-wide. When they are run by ethical, concerned researchers they can benefit participants and the larger global community. HOWEVER, there have been times when drug trials have done more harm than good. This is why all of the guidelines on ethical drug trials require informed local participants, to ensure that the trial is designed to respect people everywhere.

Does this mean there are no risks to Drug Trials?

NO. There is always a risk in a drug trial; there is also always a risk in taking medicines.

[1] AVAC, AIDS Vaccine Advocacy Coalition

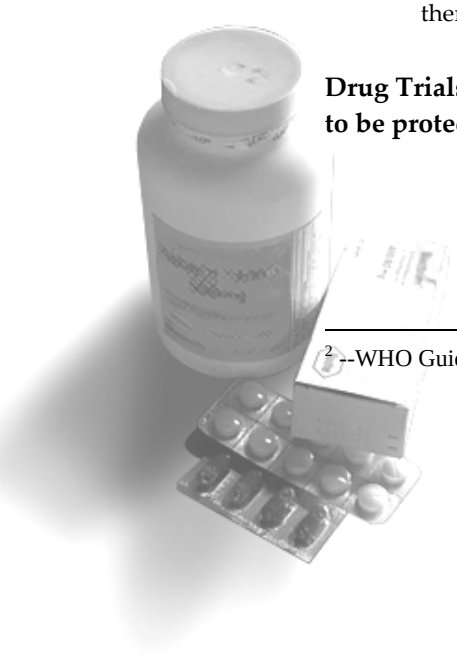
- Every person deserves the respect and dignity of fully understanding the risks, and then deciding whether or not they want to take part in a drug trial.
- Every person who participates in a drug trial deserves to know the risks, and to have the risks minimized by good research practices as much as possible.
- Every person taking part in a drug trial also deserves responsible and comprehensive aftercare for any and all affects of the drug that was tested.

You have rights in Drug Trials:

You can choose not to participate
Respect from researchers
You deserve to know about
the risks and benefits of participating
You deserve the best possible aftercare
-- Declaration of Helsinki
You deserve to be a part of trials,
not just the subject of trials
--WHO Guidelines for Ethical Trials

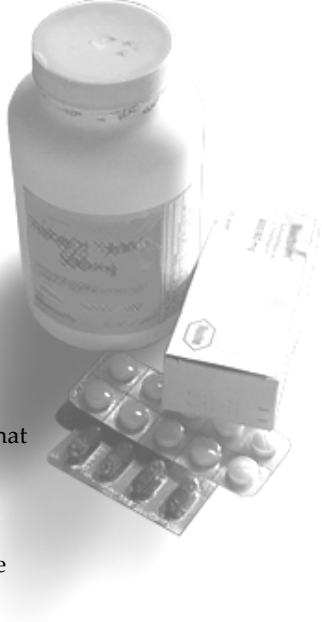
There is a debate between Governments, Drug Companies and NGOs about what ethical drug trials are:

- You have a right to ask for community development with drug trial participation
- You have a right to know ALL of the possible side affects
- You have a right to understand what is happening
- You have a right to confidentiality about your participation in the drug trial
- You have a right to request continuing care for side affects, particularly when there is no local care available.[2]



Drug Trials can benefit everyone, but not at your expense, you have a right to be protected if you choose to participate in drug trials.

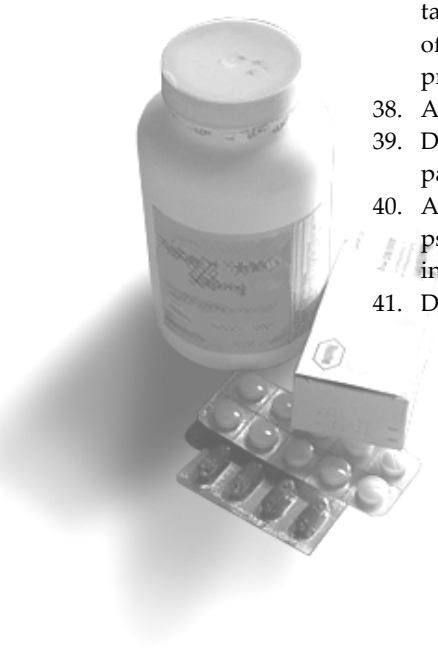
[2] --WHO Guidelines on Ethical testing, Declaration of Helsinki

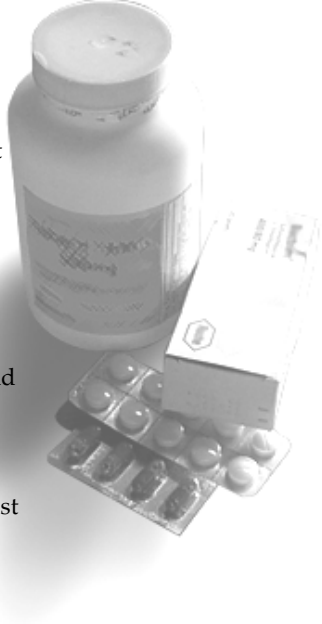


WNU's Questions for Proposed Drug Trials

1. What is the exact title of the project?
2. Who are the responsible investigators in Cambodia and globally. Name and address of all the key staff and their affiliation (and in other countries)
3. Address and location of the project
4. Sponsors of the project and the total budget of the project
5. A copy of the project proposal (Purpose, methods and procedures)
6. What are the specific risks of the project (as identified by the researchers? What method they have used to identify the risk)
7. What steps have been be taken to reduce the risk?
8. What are the direct benefits to the participants (list all the benefits)
9. What are the toxicological/ pharmacological data available on the drugs to be used in this project?
10. Is this a priority area of research in Cambodia (for eg research on locally appropriate treatment options?)
11. What is the inclusion and exclusion criteria for this project and its justifications
12. How the participants of this study will be recruited?
13. Are these criteria sensitive to (i) gender; (ii) age; (iii) vulnerable group considerations?
14. Details of the placebo arm of the study
15. Does the design include appropriate criteria for project discontinuation, by the investigator or sponsor, of (a) individual participants; and (b) the project as a whole?
16. Are the project staff sufficiently qualified (on basis of education, experience, reputation) to carry out this project? (CVs of the key investigators)
17. Details of the process of "community consensus-building" prior to initiating the project, i.e. consultation/discussion of impact of project and its relevance to (a) potential beneficiaries, (b) participants' communities?
18. To what degree possible, are (a) potential participants; (b) beneficiaries; (c) other community members; (d) local clinicians, researchers, involved in: (i) the design; (ii) evaluation; (iii) analysis; (iv) publication and/or dissemination of the proposal, (v) implementation results?
19. Specific plan for the implementation of the result of the project in Cambodia
20. How does this project contribute to local capacity building, e.g. local researchers, local clinicians?
21. Are the communities from which participants are drawn likely to benefit from the project?
22. Will the product (if any), if successful, be reasonably available to participants and the communities from which they are drawn?

23. What specific steps are taken to ensure that the potential products would be available to the community at the earliest?
24. Have adequate arrangements been made to ensure that the results findings of the project are made available to (a) participants; (b) relevant communities, within a reasonable time frame?
25. Who all will be the authors of the result of this study
26. Who will hold the patents of the potential product of this study?
27. Details of reviews carried out by any other relevant national or institutional ethical review committee(s)?
28. Details of procedures to ensure that the project is appropriately monitored as it progresses
29. Does the recruitment process include adequate protections for the privacy and psychosocial needs of potential participants?
30. Is voluntary, non-coercive recruitment/participation ensured by informing participants that hey may refuse to participate
31. Does the participation ensure that the participant may withdraw from the project at any time without penalty or adverse consequences?
32. Has voluntariness of consent been adequately ensured for vulnerable/ hierarchical groups/individuals?
33. A copy of the informed consent form
34. Does the informed consent form/information sheet provide sufficient information regarding: (i) purpose of the project; (ii) procedures to be carried out; (iii) risks (including possible discrimination); (iv) discomforts; (v) inconveniences, including the time required for participation; (vi) benefits to participants and others; (vii) alternatives to participation; (viii) additional costs, if any, to participants and whether those costs will be reimbursed?
35. Is the informed consent form/information sheet written or presented (a) in lay language; (b) at an appropriate level of simplicity to ensure that participants can understand, and (c) specify contact person/s to discuss and explain details of the study?
36. Details of the procedures of acquiring informed consent?
37. Does research protocol and consent form/information sheet (a) describe steps taken to protect confidentiality; and (b) ensure that participants are informed of the extent to which confidentiality can be maintained and possible protective steps to be taken, if breached?
38. Are inducements provided for participation?
39. Do the inducements constitute an undue inducement or influence for participation?
40. Are there adequate provisions to deal with adverse consequences (medical, psychological, social) arising from the project, including compensation for injury/loss?
41. Details of the proposed compensation for injury or loss

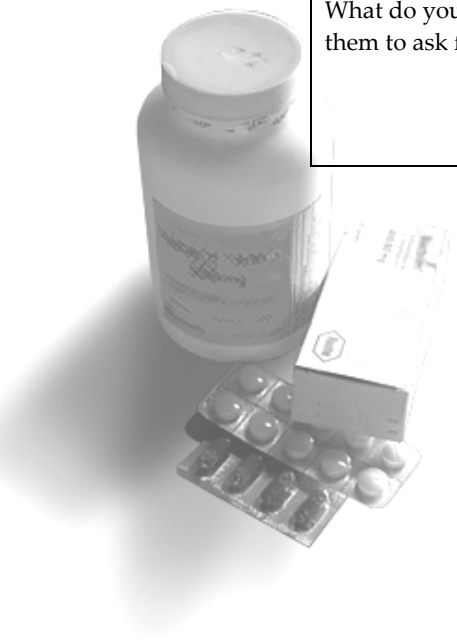


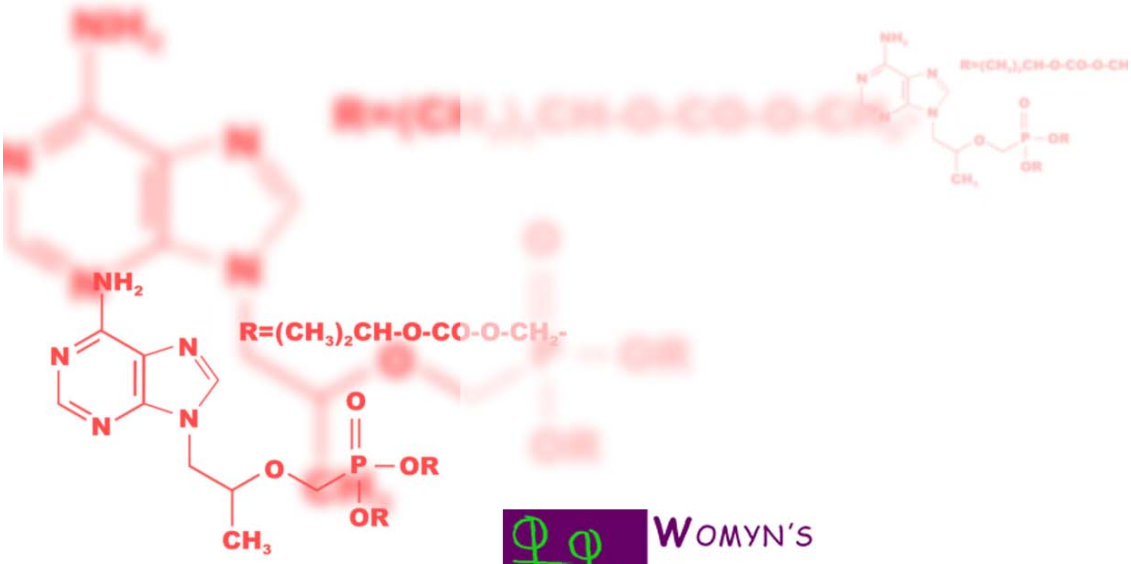


42. Is it likely that the participants could be infected with HIV during the project lifecycle?
43. What percentages of participants are likely to be infected?
44. Do they belong to any particular groups?
45. What specific steps will be taken to reduce/eliminate such chances?
46. What are the potential adverse incidents anticipated in this project?
47. Are participants (and if appropriate, their families) given adequate support (medical/psycho-social, e.g. provision of or referral to counselling) during and after the conduct of project? (Spell out the details of these support)
48. What steps will be taken to register these adverse events and who will have access to this registry?
49. Details of the ethics review committee (s) reviewing the project proposals (List of members of the ERC)
50. Recommendations and suggestions of the ethic review committee (S)
51. Conflict of interest of the investigators
52. Conflict of interest of the ERC members

Negotiation Grid

Questions	WNU	Researchers
What do you need to make working with each other worth it? (If this is not given- you will walk away)		
What would you like in addition to what you need?		
What will happen if both sides CANNOT agree?		
What will happen if both sides CAN agree?		
What do you think is fair for you to ask for?		
What do you think it is unfair for them to ask for?		





WOMYN'S AGENDA FOR CHANGE

#1, Sisowath Quay, Sangkat Srah Chok,
Khan Daun Penh, Phnom Penh, Cambodia

P.O.Box 883
Phnom Penh 12000, Cambodia

Tel: +855 (012) 222 171
Fax: +855 (023) 722 435

e-mail: wac@womynsagenda.org
web: www.womynsagenda.org