

# Ethical Issues in SRH Research

**Dr. Sheryl Vanderpoel**  
**Medical Officer/Scientist**  
WHO/RHR-HQ, Geneva

With appreciation to Drs. David Griffin, Ruth Macklin and Dan Wikler

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## Question:

- If you are about to write a research proposal, and you know that you must include ethical considerations, what is the first thing that comes to your mind???



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# Ethical Issues in SRH Research

- (is it all about) Informed Consent?



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# What is an informed consent form?



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Why has so much emphasis been placed on the informed consent form?

What ethical considerations should you have when writing a research proposal?



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We can also answer these questions with another:  
What drove the field of research ethics and the  
generation of ethical guidelines?



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*Origins of Contemporary Research Ethics:*  
What drove the field of research ethics and generation of ethical guidelines in the past?

Ethical guidelines were not proactive but rather reactive as 'recipes' to resolve research situations or outcomes that had caused harm to its participants.



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# Harm

- During times of war:
  - Human Experimentation during WWII
    - German-supported research throughout Europe
    - Japanese-supported research in China



A victim of a Nazi medical experiment is immersed in icy water at the Dachau concentration camp. SS doctor Sigmund Rascher oversees the experiment. Germany, 1942



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Unit 731's human experimentation was carried out in China during the WW2. More than 3,000 Chinese people were tortured and killed by Japanese doctors. This human experimentation included vivisections for medical training, intentional infection, and limits of tolerance on the human body.



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# Response



- 1946-1947, Nuremberg "Doctors' Trial"
- 1947, Nuremberg Code (Crafted by Dr. Leo Alexander; initially a 6-point code defining legitimate – within a legal framework - human research)
  - Addressed voluntary consent by informed human subjects
  - Addressed issues of protection and safeguards to prevent harm
  - Assessing risk versus benefit
  - Addressed issues concerning quality of the experimentation with regards to the experimental design
- 1948, UN Universal Declaration of Human Rights



# Response: 10 point Nuremburg 'CODE'



1. The voluntary consent of the human subject is absolutely essential
2. Scientific rigor
3. Good design
4. Avoid unnecessary suffering
5. Death or serious injury should not be an expected outcome
6. Risks weighed against importance of the problem
7. Preparation/facilities to protect subject
8. Scientific qualifications of researcher
9. Subject must be free to withdraw at any time
10. Be able to stop study at any time



An individual should voluntarily and  
knowledgably agree

- to an experimental intervention
- via a properly generated informed consent  
process
- through a study that incorporated the 10  
Guidelines of the 'Code.'



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An individual should voluntarily and knowledgably agree (signature?)

- to an experimental intervention
- via a properly generated informed consent process (form?)
- through a study that incorporated the 10 Guidelines of the 'Code.'



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# Harm

- During post-war history:
  - Human Experimentation in the USA
    - 1932-1972 Tuskegee (Alabama), US Public Health Service
    - 1963 Jewish Chronic Disease Hospital (Brooklyn)
    - 1967 Willowbrook State School (New York)



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# Response

- 1964, World Medical Association: Declaration of Helsinki
  - Addressed **deficiencies in the Nuremberg Code**, specifically with regard to research in legally incompetent, or 'vulnerable' populations
  - Introduced the concept of therapeutic versus non-therapeutic research
  - **Focused on the physician:**
    - "It is the mission of the physician to safeguard the health of the people."





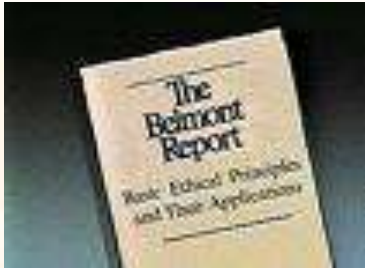
# Response

- 1964, World Medical Association: Declaration of Helsinki
  - Focused on the physician:
    - "It is the mission of the physician to safeguard the health of the people."
      1. **Beneficence** - 'do positive good'
      2. **Non-Maleficence** - 'do no harm'
      3. **Informed Consent**
      4. **Confidentiality/ Anonymity**





# Response



- 1979, Belmont Report (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, US)
  - Boundaries between Practice and Research
  - **Basic Ethical Principles** (autonomy, beneficence, justice)
  - Applications (Informed consent, Assessment of risk and benefit, and 'Subject' Selection.)



# Harm



- Experimentation in Developing Countries:
  - Human Experimentation
    - *Oral contraception (Mexico, 1950s)*
    - Breast Cancer (South Asia)
    - Treatment for HIV/AIDS (Africa)



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# Response



- Council for International Organization and Medical Sciences (CIOMS) formed by WHO and UNESCO.
  - 1970s, CIOMS undertook research on bioethics in cooperation with the WHO, resulted in 1982, with the "Proposed Ethical Guidelines"
  - 1991, CIOMS International Ethical Guidelines for Ethical Review of Epidemiological Studies
  - 1993, CIOMS International Ethical Guidelines for Biomedical Research



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# Response

- 1993, CIOMS International Ethical Guidelines for Biomedical Research (updated 2002)
  - Highlighted **basic ethical principles of research** (3)
  - Acknowledged Nuremburg Code, enlarging and complementing the Declaration of Helsinki but, at the same time attempting to adapt and apply concepts to current practice
  - Addressed issues associated with developing countries, mentally or physically impaired persons, children, pregnant women, ethics committees, inducement, sponsor obligations, confidentiality, compensation... **yielding 21 Guidelines.**



# Harms: Two perspectives

## 1. Individualist perspective:

- Researchers accept a principle that the well being of the group should have priority over the well being of the individual. Individuals may be sacrificed for the benefit of the group.

## 2. Egalitarian perspective:

- Researchers believe that some human groups (races, ethnic groups) are inferior to others. Their operating principle was that members of inferior groups may be sacrificed for the benefit of those in superior groups.



# Harms: Two interpretations

## 1. Individualist perspective:

- According to the "individualist" perspective, this issue represents a form of collectivism. (one sacrificing for all)

## 2. Egalitarian perspective:

- According to the "egalitarian" perspective, this issue represents a form of racism.



# Historical lessons

- History of research abuse is the history of collectivism, racism, class injustice and other forms of bias and discrimination.
- The ethical starting point is not individual vs society, but equality and human rights.
- Ethical review:
  - Protect human participants.
  - Treat human participants fairly.
  - Treat human participants equally.





# Historical lessons

- History of research abuse is the history of collectivism, racism, class injustice and other forms of bias and discrimination.
- The ethical starting point is not individual vs society, but equality and human rights.
- Ethical review:
  - Protect human participants. (individual over the group?)
  - Treat human participants fairly. (no risk-taking without consent and without scientific justification)
  - Treat human participants equally. (no discrimination, racism or bias)





# Ethical theories vs Ethical principles

- No agreement on any one theory
- Acceptance of many principles,
  - many plausible sets of principles, differing in content and number.
  - no agreement on priority



# Fundamental guiding principle

- **Respect for the individual**
  - Each person matters, regardless of position, ability or wealth
  - No person should be valued merely as a means to further the interests of others



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# Ethical Principles in Research

- **Respect for Human Beings/Respect for Autonomy**

1. Individuals should be treated as autonomous agents (voluntary informed consent) – individual vs community
2. Individuals with diminished autonomy are entitled to protection (minimize risk and avoid harm)

- **Beneficence**

- Not "kindness" but an "obligation" placed upon not just investigators but stakeholders and society at large, to

1. Do no harm
2. Maximize possible benefits and minimize possible harms

- **Justice (Distributive)**

1. An individual receives benefit from research, not being denied what is entitled and
2. An individual bears the burden, but not imposed unduly.



# CIOMS – 21 Guidelines

- 1. Ethical justification and scientific validity of biomedical research involving human beings
- 2. Ethical review committees
- 3. Ethical review of externally-sponsored research
- 4. Individual informed consent\*\*\*
- 5. Obtaining informed consent: essential information for prospective research subjects
- 6. Obtaining informed consent: obligations of sponsors and investigators
- 7. Inducement to participate
- 8. Benefits and risks of study participation
- 9. Special limitations on risk when research involves individuals who are not capable of giving informed consent.
- 10. Research in populations and communities with limited resources
- 11. Choice of control in clinical trials



# CIOMS – 21 Guidelines

- 12. Equitable distribution of burdens and benefits in the selection of groups of subjects in research.
- 13. Research involving vulnerable persons
- 14. Research involving children
- 15. Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent
- 16. Women as research subjects
- 17. Pregnant women as research participants
- 18. Safeguarding confidentiality
- 19. Right of injured subjects to treatment and compensation
- 20. Strengthening capacity for ethical and scientific review and biomedical research
- 21. Ethical obligations of external sponsors to provide health care services.



# All stakeholders responsibility, beneficence: Harm minimally, benefit maximally

- Eliminate unnecessary risk:
  - with emphasis on safety
  - avoid human participants if possible
- Any risk to participants requires justification
  - research requires risk-taking
  - high likelihood of benefit to others
  - full voluntariness
- No brutal or inhumane treatment



# All stakeholders responsibility, justice: *Harm minimally, benefit maximally*

- Fair recruitment procedures
  - "our descendents have no right that would require us to sacrifice ourselves"
  - "no one has the right to choose martyrs for science"
  - "participants should not selected for their vulnerability" - exploitation
    - Desperate patients
    - Poor
    - Institutionalized, incarcerated
- Benefits of research should be fairly distributed.





# What do you think?

- Does anyone have a duty to serve as an experimental participant?
- **Facts:**
  - New doctors require training
  - Doctors in training must treat someone their first time
- **Question:**
  - On what basis would you insist that someone else accept doctors in training so that you may avoid them?





# What do you think? (laproscopic investigation)

- Does anyone have a duty to serve as an experimental participant?
- **Facts:**
  - New doctors require training
  - Doctors in training must treat someone their first time
- **Question:**
  - On what basis would you insist that someone else accept doctors in training so that you may avoid them?



# What do you think?

- Does anyone have a duty to serve as an experimental participant?
- **Facts:**
  - Medical science must advance for humans to benefit
  - Ineffective, unsafe, or inferior treatments need to be identified and eliminated
  - Progress in medicine requires experimentation with appropriate controls
- **Question:**
  - If humans are equal, who should be carrying the burden of experimentation?



# What do you think?

## (microbicide research without use of condoms)

- Does anyone have a duty to serve as an experimental participant?
- **Facts:**
  - Medical science must advance for humans to benefit
  - Ineffective, unsafe, or inferior treatments need to be identified and eliminated
  - Progress in medicine requires experimentation with appropriate controls
- **Question:**
  - If humans are equal, who should be carrying the burden of experimentation?



# **Checklist** for the consent process: The CIOMS Guidelines (1/2)

- Inform the participant why they are being approached ✓
- Ensure that consent is voluntary – no coercion - ✓
- Explain freedom to withdraw (participant has a veto) ✓
- Protection for those lacking capacity for self-determination
- Explain the purpose of the research – participant know what they are getting into
- Describe the trial design in lay terms
- Explain duration of participation required
- Discuss any remuneration
- Discuss mechanisms to inform participants of study results
- Notify participant of confidentiality arrangements and safeguards about access to individual data
- **Confirm ethical consent (informed or understood) has been obtained**



## What do you think?

### Informed versus understood: "A sense of proportion"

- **Thesis:** The importance of full comprehension in informed consent is proportional to the degree of risk of harm or discomfort.
  - Risk is high, full comprehension essential
  - Risk is low, insisting on full comprehension costly and potentially burdensome
- **Moral:** Insistence on full comprehension is only required if net risk is high.



# Checklist for the consent process: The CIOMS Guidelines (2/2)



- Discuss foreseeable risks
- Discuss possible benefits to the individual or community
- Will the treatment be available after study completion?
- What are the alternative treatments to study medication or therapy?
- Is there a distinction between the role of the investigator and the patient's physician?
- Are medical services provided for the subject during the study?
- Explain what arrangements have been made to deal with research-related injury.
- How will the subject be compensated in the event of research-related injury?
- **Are any secondary studies proposed?**





# What do you think? The "Un-informed"

- May participants be asked to consent to research even though details are not provided?  
Is un-informed consent, a contradiction?
  - Deception designs in social psychology?
  - Tissue or blood samples for use in future studies without re-consent
  - Medical records from epidemiological studies for future retrospective studies



# What do you think?

## The "non-consenting" participants

- May participants part of a research study without consent?
  - Emergency medicine research (non-pneumatic anti-shock garment)
  - Research defined as 'minimal risk'
  - Who consents for future generations from gamete or germ cell exposure?





You are a researcher. You have just orally presented a research proposal to your institutional ethics review board.

*Why would the members of your IRB/ERC only request to see the informed consent form of your study?*



“It is all a matter of interpretation: Kind of guidelines, if you will...”



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Ethical guidelines were not proactive but rather reactive as 'recipes' to resolve situations that had caused harm.

Many IRBs and researchers maintain a perception/misconception that ethics is really only about the informed consent form;  
and, if this form is found to be appropriately drawn it would reveal/and or address all ethical issues associated with a research proposal.



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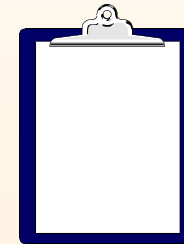
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# Ethics Committee recommendations and requirements often take the form of a prescriptive ticked sheet:

- Please disclose this information in your *informed consent form*:
  - Research description
  - Risks
  - Benefits
  - Alternatives
  - Confidentiality
  - Compensation
  - Contacts
  - Voluntary participation



Ethical guidelines were not proactive but rather reactive as 'recipes' to resolve situations that had caused harm.



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Is the same happening with new guidance challenges and guideline generation?  
Is ethics based on trends or based on time-honoured principals?



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# Is ethics based on trends or based on time-honoured principals?

- Placebo:
  - In 1982, a placebo was introduced in an arm of an HIV intervention trial.
    - What do you believe the IRB/ERC members decided upon review of this proposal?
    - Did they allow this protocol to proceed?
    - Why or why not?



# Placebo versus Standard Care-

## Ethical considerations and justifications

- Ethical justifications for Placebos versus Standard care:
  - Why use a placebo in an arm of your study?
    - Justification is based upon efficacy versus clinical considerations when there are no treatments or interventions which are clinically better than placebo.
  - Why use a standard therapy in an arm of your study?
    - Justification is to protect the study participants, and provide the best possible treatment.





# Is the same happening with new guidance challenges and generation?

- Placebo:
  - In the 1980s, utilizing a placebo in an arm of an HIV trial **was** considered ethically acceptable.
  - Today, with access to standard care (AZT, for example, available since 1994) and therapy, a placebo is no longer considered acceptable.
- In many instances, clinical research proposals from 10 years ago would appear harmful, would be perceived to render high risk, and/or would be regarded as unethical today.



# A New Guidance Challenge, I

- 1997-1998, Research clinical study:
  - Utilizing placebo versus low-dose (1/10 dose utilized in developed world) AZT (zidovudine) in pregnant woman to study mother-to-child HIV transmission in Africa and Asia.



# What was the RESPONSE from WMA and CIOMS?

## Discussions with changes to their guidelines...

...should standard care be determined on an "international" scale?

...should the study have compared normal-dose against low-dose? This would then be proper clinical equipoise? Yes, but it would be malpractice under the 'best interests of the patient' rule.



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# WMA Declaration of Helsinki, paragraph 29, (revision 2000)

- "The WMA hereby reaffirms its position that extreme care must be taken in making use of placebo-controlled trials and that in general this methodology should only be used in the absence of existing proven therapy.
- However, a placebo-controlled trial *may be ethically acceptable*, even if proven therapy is available, under the following circumstances:



# WMA Declaration of Helsinki, paragraph 29, (revision 2000)

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic therapeutic method
- *OR*
- Where a prophylactic, diagnostic or therapeutic method being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm."



# CIOMS/WHO Guidelines

- **Guideline 11. ....**
  - Placebo may be used when there is no established effective intervention; When withholding an established effective intervention would generate in subjects to, at most, temporary discomfort or delay in relief of their symptoms; When use of an established effective intervention as comparator would not yield scientifically reliable results
  - *AND*
  - use of placebo would not add any risk of serious or irreversible harm to the subjects.



# What was the RESPONSE from WMA and CIOMS?

Discussions resulted in document changes to their guidelines (with single words making significant changes, also in language translations\*)...  
....and divergence between international ethical guidelines became more evident.

"Assess to..." .... versus.... "Assured of assess to..."



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# New guidance challenges and trends?

With change of time, change of ethical considerations:

- Harms or perception of harm to a research subject\* can change. Even the way the patient is addressed within these documents changes.
- 'Vulnerability' and what constitutes a vulnerable individual is changing.
- Influence of a single disease affects change but this trend should not bias international over-arching ethics-based guidance.
- Compensation and stakeholder participatory practices are changing.

\*(or human being or research participant or individual or subject)



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# A New Ethical Guidance Challenge - II



- Large, worldwide, multi-centre trials:
  - Single protocol,
  - Often generated in the developed world,
  - Implemented internationally in developing countries.



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# New Guidance Challenges - II

## ● Ethical Challenges?

- Ethical issues may generate (subtle or not subtle) differences due to diversity of sites (may or many not be depend upon religious, legal, moral or political diversity.)
- Access to (standard) treatment may or may not affect study design and participatory practice guidelines for stakeholders
- Altered informed consent or informed consent procedure at each site may or may not be due to language translation issues, or the literacy level of participants.
- Incentives or coercion may or may not vary in strength and weight dependent on site
- Monitoring issues for compliance, consistency, and comparison from a distance
- Local versus international ethics review committee decisions



# Response



- "Ethical challenges in study design and informed consent for health research in resource-poor settings."
- WHO-Special Programme for Research and Training in Tropical Diseases (WHO/TDR) sponsored by UNICEF/UNDP/World Bank/WHO



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# Executive Summary

- Recommendations for researchers and policy makers concerned about ethical practices in multi-national studies conducted in resource-poor settings:
  - Strengthen capacity for developing collaborative partnerships
  - Strengthen education in research ethics for investigators
  - Strengthen capacity for independent ethical review of protocols
  - Develop culturally meaningful approaches to informed consent
  - Apply appropriate standards of care and provisions for medical treatment
  - Provide ongoing feedback to the study participants and community
  - Develop plans for resolving conflicts surrounding research implementation
  - Respect the cultural traditions of study populations and communities



# Individual versus a community

- Delegated authority versus autonomy; and, Respecting women versus respecting cultures
  - Do communities have rights?
  - Who speaks for a community?
  - May a chief or religious leader consent for a group of people?
  - Husband and wife relationships
  - Children, adolescents and 'young adults'



# Trends in research within low resource communities: Post-trial benefits for patients and communities

- Research participants are **recipients** of research not merely **used** for research needs.
- Host communities may legitimately insist that access to their populations is contingent on potential benefit.
- These requirements help alleviate imbalance between research sponsors and host communities.



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# Trends in research within low resource communities: Post-trial benefits for patients and communities

- Positive aspects:
  - Targeted malady or condition is a significant problem for this population, thus targeting conforms to local priorities.
  - Information or products resulting from the research will be accessible to the local population.
  - Host government sovereignty is respected, and their population not merely a convenient resource for drug development.
  - Requiring benefits assists governments unable or unwilling to support.



# Trends in research within low resource communities: Post-trial benefits for patients and communities

- Negative aspects:
  - Are these moral requirements or just good to do?
  - Why is it inappropriate to learn from research on one group to help another?
  - The pockets of research sponsors are being used to alleviate health suffering in the developing world. Who is taking advantage of who?
  - These additional stakeholder requirements may deter needed research. Even research without additional post-trial benefits is often valuable to the host site.



Standard of care, Primary health care debate,  
Single versus double standards debate,  
Rights and entitlements,  
Privacy versus confidentiality,  
De-identification issues,  
Waiver of authorization,  
Waiver of ethics review

Ethics review body governance, constitution and  
function, etc...

No time for this or other issues, as well as how HRP views  
these issues when unique and specific to sexual and  
reproductive health.



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# Your Current Ethical Challenges:

- Informed consent
- Risk-benefit analysis
- Confidentiality
- Eligibility criteria
- Research ethics review committees
- Good participatory practices
- .....
- How do you decide
  - Which ethical guidelines to follow?
  - Which checklist to be conscious of?



# "Ethical Document Shopping"

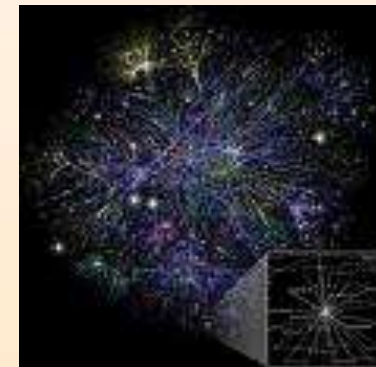
- The Nuremberg Code (1947)
- UN Universal Declaration of Human Rights
- WMA: Declaration of Helsinki (*Updating, 2007/2008*)
- The Belmont Report (1979)
- CIOMS International Guidelines for Epidemiological Studies (1991) (*Updating, 2007/2008*)
- Nuffield Council on Bioethics
- CIOMS International Guidelines for Biomedical Research (updated *2002*)
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine; Convention on Human Rights and Biomedicine (1997)
- ICH, Good Clinical Practice: Consolidated Guideline (1997)
- NBAC, Research Involving Biological Materials: Ethical Issues and Policy Guidance (1999)
- UNAIDS, Ethical Considerations in HIV preventive vaccine research
- UNAIDS/WHO Guidance documents: Ethical Considerations in biomedical HIV prevention trials; and, Good Participatory Practice for biomedical HIV prevention trials. (*2007/2008*)
- WHO/TDR Ethics challenges in study design and informed consent for health research in resource-poor settings (*2008*)
- WHO, Operational Guidelines for ethics committees that review biomedical research. (2000)





# CIOMS International Guidelines for Epidemiological Studies (1991) (*Updating, 2007/2008*)

- An additional 3 Guidelines all effect ICFs:
  - 22. Disclosure and review of potential conflicts of interest
  - 23. Use of the internet in epidemiological research
  - 24. Use of stored biological samples and related data



-future ethical review requirements  
due to repository storage



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# SERG

[http://www.who.int/reproductive-health/hrp/serg\\_guidelines.html](http://www.who.int/reproductive-health/hrp/serg_guidelines.html)

- **Ethical Issues in Reproductive Health and Research**

- Scientific and Ethical Review Group (SERG)
- **Guidelines** for research
  - Gender considerations
  - Reproductive health involving adolescents
  - Reproductive health research and partners' agreement
  - Data management and statistical procedures
  - Establishment of scientific and ethical review bodies
  - Guidelines for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research



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# Ethical Issues in Research

- (is it all about) Informed Consent?



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# ...most assuredly not.

- Consent is a continuing process, not an event or signed form.
- Projects dealing with beings, human beings, must maintain a level of research\* ethics that reflect greater subtlety and sophistication in their ethical considerations which include AND go beyond 'informed consent.'
- Most areas of ethics are still young fields. Ethicists are challenging not only terminology (macro and micro) and existing guidelines, but even the mechanisms and proper scope of ethical guidance.
- Recommendations for future research are to address informed consent practices, community consultation for research, IRBs and ERCs, collaborative research partnerships, and development of instruments to study ethical challenges in research design and implementation.

\*(scientific, clinical, animal, anthropological, social science, operational...)



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# The Balance of Ethical Guidance



- Non-maleficence: All persons have a duty to prevent harm to other persons insofar as it lies within their power to do so without undue harm to themselves.
- Your responsibility is to your patient participant, and your levels of protection are focussed on your patient participant (and his/her community.)
- Maintain a status of being ethically-informed and work together with your ethics focal points.



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# Thank You

Contact:

Dr. Vanderpoel

[vanderpoels@who.int](mailto:vanderpoels@who.int)



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# Case Review, 1/3

## Submitted by Ronnie Johnson, RHR

### Pregnancy in Health Research

- Researchers from an international non-governmental organization based in North America received a grant to test a vaginal micro-bicide to see if it might prevent new HIV infections. The ideal study locations would allow researchers to recruit a large number of women who are HIV-negative but who are at exceptionally high risk for contracting HIV. Many of the study participants, therefore, might be commercial sex workers in a country with high rates of HIV prevalence. After some investigation into potential research locations it was decided that the multi-site study would be conducted in four African countries and one in South Asia.
- The drug being tested has not yet undergone any Segment III pre-clinical studies and so cannot be used safely by pregnant women. Thus, pregnancy or a desire to become pregnant during the coming year precludes study participation. This exclusion criterion is clearly stated in the study protocol and is carefully implemented during study recruitment. The investigators do distribute and provide counselling for use of condoms to each participant. Additionally, study investigators conduct monthly pregnancy testing to ensure that any woman who becomes pregnant during the study suspends her participation until she is no longer pregnant. The informed consent reiterates that the contraceptive effect of the study drug is unknown and that if a woman becomes pregnant while "on-study" she should cease use of the drug immediately and end her study participation until she is no longer pregnant.





## Case Review, 2/3

- A few months after the study commences, researchers notice that many women are suspending study participation because they are getting pregnant. After further investigation, researchers document that the average time that a woman is off-study due to pregnancy is just under three months. Thus, it appears that many of the women that become pregnant are having either spontaneous or induced abortions and then rejoining the study.
- Among the countries participating in the study, abortion on request during the first trimester of pregnancy is permitted in only two, countries A and B; however, for numerous reasons, in both of these countries availability of safe abortion remains out of reach to many women. In country C, abortion is permitted for multiple health indications, including preservation of the mental health of the woman, but abortion on request is not legally permitted. Also in country C, it is not always easy for a woman to find a provider willing to perform abortion on mental health grounds and the cost of such procedures is usually quite high. In countries D and E, legal abortion is available only to save the life of the woman; however, both safe and unsafe services exist for price.



# Case Review, 3/3

## Questions :

- What should the researchers do now that they know many participants are becoming pregnant on-study and that many are probably having illegal and perhaps unsafe abortions?
- Should the study sponsors provide safe abortion to women who inadvertently become pregnant while on-study?
- What if a donor prohibits grant recipients from providing any information or services related to abortion?
- Should the study sponsors warn prospective participants that *unwanted* pregnancy is a study risk and abortion in their country is not available (or not widely available) on request; and, that having an unsafe abortion presents a great risk to a woman's health and life?
- Knowing what we know now, should such studies ever be done in countries where safe abortion on request is not legally and readily available?
- Under what circumstances would you be comfortable conducting such a study in the countries listed? In other countries?

