The problem

• The world contains a vast number of cultures with varying customs and traditions
• Multinational research is a global enterprise
  > Sponsors include industry, industrialized country agencies, international organizations
• Can universal ethical principles be applied to these culturally diverse settings?
A Shariah official canes an Indonesian woman for “unlawful contact with an unmarried man.”
Clarifying concepts

• Confusion between ‘absolutism’ and ‘universalism’
  > ‘Absolutism’: there exist exceptionless moral rules that are valid for all cultures at all times and places
  > ‘Universalism’: there exist fundamental moral principles that are universally applicable
• Moral rules are specific, and often have exceptions
• Moral principles are general, and always require interpretation
Cultural sensitivity

• A widely held view calls for researchers and sponsors to be “culturally sensitive”
• “The general duty of respect implies a duty to be sensitive to other cultures….The variety of beliefs and practices that exist may challenge the notions of overarching ethical principles. This in turn prompts an analysis of the relationship between the requirement of sensitivity to cultural differences and the concept of moral relativism”

A man rejoices when a son is born, but completely ignores any female children.

Did you know that in Khazoo, women cannot have any possessions of their own?

Quiet, girls! It's not for us to question the ways of another culture.
Normative ethical relativism

• What is right in one society may be wrong in another
  > Intended as a normative claim: “What actually is right in one society may actually be wrong in another”
• Normative ethical relativism is the only position consistent with the facts of descriptive relativism
• There are no universally valid ethical principles
• It is wrong to criticize or seek to impose one culture’s ethical norms on another
Traditional belief systems

- When research subjects are unacquainted with the concepts and methods of modern science or biomedical research
  - To preclude the possibility of research could deny members of such societies the eventual benefits of research
  - Researchers should seek creative ways of presenting information
    - For example, using analogies readily understood by the population
- Major danger: such individuals may be completely unaware they are subjects in research that may not benefit them and may even harm them
Respect for Persons
Cultural relativism and research ethics

• Respect for persons
  > Does the principle require that informed consent be obtained from each individual participant, even if a culture does not recognize or respect the autonomy of each individual?
Ethical imperialism & informed consent

• “It is ethical imperialism at its worst to assume that the informed consent requirement, which does indeed serve one (only one) moral principle in the Western setting, is in itself such a universal ethical standard.”

Ethical universalism & informed consent

• “Appeals to cultural sensitivity are no substitute for careful moral analysis. We see no convincing arguments for a general policy of dispensing with, or substantially modifying, the researcher’s obligation to obtain first-person consent in biomedical research conducted in Africa.”

Informed consent
Ethical relativism and informed consent

- Two situations defended by relativists that depart from accepted ethical standard for informed consent
  - Perceived need to withhold key information from potential research subjects
  - Cultural custom of requiring husbands to sign consent forms for research in which their wives are participants
Breast cancer study in Vietnam

• U.S. researcher said: “American standards would not be acceptable to Vietnamese physicians, political leaders in Vietnam, or the vast majority of Vietnamese patients”
  > Patients do not participate in medical decisionmaking in Vietnam
  > Necessary to withhold from potential subjects any elements that would convey uncertainty
    • Explanation that proposed treatment determined by randomization
    • Existence of alternative therapies
Birth defects study in China

• Chinese researcher collaborating with CDC opposed informed consent requirement
  > Obtaining informed consent is not done in medical practice, so it would arouse suspicion in research context
    • Doctors normally do what is best for their patients without asking
  > Could not mention placebo control or because no one would enroll in the trial
    • Concept of RCT with placebo control is unheard of in China, and people would not accept “dummy pill”
Spousal permission

• Some cultures maintain the custom of requiring husbands to sign consent forms for their wives to participate in research
  > Requirement exists as well for medical treatment
• Researchers in those countries typically accept the requirement
  > Consent forms have a line for husband’s signature
Relativists’ defenses

- Departures from widely accepted ethical standards are justified by the cultural context in the country or community where the research is carried out
  > Cultural relativism
- It would be impossible to conduct research without these deviations from “Western” requirements
  > Pragmatic defense
- Requiring adherence would result in a loss of contributions to medical science and lack of consequent benefits to the population in those countries or communities
  > Appeal to justice
Permission from community leader

- In many societies, permission must first be obtained from a community leader, tribal chief, or council of elders before researchers may enter and approach individuals
  > This process is mistakenly referred to as “community consent”
  > It is not “consent to enroll participants”
    - It is permission to enter the community
  > No different, in principle, from permission gained from a school principal or factory owner to enter the premises in order to conduct research
Ethical standards

• All guidelines and regulations governing research require prospective review by an independent research ethics committee

• In externally sponsored research, which ethical standards should be used by such committees?
  > Standards used in the sponsoring country
    • Ethical imperialism?
  > Standards used in the host country
    • Possibly a “lower” standard?
Harmful traditional practices

- FGM/FGC/Female circumcision
  - Research conducted by advocacy groups in countries where FGM is practiced
    - Can the research be carried out objectively?
    - May researchers convey their viewpoint to participants when the research is concluded?
    - Must the researchers be from the country where the harmful traditional practice occurs?
      - May they be from North America or Europe?
Conclusions

• Ethical principles governing research involving human subjects are universally applicable
  > Yet procedural mechanisms for implementing the principles may differ from place to place

• Custom, culture, and tradition cannot provide a justification for departing from ethical principles
  > Culturally sensitive approaches can show “respect for cultures” without violating fundamental ethical principles
Conclusions

• ‘Ethical imperialism’ is a slogan used by those who seek to conduct or justify research to which others have ethical objections.

• Genuine ethical disagreement remains on the question of whether some research that may not be conducted for ethical reasons in industrialized countries may nevertheless be conducted in developing countries.
"Your Honor, my client pleads not guilty by reason of cultural relativism."