Ministry of Health and Sports

Research with vulnerable populations

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Research involving human participants (sometimes termed "human subjects" in research protocols and reports)

when human beings:

- are exposed to intervention, manipulation, *observation*, or *other interaction* with investigators either directly or through alteration of their environment, or

- become individually identifiable through investigators' collection, preparation, or use medical or other records or of biological material from human beings.

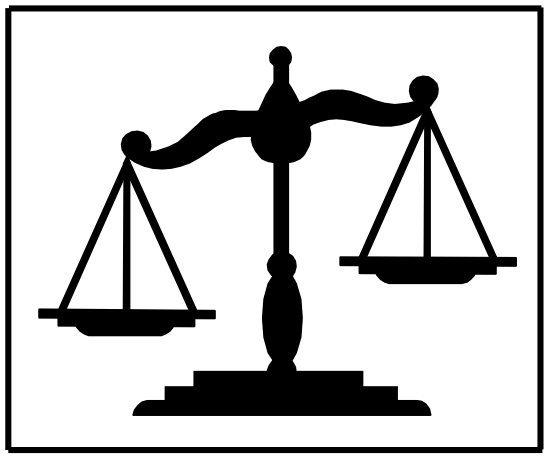
The Common Rule (Protection of Human Subjects 2009) defines a human subject as:

A living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information.

Three Fundamental Principles of Research Ethics

- Respect for persons
- Beneficence
- Justice



Autonomy

auto - "self"
nomos - "rule", "law", "governance"
Self rule/self governance

Personal autonomy- self rule free from controlling interference by others & from limitations - inadequate understanding that prevent meaningful choices

Diminished Autonomy

- An individual's autonomy can be affected by several factors including age, cognitive impairment, illness, and treatments.

An individual's capacity to consent to a particular study should be assessed based on:

- The individual's level of capacity, and
- The complexity and risks of the study, i.e., the capacity needed for an individual to be able to understand the study well enough to consent to participate

Vulnerability

- WHAT MAKES A PERSON VULNERABLE?
- the research subjects were, for one reason or another, incapable of protecting their own interests

- arising from limitations in decision-making capacity…or situational circumstances…or because they are especially at risk for **exploitation**."

- **broad areas of vulnerability: cognitive or communicative, institutional, medical, economic, and social.**

- **cognitive vulnerability** - subjects to some extent lack capacity to make informed choices. Examples might include young children or adults with cognitive impairments that affect decision-making.

- **Situational vulnerability** - subjects do not lack capacity but are in situations that do not allow them to exercise their capacities effectively. Examples might include when a subject is distracted or during an emergency situation, such as an acute illness or injury.

- **Communicative vulnerability** - subjects do not lack capacity, but due to limited ability to communicate with the researchers are not able to exercise their capacities effectively. Examples might include subjects who speak or read different languages than researchers do, or subjects who have speech impairments or difficulty reading.

- **Institutional Vulnerability**

Persons who are subject to the formal authority of others

These individuals have the cognitive capacity to consent but may not be able to make a truly voluntary choice/ unduly influenced (or coerced) to participate.

Institutional vulnerability may arise when subjects are prisoners, enlistees in the military, employees, or college students(dependent relationships)

- Program directors seeking enrollment in research from residents they directly supervise
- Faculty members recruiting students they currently teach
- Commanding officers seeking enrollment in research from soldiers or military personnel that report to them through the chain of command

- **Medical Vulnerability**

when prospective subjects have serious health conditions for which there are no satisfactory standard treatments. Such subjects may not be able to adequately weigh the research's risks and potential benefits, may overestimate the benefits and informed consent would therefore be compromised.therapeutic misconception may augment medical vulnerability .

- **Economic Vulnerability**

when prospective subjects are disadvantaged in the distribution of social goods and services (income, housing, or healthcare). Participation in research offers the possibility of payment or attainment of healthcare or other services that are otherwise not available and induces persons to enroll in a research.

- **Social Vulnerability**

Prospective subjects who belong to undervalued social groups may be subject to social vulnerability. The perception of these groups as less valuable to society could lead to reduced concern (by researchers) for risks and burdens on those groups, and increase the risk of exploitation.

Prospective research subjects who are not able to comprehend information, deliberate, and make decisions about participation in a proposed research study have a:

- Cognitive/communicative
- Physical
- Social
- Economic
- Institutional

A subject participates in a drug study because treatment is available at no or reduced cost, and he could not otherwise afford it. This is an example of:

- Social vulnerability
- Economic vulnerability
- Institutional vulnerability
- Cognitive vulnerability

Subjects with a serious illness may be at risk for exploitation because they may be desperate for a possible cure. This is an example of:

Social vulnerability
institutional vulnerability
Medical vulnerability
Economic vulnerability
Cognitive vulnerability

Who Are Vulnerable Persons?

- Minors, pregnant women, prisoners
- Persons with mental disabilities
- Persons who are illiterate or have limited formal education
- Persons with limited access to health services
- Women in some settings
- Refugees

Common Types of Abuses in Human Research

Type of Abuse	Explanation
Physical Control	Subjects who are physically forced to participate in research. This represents a complete lack of voluntariness. When subjects have no choice about whether or not to participate in research and are under the complete physical control of the researchers.
Coercion	The use of a credible threat of harm or force to control another person. This also represents a lack of voluntariness.
Undue Influence	The misuse of a position of confidence or power to lead or influence others to make a decision they would not otherwise make.
Manipulation	The deliberate design and management of conditions or information intended to lead subjects to make a decision they would not otherwise make. Examples include lying about information, withholding information, or exaggerating information.

Some eg of exploiting vulnerable population

- Oregon State Prison from 1963 to 1971, researchers x-rayed the testicles of 67 male prisoners, to study the effects of radiation on sperm function
- The Willowbrook Study (1963-1966), Research done at a state school of mentally handicapped children. Deliberate infection with live Hepatitis virus.
  Poor public had no other institutional choice. Parents were not completely told what study involved.

Vulnerable populations in research

WHEN SHOULD VULNERABLE POPULATIONS INCLUDED IN RESEARCH?

- including vulnerable populations may be essential in many cases, it is the source of their vulnerability which researchers are attempting to better understand, or to devise ways to mitigate, reduce, accommodate, focus efforts on, or prevent
- whether the research could include a less vulnerable population instead, and still answer the research question.

ERC/IRB's judgement

- Is it justifiable ?Is the research question focusing on vulnerable populations. Will they benefit from the study?
- Are there protective measures/mechanisms to promote their decision making capacity
- ICF procedures promote independent decision making?
- May need close monitoring/continued review

Case Study: Sleeping Sickness Study on Campus

- An investigator, who is a professor at a large university, is developing a grant application for submission to the MoHS to study sleeping sickness (trypanosomiasis). This study will investigate surface antigen expression in trypanosomes, the parasite that causes sleeping sickness, in order to develop a vaccine. These parasites grow in human blood and lymph.

- The study will require fresh human blood daily for several months, and thus will require research participants. A research assistant will maintain a schedule of research participants to ensure that the study performs one collection per day i.e., healthy, weigh at least 110 pounds, and have not donated a pint (570 ml.) of whole blood in the last 8 weeks (56 days). Participants will be compensated.
- It is now time to make a decision about ***recruitment*** of the research participants.

Case Study: Sleeping Sickness Study on Campus

- Based on the number of students and employees in her classes and lab, the researcher feels confident that she will have enough participants needed for the proposed research if she simply recruits among them. But she knows that some colleagues advertise their studies through postings on campus.

The investigator is faced with two possible options for recruiting normal, healthy research participants:

- Recruit the students in her upper level classes and the technicians from her lab, and give $5 compensation to participants per blood draw, or
- Recruit from the general university population (students, faculty and staff) by posting fliers around campus, and give $5 compensation to participants per blood draw
- The investigator discusses the grant application and proposed research procedures with you. You think that the compensation plan is appropriate and that $5 would not be an undue influence for either population to participate.

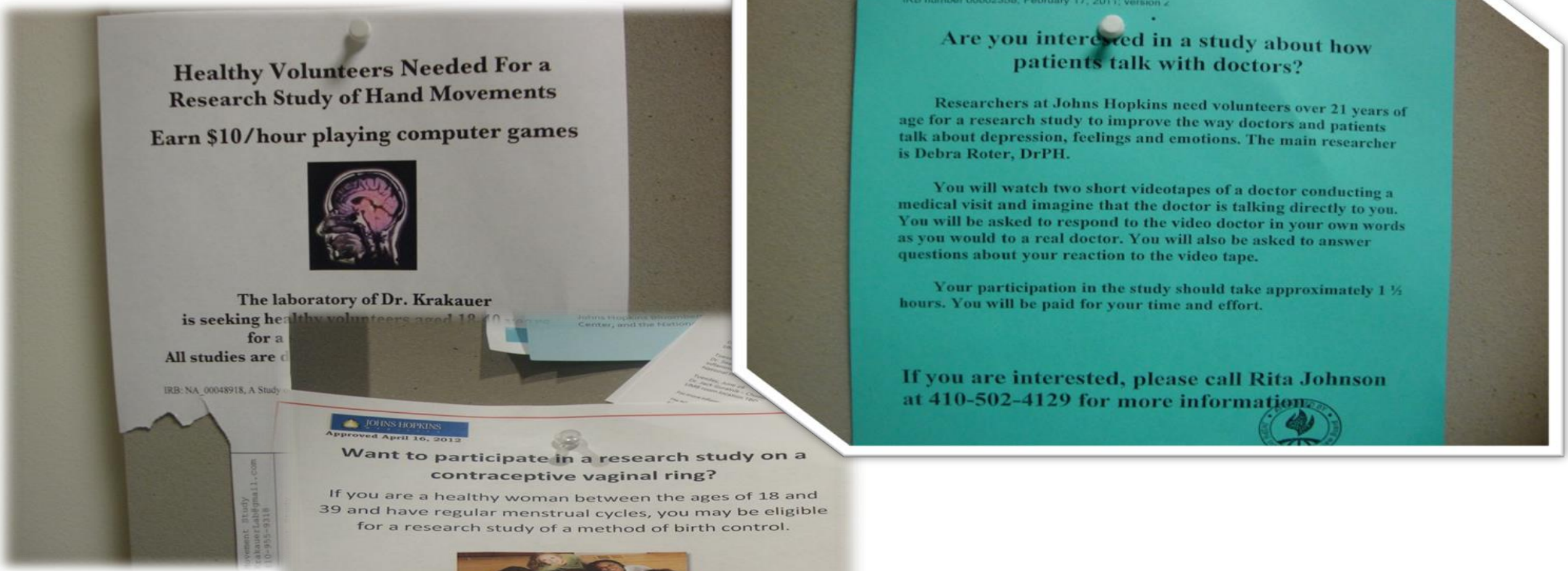
From which population would you advise the researcher to recruit?

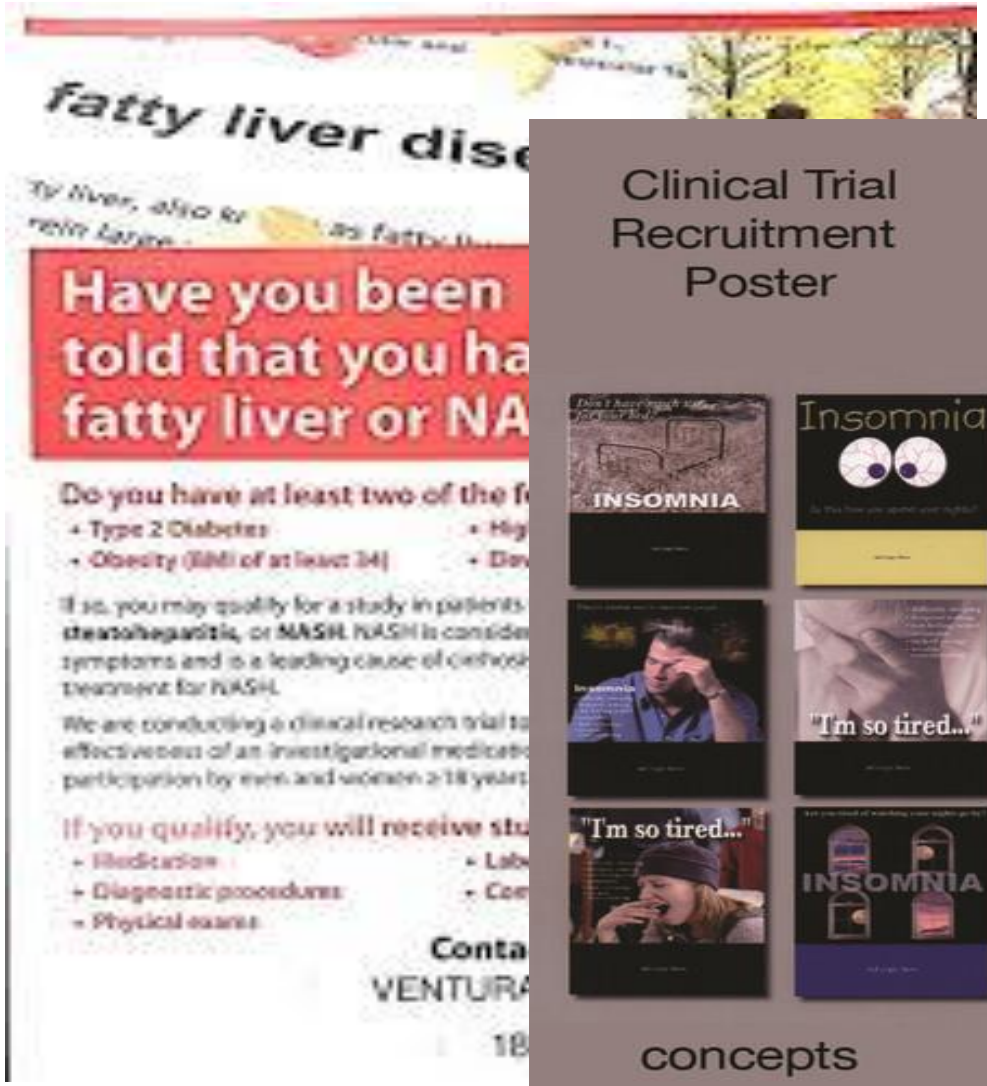
Best approach: Recruit from general student population

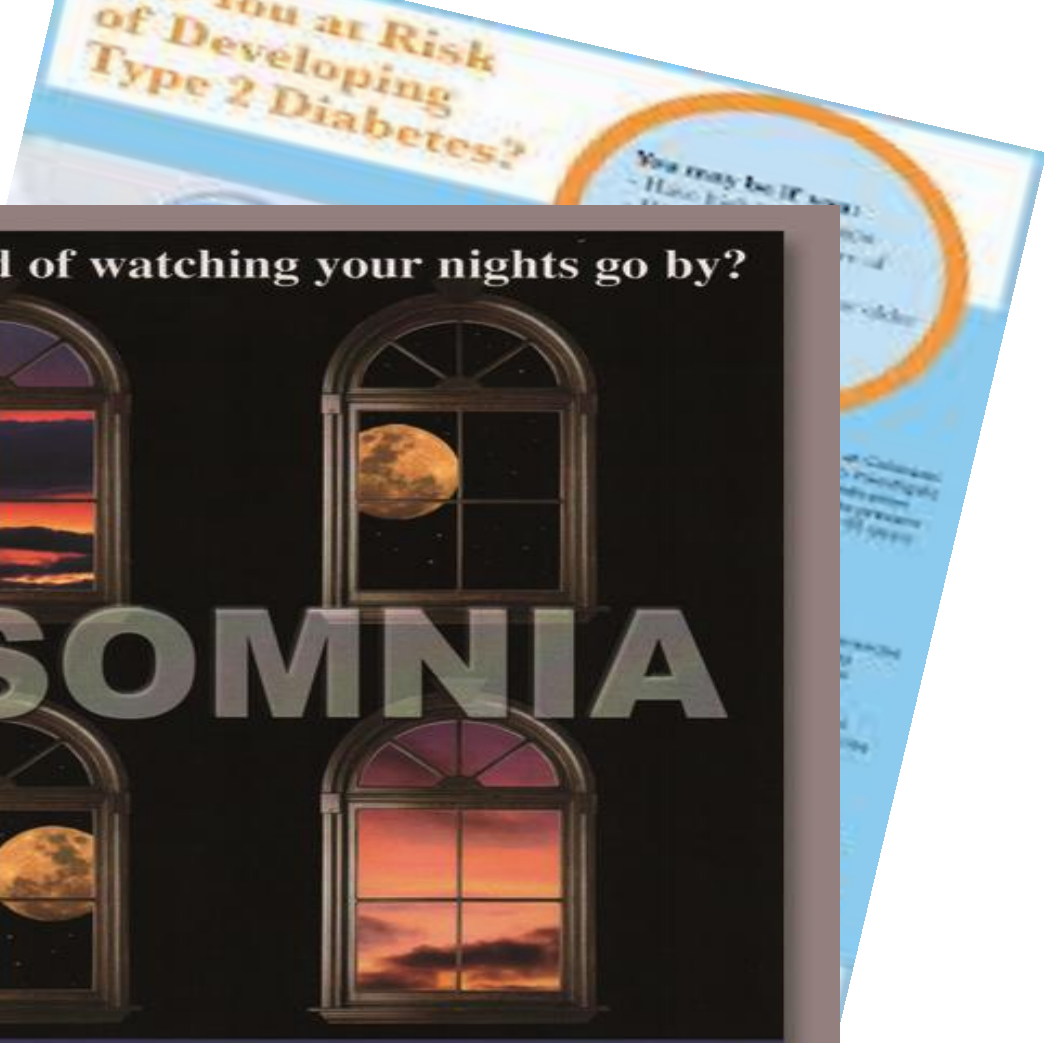
- Asking for study participants from a population over which a researcher has authority is not the best idea.
- It is generally agreed that students and employees are groups that can be vulnerable to coercion.
- students and employees might feel pressured to participate simply because she is in a position of authority.

Recruitment

- Inviting potential participants into a research study without bias/without targeting a specific group who may be vulnerable
- Giving essential information (inclusion criteria, procedure, incentive)in recruitment material in a form of pamphlet/advertisement/notice board/on line
- Provide contact information of researchers
- More information provided when the potential participant contact the researcher and informed consent process follows
- Recruitment procedures need to be elaborated in studies


Healthy Volunteers Needed For a
Research Study of Hand Movements
Earn $10/hour playing computer games
The laboratory of Dr. Krakauer
is seeking healthy volunteers aged 18-40
for a
All studies are
IRB: NA_00048918, A Study
JOHNS HOPKINS
Approved April 16, 2012
Want to participate in a research study on a contraceptive vaginal ring?
If you are a healthy woman between the ages of 18 and 39 and have regular menstrual cycles, you may be eligible for a research study of a method of birth control.
This study will evaluate the effects of receiving two birth control hormones in a vaginal ring.
- Multiple, frequent study visits over an eight mo period
- Visits will occur at Johns Hopkins Bayview
- Participants should be using a non-hormonal method of contraception, or not be at risk for pregnancy
- Compensation for participation and travel
Please call 410 550 3060 or email whrap@jhmi.edu
PI: Anne E. Burke, MD, MPH
Study Number: NA_00068632
IRB number 00002358; February 17, 2011; version 2
Are you interested in a study about how patients talk with doctors?
Researchers at Johns Hopkins need volunteers over 21 years of age for a research study to improve the way doctors and patients talk about depression, feelings and emotions. The main researcher is Debra Roter, DrPH.
You will watch two short videotapes of a doctor conducting a medical visit and imagine that the doctor is talking directly to you. You will be asked to respond to the video doctor in your own words as you would to a real doctor. You will also be asked to answer questions about your reaction to the video tape.
Your participation in the study should take approximately 1 ½ hours. You will be paid for your time and effort.
If you are interested, please call Rita Johnson at 410-502-4129 for more information.





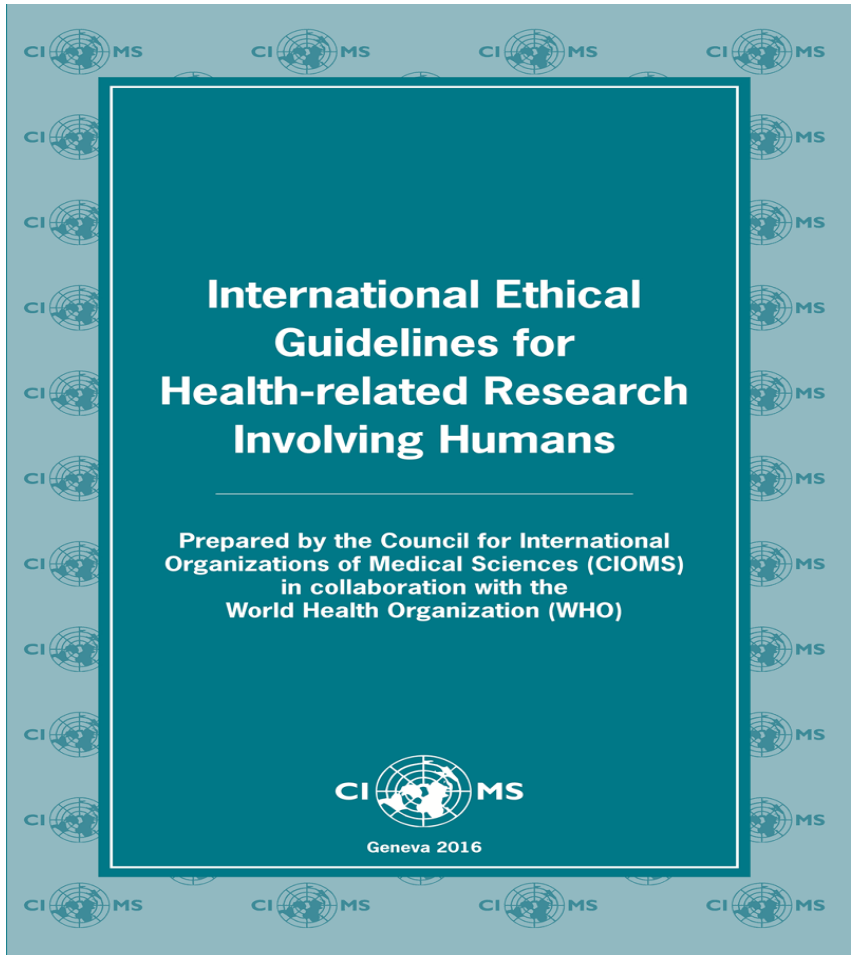
Clinical Trial Recruitment Poster

concepts

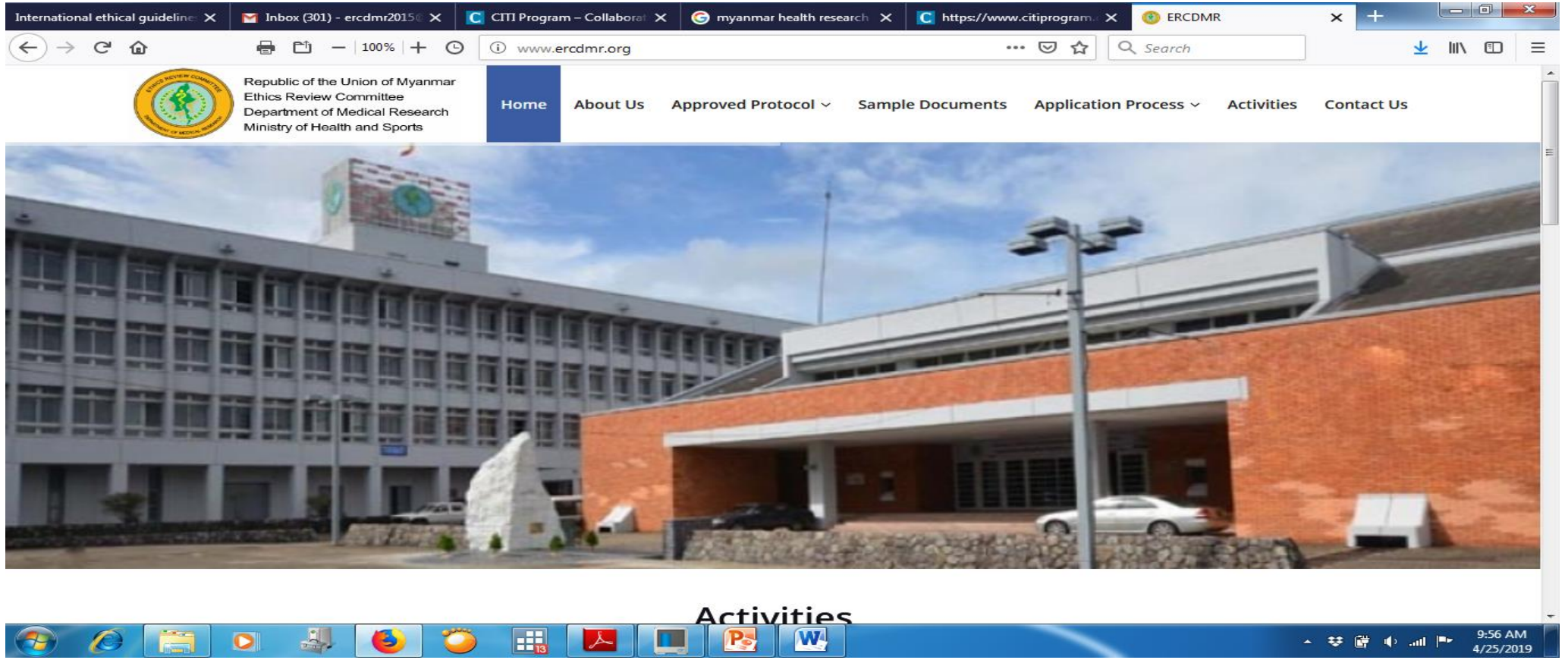
finished product

- ✓ **HONESTY** — conveying information truthfully and honoring commitments,
- ✓ **ACCURACY** — reporting findings precisely and taking care to avoid errors,
- ✓ **EFFICIENCY** — using resources wisely and avoiding waste, and
- ✓ **OBJECTIVITY** — letting the facts speak for themselves and avoiding improper bias.


WMA
Declaration of Helsinki
Ethical Principles for Medical Research
Involving Human Subjects
2013


International Ethical
Guidelines for
Health-related Research
Involving Humans
Prepared by the Council for International
Organizations of Medical Sciences (CIOMS)
in collaboration with the
World Health Organization (WHO)
CIOMS
Geneva 2016

www.irbdmr.gov.mm



- Facebook page- Myanmar Health Research Ethics Initiative

Questions, Comments & Suggestions