Ethical Consideration in Social Studies

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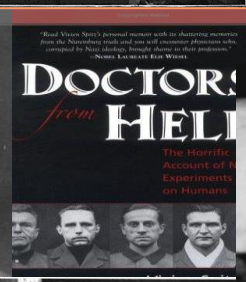
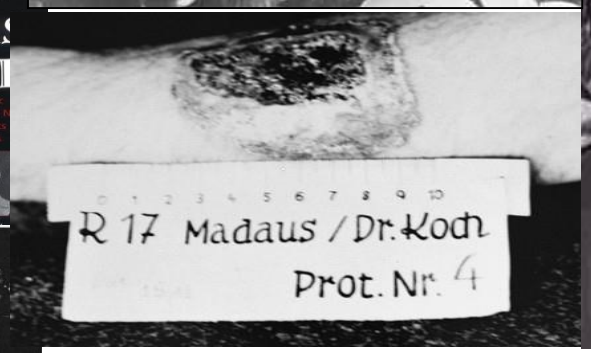
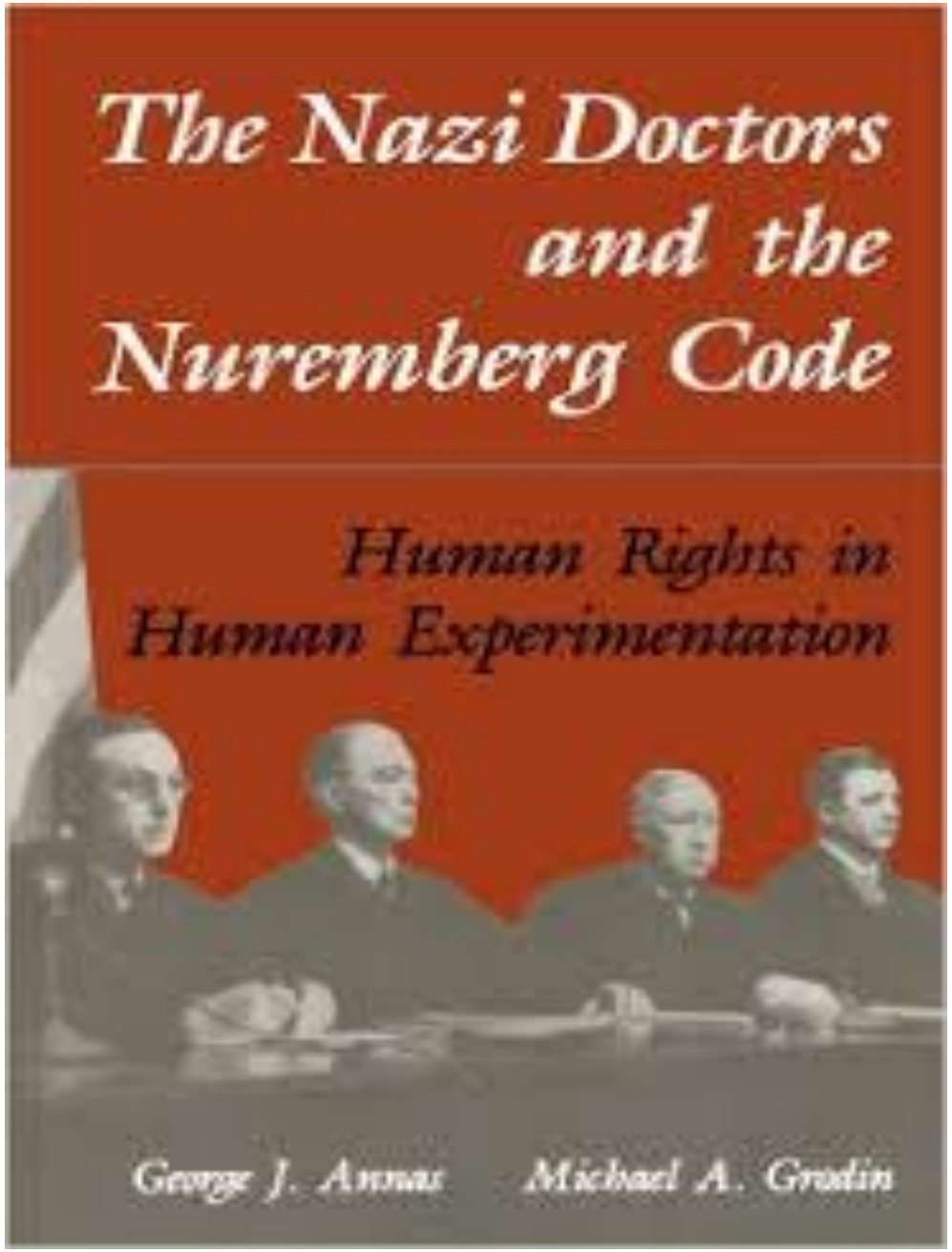
Historical Perspective



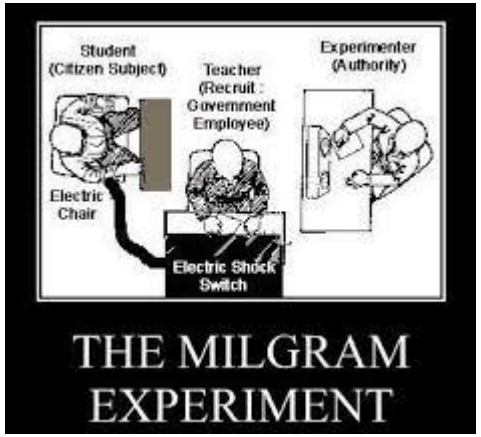


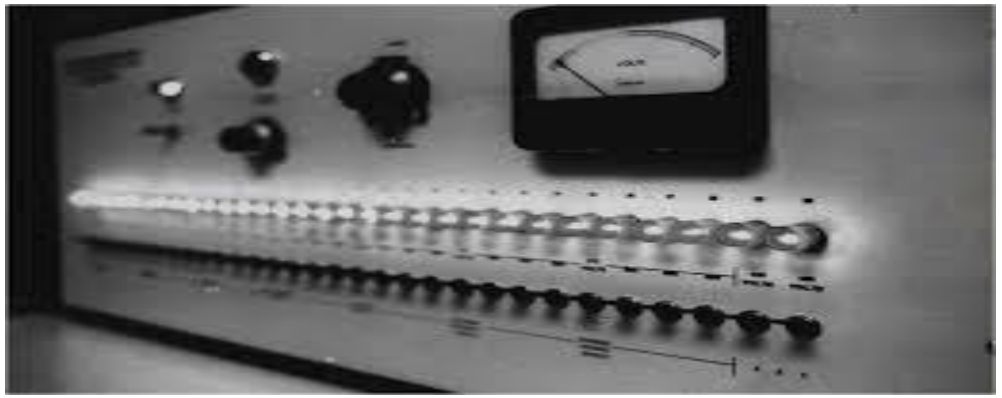
Nazi Medical Experiments (1940 S)

- Nazi physician and their assistants forced prisoners into participating.
- they did not willingly volunteer and no consent was given for the procedures.
- The experiments resulted in death, trauma, disfigurement or permanent disability, and as such are considered as examples of medical torture.


The Nazi Doctors and the Nuremberg Code
Human Rights in Human Experimentation
George J. Annas
Michael A. Grodin

Milgram Experiment





- The Milgram experiment on obedience to authority figures was a series of social psychology experiments conducted by Yale University psychologist Stanley Milgram.
- They measured the willingness of study participants, to obey an authority figure who instructed them to perform acts conflicting with their personal conscience
- Deception – the participants actually believed they were shocking a real person, and were unaware the learner was a confederate of Milgram.
- Protection of participants - Participants were exposed to extremely stressful situations that led them to cause psychological harm.

Ethical consideration

A. Coercion?

B. Privacy?

C. Confidentiality?

D. Risk?

E. Others?

Tearoom Trade study

- **Tearoom trade**: a study of homosexual encounters in public places is a 1970 book by Laud Humphreys, whose Ph.D. dissertation was also titled "**Tearoom trade**.“
- The study is an analysis of male-male sexual behavior in public toilets.
- Humphreys got his information by acting as "watch queen", playing the role of lookout and warning the men if anyone was coming. The men involved did not know he was a researcher.
- They would have been severely stigmatized, their family lives ruined, they could have lost their jobs, or even been arrested and imprisoned.

Ethical consideration

A. Coercion?

B. Privacy?

C. Confidentiality?

D. Risk?

E. Others?

Hawasupai indian genetic

- In 1989, researchers from Arizona State University (ASU) embarked on a research the Diabetes Project with the Havasupai Tribe
- The Diabetes Project with the Havasupai included health education, collecting and testing of blood samples, and genetic association testing to search for links between genes and diabetes risk
- The results were not found a genetic link to Type II Diabetes.
- They used the blood samples containing for other unrelated studies schizophrenia, migration, and inbreeding, all of which are taboo topics for the Havasupai.

Ethical consideration

A. Coercion?

B. Privacy?

C. Confidentiality?

D. Risk?

E. Others?

Social and behavioral research

1. Quantitative study
2. Qualitative study
3. Mix method

Social and behavioral research focuses *not only individuals but also communities.*

Social and behavioral research focuses *not specifically on biomedical, but rather on the areas of attitudes, beliefs, and behavior.*

Sensitive Issues / Stigma?

Ethical principles

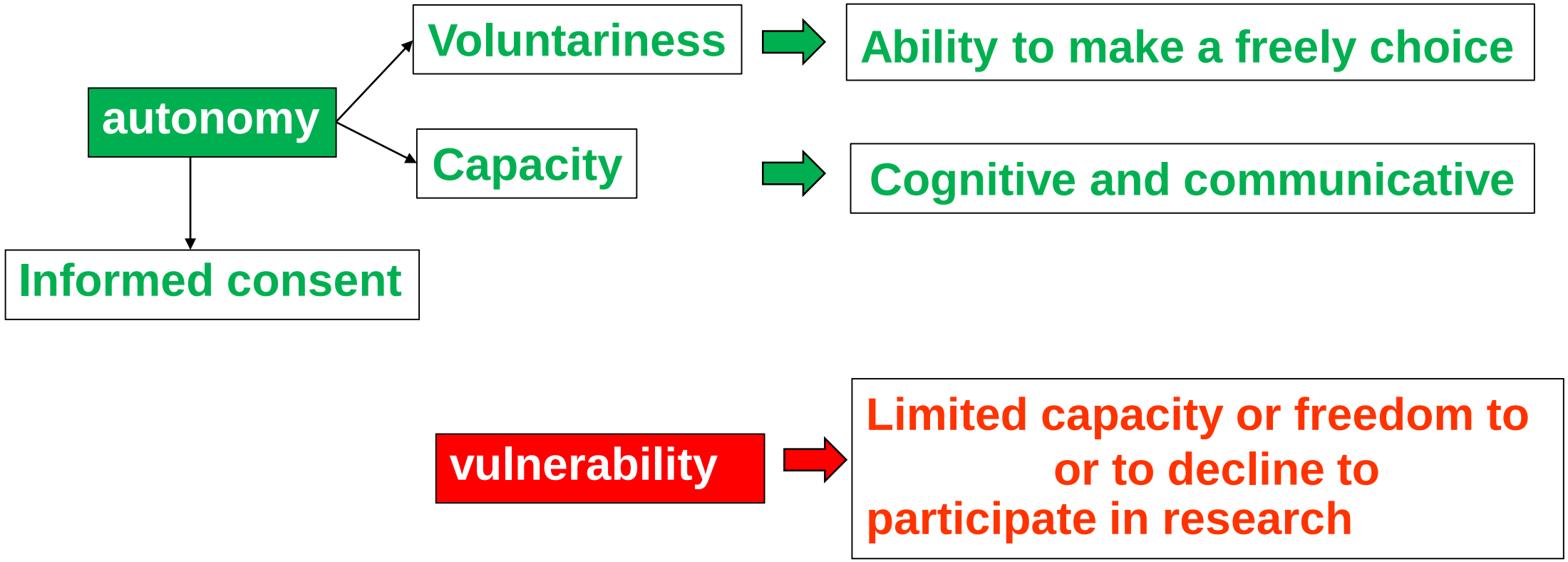
The Belmont Report

- **Respect for persons**
- **Beneficence**
- **Justice**

Permission ***(INFORMED CONSENT)***

Affirmative agreement from a child ***(ASSENT)***

Vulnerability

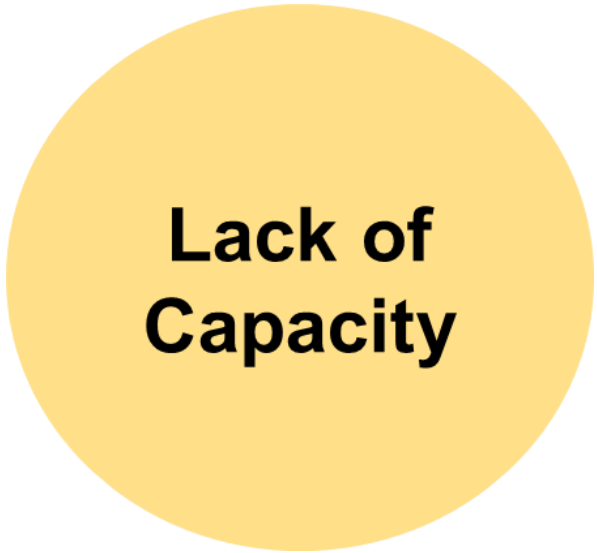


Vulnerable participant

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests

Informally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

Vulnerable participant



- *Children*
- *Mental disorder*
- *Speak/read different language*

- *Student*
- *Employee*
- *Military officer*
- *Prisoner*
- *Poor people*

Vulnerability: additional safeguards

1. Appropriate recruitment

2. Assessment or reassessment of ability to consent.

3. The person's assent should be honored and supplemented by the permission of legal guardians or other appropriate representatives.

4. More frequent continuing review/ oversight needed.

5. An independent data monitoring committee should be set up to exercise oversight of the research.

6. The research subjects and other members of the vulnerable class from which subjects are recruited will ordinarily be assured reasonable access to any products that will become available as a consequence of the research.

Informed consent

- Active *process of sharing information* between the participant and investigator

- Beginning with the *initial* approach to the participant and continuing (arguably) *till the end of the project*

Ensure that:

(1) *information* is fully (adequately) disclosed,

(2) *competent* participant fully (adequately) understand,

(3) his decision is made *voluntarily*

Informed consent

- Who should give consent?
  - Participant
  - Family member
  - Community leader
- What information?
  - How much is needed? Selective disclosure of information ?
  - Is deception allowed ?
- What method? - Voluntary action – Verbal - written

Case study : Consent I

1. การศึกษาการรับรู้และทัศนคติต่อประชาธิปไตย ของผู้ร่วมชุมนุมประท้วงทางการเมือง

Informed consent : waiver

waiver of consent

- No more than *minimal risk*
- Waiver *not adversely affect the rights and welfare of the subjects*
- The research could *not practicably be carried out without* the waiver
- The subjects will be *provided with additional pertinent information* after participation, whenever appropriate

Case study : Consent II

1. การศึกษาการรับรู้ตราบาปทางสังคม และตนเอง ของผู้ให้บริการทางเพศ

Informed consent：waiver

waiver of documentation of consent

- No more than *minimal risk*
- Involves *no* procedures for which *written consent* is normally *required outside the research context*
- The only link the subject and the research would be the *consent document* and the principal risk would be potential harm resulting from a *breach of confidentiality*

Case study : Consent III

การศึกษาปัญหาสุขภาพจิตและพฤติกรรมทางเพศและของผู้ติดเชื้อเอชไอวี ที่มาทำการรักษาที่คลินิกนิรนาม สภากาชาดไทย

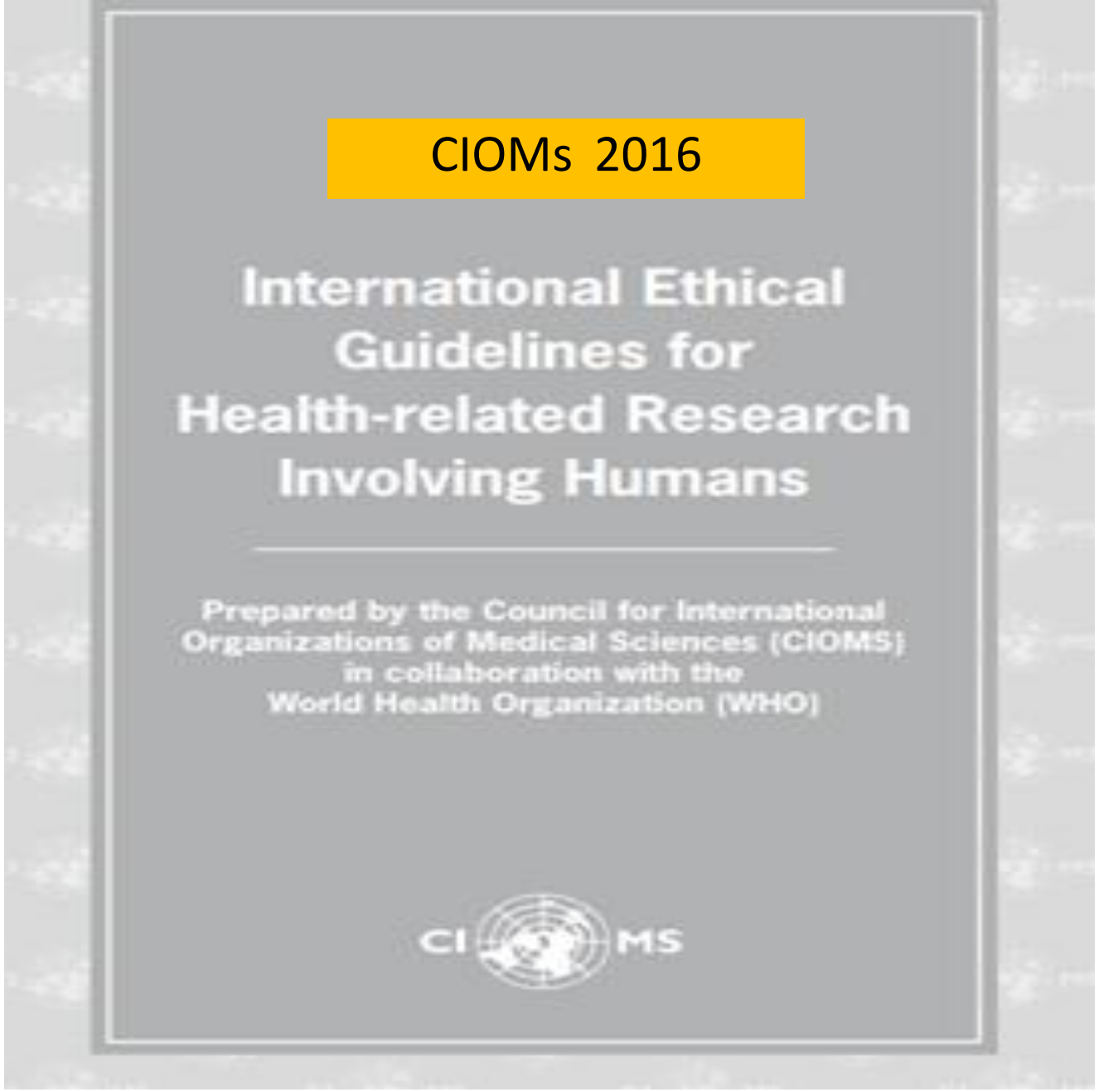
- กลุ่มตัวอย่าง : มีอายุตั้งแต่ 15 ปีขึ้นไป

- เครื่องมือที่ใช้ : แบบสอบถามข้อมูลทั่วไป และประวัติการเจ็บป่วยจาก HIVและการรักษา พฤติกรรมทางเพศ และแบบประเมินปัญหาสุขภาพจิต

ผู้วิจัยคาดว่าผลการศึกษาจะนำไปใช้ในการป้องกันและวางแผนช่วยเหลือปัญหาทางสุขภาพจิตสำหรับผู้ติดเชื้อเอชไอวี

“ผู้วิจัยระบุว่าจะเก็บข้อมูลทุกอย่างของอาสาสมัครเป็นความลับ และหากประเมินพบกลุ่มตัวอย่างที่มีปัญหาสุขภาพจิตในระดับรุนแรง จะทำการส่งตัวอย่างไปรับการรักษากับผู้เชี่ยวชาญหรือจิตแพทย์”

CIOMs 2016


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

Waiver of parental permission. In certain circumstances, research ethics committees may waive parental permission. In such cases, special protections must be devised to ensure that the best interests of these children or adolescents are being served. These circumstances might include cases in which permission of a parent is not feasible or is undesirable. In some jurisdictions, certain individuals who are below the general age of consent are regarded as "emancipated" or "mature" minors and are authorized to consent without the agreement or even the awareness of their parents or guardians. They may be married, pregnant or be parents themselves, or they may live independently. In other cases, studies involve investigation of adolescents' beliefs and behaviour regarding sexuality or use of recreational drugs. Research may also address domestic violence, sexually transmitted diseases, pregnancy, abortion, or child abuse. In these cases, parental knowledge of the topic of the research may place the children or adolescents at risk of questioning, intimidation, or even physical harm by their parents.

A research ethics committee may also allow a waiver of parental permission if the conditions set out in Guideline 10 – Modifications and waivers of informed consent - are satisfied.

Informed consent: questionnaire

- If questionnaire does not contain sensitive material, no obligation to complete, no identification, *return of the questionnaire* will *be taken as implied consent.* (Smith, 1999)

- Questionnaire may be sent out with a simple introduction at the start of the questionnaire. *Where a questionnaire is simple, its return may be adequate to indicate consent*. (Royal college of physicians, 2007)

- If questionnaire is intrusive and/or may cause distress, *participants' consent must be sought before sending the questionnaire* to them and *the fact* that some of the questions may be distressing to some individuals *should be explained in the preliminary letter*. (Royal college of physicians, 1996)

Case study : Assent

1. Genotype study of children with ADHD age between 5-7 years

Informed consent : minors

Minors are presumed legally incapable of making decision.

Minors have limit life experiences.

Minors are more likely to be emotional, financial, and intellectual vulnerability.

Minors are more likely to be under influences.

Informed consent = Parental permission + Minor assent

Assent

Assent = Active Affirmative Agreement

- Address only issues that minors care about
- Use short, simple, understandable, and meaningful language
- Written assent may not be required
- Compensation should be told after assent has been obtained

Deception

1. Pattern of parenting style among parents toward children with temper tantrum behavior.

Deception

- Minimal risk but high value

- No other research method would suffice for achieving the valid result

- Nothing has been withheld that, if divulged, would cause a reasonable person to refuse to participate

- Approved by IRB

Apology

Debrief

Respect the right to refuse the use of obtained information

Debrief

- Provide appropriate information

- Correct any misconception

- Refer for professional help if something problematic

Protecting

- Research data bases
  - protect privacy and confidentiality of data to prevent stigmatization
    and other types of harm
  - anonymize data

- Safeguard for vulnerable subject

Benefit

Potential Benefit

- To society: “develop knowledge”

  To participant: *rarely expected*

  To others: sometimes to small group

  sometimes in form of capacity building

Risk

“The probability and magnitude of harm or discomfort anticipated in the (proposed) research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”

Level of Risk

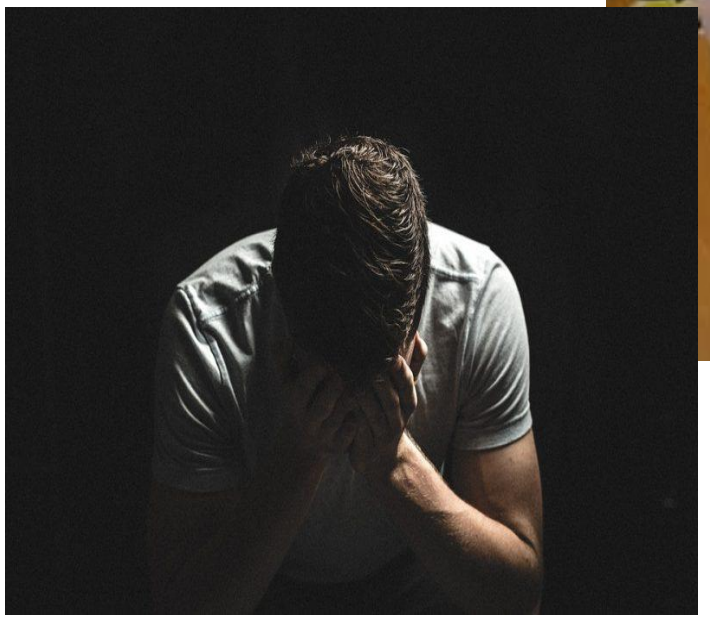
- Minimal risk: the probability and magnitude or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life

- Greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

- Greater than minimal risk and no prospect of direct benefit to the individual subjects but likely to yield generalizable knowledge

Type of Risk

- Physical
- Psychological
- Social
- Economic
- Legal



Case study : Risk in social study

- โครงการพัฒนาแบบคัดกรองเพื่อเฝ้าระวังเด็กที่ถูกทารุณกรรม
- การศึกษานำร่องความชุกของเด็กที่ถูกทารุณกรรมในชุมชนคลองเตย

Type of Risk

Risk in SBR

- Physical: not much involve
- Psychological: feeling inconvenient, unnecessary anxiety or distress, precipitation or relapse of behavior disorder, uncalled-for self knowledge
- Social: embarrassment, ostracism, stigmatization, loss of status or credibility
- Economic: job loss, decrease employability, false hope
- Legal: arrest, prosecution

Risk

Level of harms

. *Primary subject level*: distress or discomfort

. *Secondary subject level*: someone else's information

. *Community level*: group stigma

Justice

- ***Justice : Distributive***
  - This principle requires that there be *fair procedures* and outcomes in the selection of research subjects.

Privacy

Privacy determination

Publicness in the location *(public place ?)*

Publicness of the person *(public-figure ?)*

Degree of anonymity *(linkable ?)*

Nature of information *(sensitive ?)*

Webb et al, 1981

Confidentiality

The right to maintain the privacy of personal data divulged during a scientific or professional relationship with another party.

Preserving confidentiality

Restrict access

Anonymity

Informed consent

Confidentiality

General principles

1. Personal data should be *held only for* specified purposes.
2. Data must be *used only for* those purposes.
3. Personal data should be *held no longer than* is necessary for purposes.
4. Personal data must be *adequate, relevant and not excessive* in relation to the purposes.
5. Personal data shall be *accurate* and kept *up to date.*
6. Data must be *disclosed only to* those people described in the protocols or informed consent form.
7. Individuals have the *right to access* data held about themselves and where appropriate to have the data corrected or deleted.
8. *Appropriate security measures* shall be taken against unauthorized access to, or alteration, disclosure or destruction of personal data and against its accidental loss.
9. Research *results must not be disclosed without participants' consent.*

Confidentiality

For access to records without contacting participants

1. An officer gives *written permission.*

2. The principal *recipient* of the information *should be professional* who is subject to an effective disciplinary code enforced by their professional body over any breach of confidentiality.

3. *State the reason* for which the records are needed and what *steps* will be taken to keep them confidential.

4. Persons who will have access to the records should sign a declaration of confidentiality.

5. Participants should be *identified only by code.*

Confidentiality

Contacting participants

1. When direct contact with participants with a particular condition is involved, *individual consent* is required,

2. Initial contact should be *made through the primary doctor*, or doctors employed in the same department,

3. For a home interview, interviewer should be accompanied on the first visit by the participant's family doctor or *someone else who is personally known to them*. If not possible or inappropriate, *a definite appointment should be made* and the name of the interviewer should be conveyed in advance and identification should always be shown.

4. Contact using letter has a potential serious source of breaches of confidentiality.

Confidentiality

Use of audio/video recordings (RCP 2007)

1. There should be *provision for removal of consent after the recording has been made and an offer to review the recording* if wished. Material can then be destroyed if wished.

2. Many audio and video recordings represent a valuable store of data. *REC approval should not normally be contingent upon destruction of data on completion of the project.*

3. If data storage is planned, the REC should *assess the security, access and possible future uses of the data. Any future project should be the subject of further research ethics approval*.

4. *Consent should always be requested from patients for all medical photography and for subsequent use of their images*, whether or not they can be identified.

Framework for ethical consideration

- Research value
- Research validity
- Appropriateness of recruitment
- Risks/benefits analysis
- Vulnerability and additional safeguard
- Informed consent
- Community and cultural concerns
- Confidentiality

Social science & Anthropology

“ มายาคติอาข่าในสังคมไทย คลายปมมิดะและลานสาวกอด”

จัดโดย

ชมรมอาข่าแห่งประเทศไทย

โครงการจัดตั้งพิพิธพันธ์อารยธรรมลุ่มน้ำโขง มหาวิทยาลัยแม่ฟ้าหลวง

Community

- Identifying areas of particular ***concern*** to communities

- Determining how to ***contact*** community members

- Designing ***consent*** seeking procedures

- Providing feedback of research ***conclusion*** to the community

- Considering community-level ***confidentiality***

Community research: concern

- Respect for community autonomy
- Eliciting ideas for interventions to improve population health
- seeking to enhance community capacities

Buchanan, Miller, Wallerstein. 2007

Conclusion

Most SBR are minimal risk research but not without risk.

Data collection methods of SBR determine most risk considerations.

Carefully consider issues of deception, privacy, and confidentiality.

กรณีศึกษา

ปัญหาเด็กพัฒนาการล่าช้าทางสติปัญญา ในชนเผ่า ทางภาคเหนือ

ผู้วิจัยได้รับรายงานจากสาธารณสุขและครู ในเขตพื้นที่ จังหวัดแม่ฮ่องสอน ว่าในชนเผ่าโอ้ลัลล้า มีเด็กที่มีพัฒนาการล่าช้าหรือปัญญาอ่อนเป็นจำนวนมาก

ผู้วิจัยสนใจ ภาวะโภชนาการ เรื่องการมีเพศสัมพันธ์ในหมู่เครือญาติ และการพันธุกรรม ว่าเป็นสาเหตุหนึ่งของการเกิดปัญญาอ่อน

- มีประเด็นอะไรที่ควรพิจารณาทางจริยธรรมการวิจัยในการวิจัยนี้เป็นพิเศษ?

References

- Bernard Lo. Ethical Issues in clinical research: A practical guide.2010.
- Robert Amdur & Elizabeth A. Bankert. Institutional Review Board Member . Third edition, 2011.