

# โครงการวิจัยทางด้านสุขภาพ

# Good Health Research Proposal

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การประชุมเชิงปฏิบัติการ

โครงการฝึกอบรมคณะกรรมการจริยธรรมการวิจัย ระดับเขตและจังหวัด

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- **Review of Research Process**
- **Characteristics of a Good Research**
- **Ethical basis criteria for decision-making in Good Health Research Proposal**
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# Research Process

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- 1. Selection & formulation of Research Problem**
- 2. Literature survey**
- 3. Development of working hypotheses**
- 4. Research design**
- 5. Sampling strategy or sample design**

# Research Process

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- 6. Ethical issues**
- 7. Data collection**
- 8. Processing & analysis of data**
- 9. Testing hypotheses**
- 10. Interpretation & generalization**
- 11. Preparation of the report**

# Characteristics of a Good Research

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- It demands a clear statement of the problem (Research Question).
- It requires clear objectives and a plan (it is not aimlessly looking for something in order to come across a solution).
- It builds on existing data, using both positive and negative findings.
- New data should be systematically collected and analyzed to answer the original research questions/objectives.

# Ethical basis criteria for decision-making in good health research proposal

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- 1. Scientific design and conduct of the study*
- 2. Risks and potential benefits*
- 3. Selection of study population and recruitment of research participants*
- 4. Inducements, financial benefits, and financial costs*
- 5. Protection of research participants' privacy and confidentiality*
- 6. Informed consent process*
- 7. Community considerations*

# 1. Scientific design and conduct of the study

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- *Research is ethically acceptable only if it relies on valid scientific methods.*
- *Research that is not scientifically valid exposes research participants or their communities to risks of harm without any possibility of benefit.*

# 1. Scientific design and conduct of the study

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- The Research design, methods should be scientifically sound, and examine the ethical implications of the chosen research design strategy.
- RECs should also assess the qualifications of the researcher(s), the adequacy of provisions made for monitoring and auditing, as well as the adequacy of the study site.



## 2. Risks and potential benefits

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- In ethically acceptable research, risks have been minimized and are reasonable in relation to the potential benefits of the study.
- The nature of the risks may differ according to the type of research to be conducted.

## 2. Risks and potential benefits

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- Risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration.
- Further, harm may occur either at an individual level or at the family or population level.

### 3. Selection of study population and recruitment of research participants

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- Ethically acceptable research ensures that no group or class of persons bears more than its *fair share of the burdens* of participation in research.
- Similarly, no group should be deprived of its *fair share of the benefits* of research;
- Benefits include the direct benefits of participation as well as the *new knowledge* that the research is designed to yield.

# 3. Selection of study population and recruitment of research participants

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- Ethically acceptable research includes
  - *Recruitment strategies*
  - that are balanced and objectively describe the purpose of the research,
  - the risks and potential benefits of participating in the research, and other relevant details.
  - Inclusion and Exclusion criteria

## 4. Inducements, financial benefits, and financial costs

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- It is considered ethically acceptable and appropriate to reimburse individuals for any costs associated with participation in research, including
  - transportation
  - child care, or lost wages.

## 4. Inducements, financial benefits, and financial costs

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- it is ethically acceptable to compensate participants for their time.
- However, payments should not be so large, or free medical care or other forms of compensation so extensive, as to induce prospective participants to consent to participate in the research against their better judgment or to compromise their understanding of the research.

# 5. Protection of research participants' privacy and confidentiality

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- Invasions of privacy and breaches of confidentiality are
  - disrespectful to participants
  - feelings of loss of control or embarrassment
  - social stigma
  - rejection by families or communities
  - lost opportunities such as employment or housing

# 5. Protection of research participants' privacy and confidentiality

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- RECs should therefore examine the precautions taken to safeguard participants' privacy and confidentiality.



# 6. Informed consent process

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- The ethical foundation of informed consent is the principle of respect for persons.
- Competent individuals are entitled to choose freely whether to participate in research, and to make decisions based on an adequate understanding of what the research entails.

# 6. Informed consent process

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- Decisions for children or adults who lack the mental capacity to provide informed consent should be made by an authorized surrogate decision-maker.
- RECs may waive the requirement of informed consent only when doing so is consistent with international guidelines and national standards.

# 7. Community considerations

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- Research has impacts not only on the individuals who participate, but also on the communities.
- Duties to respect and protect communities are aimed at minimizing any negative effects on communities such as
  - stigma or draining of local capacity, and promoting, as relevant, positive effects on communities, including those related to health effects or capacity development

# 7. Community considerations

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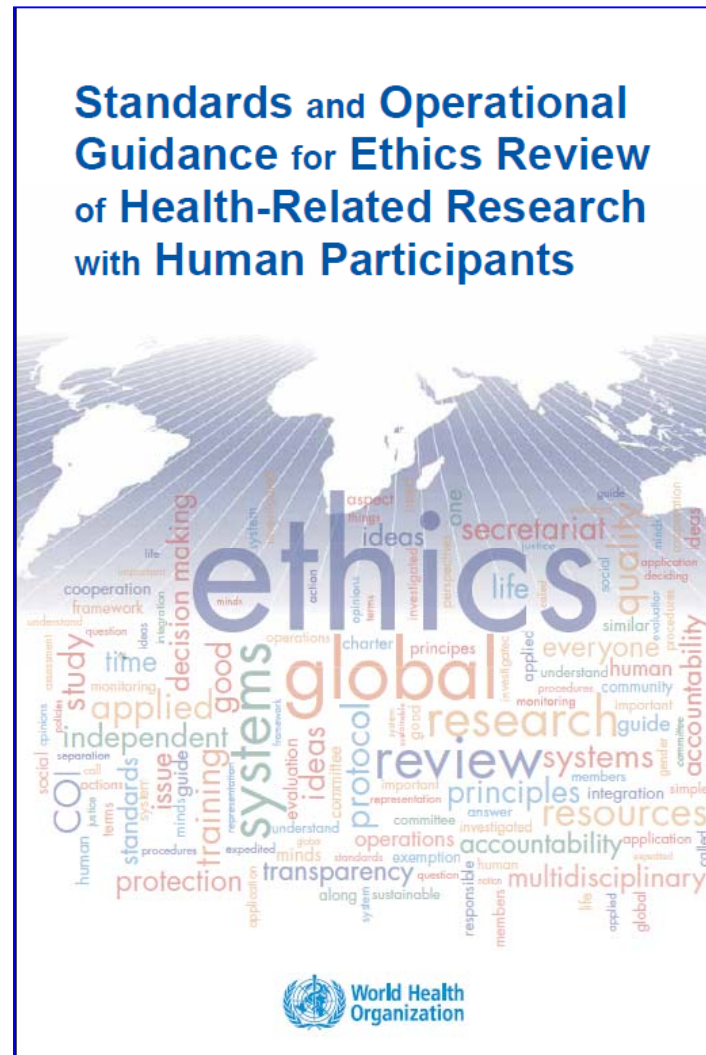
- Researchers should actively engage with communities in decision-making about the design and conduct of research (including the informed consent process), while being sensitive to and respecting the communities' cultural, traditional and religious practices.

# *Decision-making procedures for research ethics committees*

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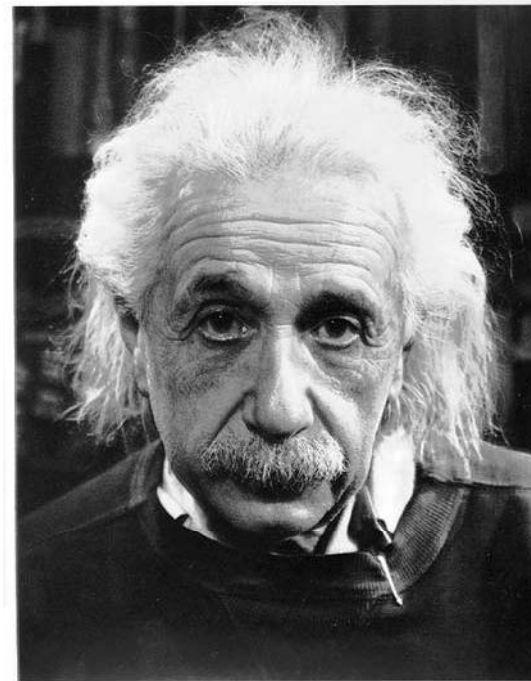
- Decisions on research protocols designated for review by the convened REC are based on a thorough and inclusive process of discussion and deliberation. **Protocols involving no more than minimal risk** and burden to research participants may be reviewed on an expedited basis by one or more members (rather than the full committee), if the REC has established written procedures permitting such a procedure.

# Reference



[http://www.who.int/about/licensing/copyright\\_form/en/index.html](http://www.who.int/about/licensing/copyright_form/en/index.html)

# Question ?



**"If you can't explain it simply, you don't understand it well enough"**

- Albert Einstein