

Introduction to Research Ethics in Clinical Trials



HIV/AIDS Treatment Access Advocacy Workshop Series



Canadian Treatment Action Council



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Workshop Overview

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1. Preliminary notions:
clinical trials and guiding ethical principles.
2. Analysis and discussion of some key paragraphs of
the Declaration of Helsinki.
3. Identifying:
 - information to receive and to understand
before consenting;
 - main obstacles to a free and informed
consent.



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Section 1

Preliminary notions:

- ▶ Clinical trials
- ▶ Guiding ethical principles



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Phases of Clinical Trials

Clinical trials can be categorized into 4 phases:

- Phase I – safety
- Phase II – dosing
- Phase III – efficacy
- Phase IV – post-approval

Phases often overlap in practice



Clinical Trials - ethical foundation

- In a clinical trial of a new drug, not all study participants receive the drug
- Study drug compared to standard treatment (“control arm”)
- How is this ethical?



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Clinical Trials - ethical foundation

- At start of trial, benefits of a new treatment are hoped for but unproven.
- Therefore, no proven advantage to either receiving, or not receiving, study drug.
- This is referred to as “**clinical equipoise**”.
- As soon as definitive data is available, this “equipoise” changes.
- (I.e., if early data clearly shows a benefit, ethics demand that study be discontinued and all participants given equal access to the treatment.)



TCPS 8 Guiding Ethical Principles

1. Respect for Human Dignity.
2. Respect for Free and Informed Consent.
3. Respect for Vulnerable Persons.
4. Respect for Privacy and Confidentiality.



TCPS 8 Guiding Ethical Principles

5. Respect for Justice and Inclusiveness.
6. Balancing Harms and Benefits.
7. Minimizing Harm.
8. Maximizing Benefit.



Section 2

Analysis and discussion of
some key paragraphs of
the Declaration of Helsinki



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Declaration of Helsinki

5. In medical research on human subjects, considerations related to **the well-being of the human subject should take precedence over the interests of science and society.**



Declaration of Helsinki

20. The subjects must be volunteers and informed participants in the research project.



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Declaration of Helsinki

22. (...) each potential subject must be adequately informed ...

[including]:

- aims, methods, sources of funding
- possible conflicts of interest
- anticipated benefits and potential risks of the study and discomforts it may entail



Declaration of Helsinki

22. (...) each potential subject must be adequately informed ...

... of the **right to abstain** from participation in the study **or to withdraw** consent to participate at any time without reprisal.



Declaration of Helsinki

31. (...) The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.



Declaration of Helsinki

22. (...) **After ensuring that the subject has understood the information**, the physician should then obtain the subject's freely-given **informed consent**, preferably in writing.



Declaration of Helsinki

8. **Some research populations are vulnerable and need special protection.**

- The economically and medically disadvantaged.
- Those who cannot give or refuse consent for themselves.
- Those under duress.
- Those for whom the research is combined with care.



Declaration of Helsinki

28. (...) When medical research is combined with medical care, **additional standards apply to protect the patients who are research subjects.**



Declaration of Helsinki

23. (...) if the subject is in a dependent relationship with the physician or may consent under duress... the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.



Declaration of Helsinki

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.



Section 3

Identifying:

- ▶ Information to receive and to understand before consenting,
- ▶ Main obstacles to a free and informed consent.



Information to receive and to understand before consenting

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- Analysis of the general information which is always required (page 12 of the participant package).
- Analysis of the additional information which may be required (page 13 of the participant package).
- What else?



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Main obstacles to a free and informed consent

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- How much time does it take to fully understand and evaluate the pros and the cons?
- Whom can a potential subject consult outside the research team?
- Is the potential subject in a state of shock?
- May the decision impact the quality of the patient-physician relationship?



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Main obstacles to a free and informed consent

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- Is it really possible for a consent form to contain all the information needed for a truly informed consent?
- Who would be able to understand such a long and complex text?
- What else?



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Final round-table discussion

- How do theory and practice compare? What are the gaps?
- Would you be interested in participating in other workshops on research ethics? If yes, what topics or activities do you propose?



Contact us:

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Tools for Action: HIV/AIDS Treatment Advocacy Workshop Series

PO Box 116, Station "F"

Toronto, Ontario M4Y 2L4

Telephone & Fax: (416) 410-1369

Email: tfa@ctac.ca

Website: www.ctac.ca/tfa



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THANK YOU!



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