Conflicts of Interest
and Financial Disclosure

2012 HA Practical Workshop on Clinical Research Compliance

Henry Yau  BSc (Biochemistry)  MBA (Finance)

Tel:  +852 9097 0567
Email:  yauhenry@hotmail.com
Conflicts of Interest and Financial Disclosure

Highlights:

- Concepts of conflicts of interest
- Conflicts of interest in clinical research
- Disclosure requirements by the Declaration of Helsinki
- Disclosure requirements by the U.S. FDA
Conflicts of Interest:
The co-existence of multiple interests, where pursuing one interest could compromise the other.

Potential conflict of interest:
A party is involved in multiple interests that might come into conflict

Real conflict of interest:
A party cannot pursue one interest without compromising another interest

How to prevent transformation of potential to real conflict of interest?
Potential and Real Conflict of Interest

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Disclosure
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Potential Conflicts of Interest in Clinical Research

- **Trial subjects:** Rights, safety and well-being
- **Public:** Integrity of data and people’s health
- **Investigators:** Significant interests in a clinical trial
Potential Conflicts of Interest in Clinical Research

- Proprietary interest in an investigational product (e.g. patent, trademark)
- Equity interest in an organization owning the rights to an investigational product (e.g. stocks, stock options)
- Financial payments or valuables other than the costs for running a trial (e.g. honoraria, donation of equipment)
- Financial arrangements liking to study outcomes (e.g. royalty interests in the sales of a product)
- Decision-making or consulting position in an organization owing the rights to a product (e.g. director, scientific committee member)
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The **protocol** should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.
Applicability:
Any investigator participating in a clinical trial targeting at supporting a marketing authorization of a medical product by the U.S. FDA (i.e. New Drug Application (NDA) or Premarket Approval of Device (PMA))

- Any equity interest in the sponsor that exceeds US$50,000
- Any proprietary interest in an investigational product
- Any financial payment or compensation of over US$25,000 in addition to the costs of conducting a study
- Any financial arrangement linked to study outcomes
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- Any financial payment or compensation of over US$25,000 in addition to the costs of conducting a study
- Any proprietary interest in an investigational product
- Any equity interest in the sponsor that exceeds US$50,000
Investigator has the responsibility to update such information during a clinical trial and one year after completion of the trial.

Any financial arrangement linked to study outcomes.
Any financial payment or compensation of over US$25,000 in addition to the costs of conducting a study.
Any proprietary interest in an investigational product.
Any equity interest in the sponsor that exceeds US$50,000.

Steps should be taken to minimize the potential bias resulting from the disclosed interests.

Any interest disclosed does not automatically prohibit an investigator from involving in a clinical trial. The FDA would assess if such interests could create bias and if measures are taken to minimize such bias.
HA REC: Investigator’s Conflict of Interest Declaration Form

In the initial research ethics review application for a clinical study:

- Complete the form and submit to a Cluster REC.
- Update the REC during the course of the study.

Disclosure Requirements by the HA
Conflicts of Interest and Financial Disclosure

Final Remarks:

• Potential conflicts of interest needs to be managed
• Disclosure is a key measure