Conflicts of Interest

and Financial Disclosure

2012 HA Practical Workshop on Clinical Research Compliance

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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 pursing one interest could compromise the other.

Potential conflict of interest:

A party is involved in multiple interests that might come into conflict

How to prevent transformation of potential to real conflict of interest?

Real conflict of interest:

A party cannot pursue one interest without compromising another interest

Conflicts of Interest:

The co-existence of multiple interests, where pursing one interest could compromise the other.

Potential conflict of interest:

A party is involved in multiple interests that might come into conflict

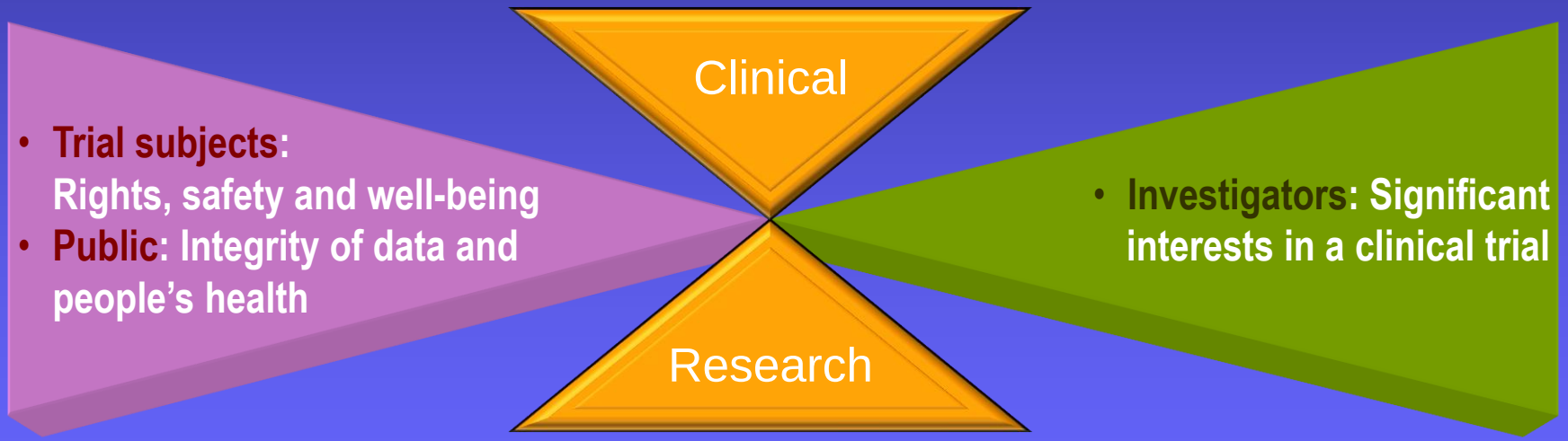
Disclosure

Real conflict of interest:

A party cannot pursue one interest without compromising another interest

Conflicts of Interest:

The co-existence of multiple interests, where pursing one interest could compromise the other.



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)

Declaration of Helsinki: Disclosure

Disclosure in Protocol

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.*

Declaration of Helsinki: Disclosure

Disclosure in Informed Consent

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.*

Disclosure Requirements by the Declaration of Helsinki

Declaration of Helsinki: Disclosure

Disclosure in Publications

30. *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.*

Disclosure Requirements by the Declaration of Helsinki

21 CFR 54: Financial Disclosure by Clinical Investigator

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

Disclosure Requirements by the U.S. FDA

21 CFR 54: Financial Disclosure by Clinical Investigator

Applicability:
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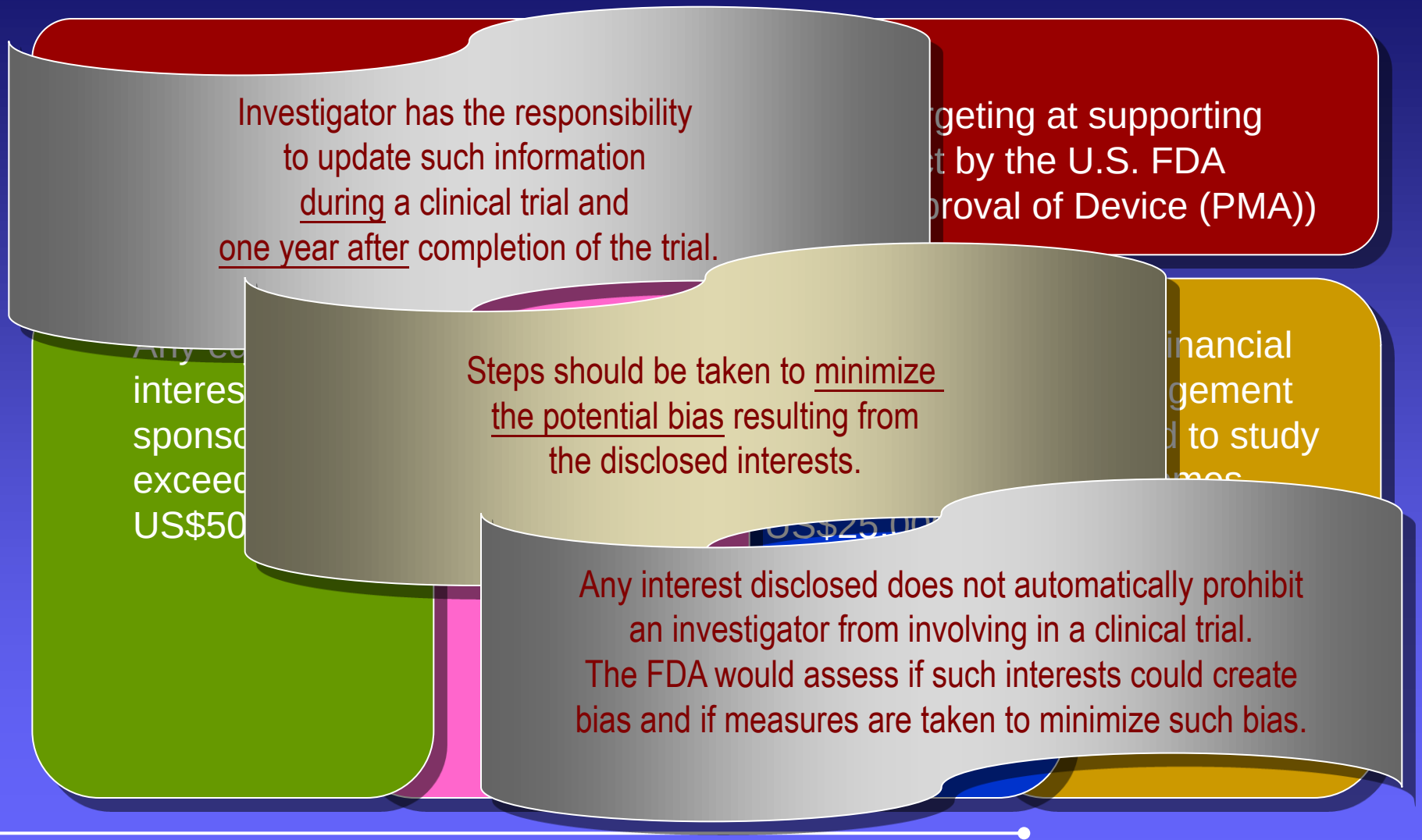
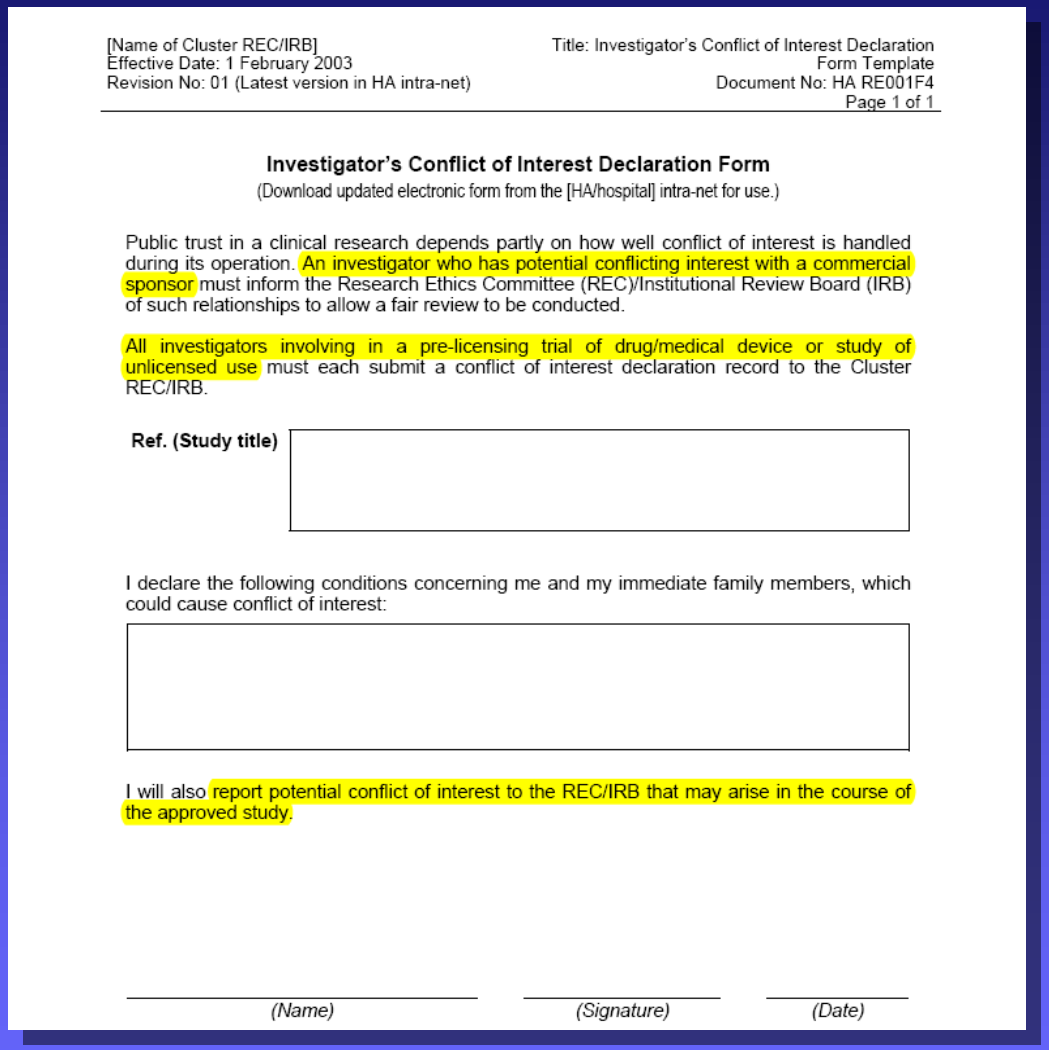
21 CFR 54: Financial Disclosure by Clinical Investigator



Disclosure Requirements by the U.S. FDA

HA REC: Investigator's Conflict of Interest Declaration Form



[Name of Cluster REC/IRB]
Effective Date: 1 February 2003
Revision No: 01 (Latest version in HA intra-net)

Title: Investigator's Conflict of Interest Declaration Form Template
Document No: HA RE001F4
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Investigator's Conflict of Interest Declaration Form

(Download updated electronic form from the [HA/hospital] intra-net for use.)

Public trust in a clinical research depends partly on how well conflict of interest is handled during its operation. An investigator who has potential conflicting interest with a commercial sponsor must inform the Research Ethics Committee (REC)/Institutional Review Board (IRB) of such relationships to allow a fair review to be conducted.

All investigators involving in a pre-licensing trial of drug/medical device or study of unlicensed use must each submit a conflict of interest declaration record to the Cluster REC/IRB.

Ref. (Study title)

I declare the following conditions concerning me and my immediate family members, which could cause conflict of interest:

I will also report potential conflict of interest to the REC/IRB that may arise in the course of the approved study.

(Name) *(Signature)* *(Date)*

- Complete the form and submit to a Cluster REC in an initial research ethics review application for a clinical study
- Update the REC during the course of the study

Disclosure Requirements by the HA

Final Remarks :

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