DEVELOPING AND IMPLEMENTING A FINANCIAL CONFLICT OF INTEREST POLICY
A FINNISH PERSPECTIVE

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1. BACKGROUND

- US funding, together with other intl. research funding, is of strategic importance for University of Helsinki (UH).
- Since 1995, to get a single dollar from the US Public Health Service (PHS), Financial Conflict of Interest (FCOI) compliance is required.
- Over 950 institutions incl. some from EU have certified compliance.

WHAT COULD A FCOI LOOK LIKE?
Think of an investigator receiving funds from the National Institutes of Health (NIH) who does not report having shares in a diagnostics company taking part in the project.

2. FCOI POLICY DEVELOPMENT

- Development process from initial UH ad hoc procedure to final UH FCOIP is shown in Figure 1.
- UH FCOIP is acknowledged by the Federal Demonstration Partnership as of 19.12.2014.

FIGURE 1. Timeline of events leading to UH FCOIP approval.

- Investigator submits Financial Disclosure (FD) to Department Director or Delegate (DD) at application stage
- DD determines if Significant Financial Interest exists
- If YES, DD along with Director of Research Affairs (DRA) will determine whether it constitutes a FCOI
- If NO, Investigator continues project. Need to resubmit FD annually, through grant duration
- DD reports FCOI to US Public Health Service & if applicable, to coordinator (=Prime awardee)
- If FCOI exists:
  - DD & DRA develop written management plan, which Investigator undersigns;
  - DD & DRA monitor compliance
- Non-compliance with FCOI or its management plan:
  a) Suspension Process is initiated by DD, with possible disciplinary action/sanction, plus notification to PHS & Prime
  b) Retrospective Review Process is initiated (as further detailed in the Policy)

FIGURE 2. Summary of the key processes under UH’s FCOIP.

WHAT IF FCOI IS NOT PROPERLY HANDLED?
If FCOI is not disclosed or properly managed, University of Helsinki & US Public Health Service can suspend all project activities.

3. UH FCOI POLICY FEATURES

- Investigator is responsible for making financial disclosure.
- Department Director/Delegate evaluates & monitors
  - If FCOI exists, a management plan is required.
- No disclosure or no management of FCOI can lead to suspension of research activities & disciplinary actions.
- Key processes in policy implementation included:
  - Assigning roles & responsibilities.
  - Informing, training & guiding investigators and departments
  - Incl. use of CITI training.
  - Training as continuous process > role of research advisors

4. CONCLUSIONS

- Long, complex, resource-demanding, but successful process, so far.
- Gradual development, partly thanks to reliance on US coordinators.
- Monitoring sub-awardees (when UH coordinates) is a major challenge.
- Challenging to keep up to date with US/international regulations.
- Collaboration at national & international level as an opportunity for joint development and improving capacities.

5. REFERENCES

- List of institutions with certified compliance with PHS FCOI rules & regulations: http://nrc59.nas.edu/pub/fcoi_list.cfm
- FCOI Policy of the University of Helsinki: https://www.helsinki.fi/en/research/research-ethics
- Federal Demonstration Partnership website, incl. model forms: http://sites.nationalacademies.org/PGA/fdp/PGA_061001
- University of Helsinki Research Services’ page: https://university.helsinki.fi/en/research/services-for-researchers

*UH Public Health Service issues FCOI regulations
*UH group is notified by US coordinator of blocking of NIH funds until FCOIP is in place
*UH allocates resources, interns
*UH adopts FDP's FCOI Model to develop UH Policy; Federal Demonstration Partnership website, incl. model forms
*UH develops FCOIP over 6-month period
*UH accepts FDP/FCOI Model to develop UH Policy; Federal Demonstration Partnership website
*UH submits FD for first time & prior to start of project
*UH submits FCOIP every 6 months
*UH adopts FDP/FCOI Model to develop UH Policy; Federal Demonstration Partnership website