



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Code of Conduct – Revision 4

A perspective from Academia

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Do we need a Code Of Conduct? ...in 2009

- 'nothing new' – transparency and scientific independence are principles that are covered under scientific integrity,
- applies to industry, not academia – we follow these rules already
- another tick-box exercise / example of red tape
- further administrative burden on the PI / researcher – duplication of effort (protocol amendments, reports) if already

-> WE JUST WANT TO GET ON WITH THE SCIENCE!!



Do we need a Code Of Conduct? ...in 2017

- ? Public confidence in scientific integrity waning
 - 'whitewash, incompetence, cover-up '
 - not just pharma but regulators, individual researchers / experts
 - Failure to publish perceived as an attempt to conceal a concerning finding
 - Publication without peer-review – does it count?
- A mechanism that increases confidence in PV/PE study findings is required

Will following the ENCePP Code of Conduct achieve this?



Work plan mandate 2017-2019

Explore how the Code could be further strengthened by:

- 1. Additional **tools to support good governance** of pharmacoepidemiological research, taking into account the provisions and governance models of the ADVANCE Code of Conduct developed for collaborative vaccine studies (private-public partnerships);*

Should reference to the ADVANCE CoC be included in The ENCePP CoC ?

e.g. "Studies in which industry/ private companies are both the funder and investigator do not comply with the ENCePP CoC. In such cases please refer to the Advance Code of Conduct "

→ opinion divided within WG2

? Ivory tower vs. real world OR a loophole that undermines the very purpose of

3 the ENCePP Code



Aspect of the practical application that still require refinement

- **Currently, the researcher undertakes a self-assessment of their scientific independence – is this sufficient?**
- **What is the mechanism for demonstrating compliance with the Code?**
- **Does compliance with the Code actually achieve what it sets out to?**
**(ie. reduce the risk of conflicts of interestsstrengthen public confidence
.....ensure highest quality standards)**



Discussion and questions to ENCePP Plenary

Do you endorse the proposed revisions to the Code and publication in Q1/2018 with:

- Clarifications on scientific independence, including the proposed
 - Definition and
 - Provisions regarding:
 - Separate powers of PLI from power of funding organization;
 - **Allow PLI role only to researchers with personal interests (no commercial, financial or institutional interests); NO – the definition of 'personal ' interests is wider than just being interested in a topic**
 - Clarify that protocol agreement is more complex if the study is requested by a regulator;
 - Make conflict of interest declaration compulsory;
- Seal related procedures moved in a separate document but maintenance of the Seal concept and conditions on a voluntary basis?
- ⁵ • Other proposed changes? -



We need feedback from ENCePP members !

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