EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Checklist of the ENCePP Code of Conduct for ENCePP Seal studies[1]

The purpose of this checklist is to emphasize the core elements of the ENCePP Code of Conduct that are relevant at the time of study start. The act of completing this checklist confirms that the study for which the ENCePP Seal is applied for complies – at the time of submission - with the key requirements of the Code. Of note, completion of the checklist does not release researchers of ENCePP Seal studies from their obligation to adhere to the entirety of the provisions of the Code.

The checklist must be completed by the (primary) lead investigator of the study for which the ENCePP Seal is applied for. The (primary) lead investigator must:

- Tick all boxes of each section thereby confirming compliance of the study with the core requirements of the Code. In case of sub-sections (e.g. 2.A. and 2.B.), tick all boxes of the sub-section that applies to your study.
- If applicable, provide additional information as requested.
- Sign the checklist.

The undersigned declares upon honour the following answers on behalf of the organisation that he/she represents. Signature should be by the (primary) lead investigator.

1. General	**Check**
The study has been designed ➢ in line with the general principles outlined in the Code (see chapter 5 of the Code), and	☑
➢ providing for a maximum level of transparency (see chapter 4 of the Code).	☑
2. Research contract	**Check**
2.A. Studies financed purely from one's own general resources (100 % self-funded)	
A declaration on the use of one's own general resources, making clear references to the study and the (primary) lead investigator and being signed by (an) authorised representative(s) of the participating study entity/ies is available.	☐

[1] Complete the Checklist on screen, then print, sign and stamp it (if applicable).

2.B. Studies receiving financing from external sources	
A research contract between the (primary) lead investigator and/or the coordinating study entity and the study funder has been concluded prior to study start.	☑
The contract includes the following information: ➢ The main objectives and a brief description of the intended methods of the research as well as a clear assignment of tasks and responsibilities. ➢ The procedure for achieving agreement on the study protocol as well as the involvement of the funder in the development of the protocol. ➢ The amount of the financial support and the payment scheme. ➢ Conditions for access to the study data. ➢ Ownership of intellectual property rights arising from the study ➢ A communication strategy for the scheduled interim (if applicable) and final results.	☑ ☑ ☑ ☑ ☑ ☑
2.B.1 Studies financed entirely from public funding schemes	
A reference to the Code is included in relevant parts of the project proposal or equivalent documents[2] in such a way that acceptance of the project proposal or equivalent document by the funding body constitutes agreement to adhere to the provisions of the Code including the requirement for unrestricted freedom of the investigator to publish.	☐
2.B.2 Studies not financed from public sources	
The statement "The parties to this agreement and individuals acting on their behalf hereby commit to adhere to the rules of the ENCePP Code of Conduct in their entirety" is included in the research contract and the latest version of the Code at the time of the signature of the contract is annexed; OR where this is not possible, a separate agreement with the funder has been concluded that clearly references the particular study, includes the above statement on adherence to the Code and states that this adherence with the relevant version of the Code is an additional requirement to those in the (clearly referenced) research contract.	☑
3. Registration of studies	**Check**
The study has been/will be registered[3] in the EU PAS Register before its start.	☑

[2] Any document that includes a description of the study to be funded and that has been endorsed or is otherwise recognised by the funding body

[3] A study is deemed registered in the EU PAS Register once the application has been approved by the ENCePP Secretariat.

4. Study protocol	Check
A full study protocol[4] has been developed before study start.	☑
The latest version of the full study protocol is uploaded to the EU PAS Register[5].	☑
A system is in place to allow for documentation of changes to the original version of the study protocol in a traceable and auditable way.	☑
Information on all parties involved in the writing and adoption of the protocol including a brief description of their contribution is being made publicly available.	☑
A detailed statistical analysis plan is described and included in or annexed to the study protocol.	☑
5. Intellectual property rights and sharing of data	**Check**
A system has been put in place in order to record the data collected and processed in the study in a way that allows corroboration of published results.	☑
A detailed description of how raw data were transformed into the data set for analysis will be available at the end of the study.	☑
All possible steps to provide for audits by competent authorities will be taken.	☑
Appropriate plans and agreements, if necessary, are being or have been made to respond to requests for data sharing in line with the *Implementation Guidance on Sharing of ENCePP Study Data* (Annex 4).	☑
A procedure for access to the analytical data is described in, or annexed to, the study protocol including the degree to which data can be shared and, if access is restricted, a justification why access is limited. Please indicate the page number in the study protocol:	☑
6. Declaration of interest	**Check**
Declarations of interests of all parties involved in the conduct of the study are documented and be made public (including members of the study steering group, if such group is being established).	☑
All persons with a financial interest in a particular outcome of the study are excluded from participation from any study activity which could influence the results or interpretation thereof in a particular direction.	☑

[4] For the purpose of the Code of Conduct, a *full* study protocol is a version of the protocol which includes enough detail in order to answer all questions in the *ENCePP checklist for Study Protocols*. The *Checklist* is available at http://www.encepp.eu/encepp_studies/documents/ENCePPChecklistforStudyProtocols.doc.

[5] When uploading the protocol in the EU PAS Register, it may not be immediately accessible to the public unless the (primary) lead investigator so chooses.

7. Study Steering Group	Check
7.A. Absence of a Study Steering Group	
Please check here if no Steering Group is foreseen for the study.	☑
7.B. Establishment of Study Steering Group foreseen	
No expert with a direct conflict of interest is appointed as a member of the Steering Group	☐
The composition of the Steering Group is being/will be made publicly available.	☐

8. Publication / Reporting of studies	Check
Appropriate plans and agreements, if necessary, have been made (e.g. as part of the dissemination and communication policy) ensuring publication of results	
➢ including results from prematurely terminated studies.	☑
➢ independent of statistical significance and whether the results are positive or negative.	☑
➢ in form of a clear summary of the main results.	☑
➢ in form of an abstract to be provided to the ENCePP Secretariat within 3 months after the final study report. (Note that requests for delays are possible pending response to peer-review comments).	☑
➢ in form of a full report of all results with a scientific or public health impact without delay (taking into account relevant legal provisions in case of a suspected public health impact).	☑
➢ independently by the (principal) lead investigator irrespective of data ownership.	☑
➢ providing for the possibility of review by the study funder prior to submission – but without unjustified delay.	☑
➢ considering comments from the study funder and enabling the study funder to request changes to the presentation of the results to delete confidential information.	☑
➢ making publicly available comments of the funder.	☑
➢ taking into account the provisions for authorship of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals by the International Committee of Medical Journal Editors (2009).	☑

9. Confidential information	Check
A definition of what constitutes confidential information has been agreed between the parties of the research contract.	☑

The definition of confidential information does not consider data and results as being confidential except in relation to relevant data privacy laws.	☑

Name of the coordinating study entity: RTI-Health Solutions

Name of (primary) lead investigator: Alejandro Arana

Date: 22/12/2017 (dd/mm/yyyy)

Signature: [redacted]

Stamp (if applicable):

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