EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Checklist of the ENCePP Code of Conduct for ENCePP 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 status "ENCePP Study" 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 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 status "ENCePP study" is applied for. The (primary) lead investigator must:

- Tick all boxes of the checklist thereby confirming compliance of the study with core requirements of the Code.
- 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**
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 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.	☒

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

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. ☒
- Ownership of and access to the data produced during the study. ☒
- A communication strategy for the scheduled interim (if applicable) and final results. ☒

3. Registration of studies	Check
The study has been registered[2] in the ENCePP Register of Studies.	☒

4. Study protocol	Check
A full study protocol[3] has been developed before study start.	☒
The latest version of the full study protocol is uploaded to the ENCePP Register of Studies[4].	☒
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. Data ownership and access to 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 verification of published results.	☒
Appropriate plans and agreements, if necessary, are being or have been made to grant, upon request, access to data and results as detailed below once the final study report is available:	
➢ Data set used for analysis.	☒
➢ Detailed description of how the raw data were transformed into the data set for analysis.	☒
➢ All scheduled interim and final study findings irrespective of positive or negative results.	☒

6. Declaration of interest	Check
Declarations of interests of all parties involved in the conduct of the study are collected and documented (including members of the study steering group, if such group is being established).	☒

[2] A study is deemed registered in the ENCePP Register of Studies once the application has been approved by the ENCePP Secretariat.

[3] 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 *Checklist of Methodological Standards for ENCePP Study Protocols*. The *Checklist of Methodological Standards for ENCePP Study Protocols* is available at http://www.encepp.eu.

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

Details of participation in the study of parties with a conflict of interest (if any) are documented and are being made publicly available.	☒
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.	☒

7. Study Steering Group	Check
If a study steering group has been/will be established, the following rules are/will be applied:	☒
➢ No expert with a 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	

Please tick all of the above boxes in section 7 if no steering group is foreseen for the study, as well as the following box. ☒

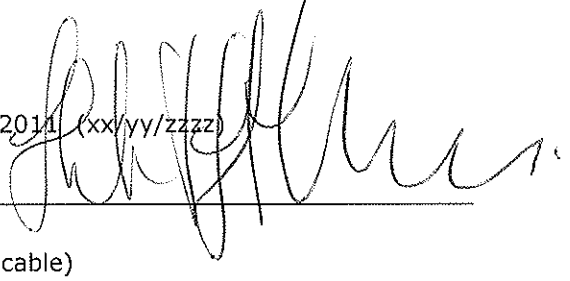
8. Publication/Reporting of studies	Check
Appropriate plans and agreements, if necessary, have been made (e.g. as part of the dissemination and communication policy) ensuring publication of results	
➢ including results from prematurely terminated studies.	☒
➢ independent of statistical significance and 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: Department of Clinical Epidemiology Aarhus University Hospital

Name of (primary) lead investigator: Professor Henrik Toft Sørensen, MD, PhD

Date: 21 / 1 / 2011 (xx/yy/zzzz)

Signature: 

Stamp (if applicable)