EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Code of Conduct:
Implementation Guidance for Access to Study Data

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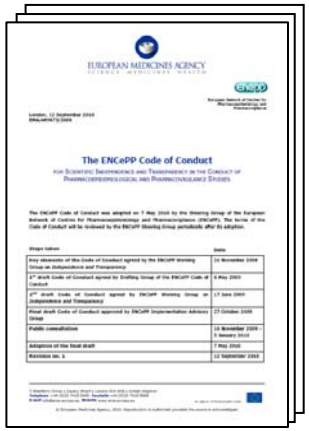
The Code – Relevant documents

Code of Conduct
(adopted on 7 May 2010, Rev. 1 on 12 Sept 2010)

3 Annexes:

- Definitions (Annex 1)
- Checklist for ENCePP studies (Annex 2)
- Declaration on compliance (Annex 3)



NEW

Implementing Guidance for Access to Study Data (12 Sept 2010)

Available on ENCePP website at http://www.encepp.eu/code_of_conduct/index.html

Purpose

- Provide guidance on the implementation of the Code's provision requiring researchers of ENCePP studies to provide access to data upon request.

- Define clear (minimum) criteria based on which access should be granted as well as the procedure for handling such requests.

Provision on access to data

Code of Conduct, Chapter 12
"Data Ownership and Access to Data"

(...) Access to the data set used for analysis, as well as a detailed description of how the raw data were transformed into the data set for analysis, and all scheduled interim and final study findings - irrespective of positive or negative results - should be provided on request once the final study report is available. (...)

Open issues/questions

- Who should be able to gain access?
- When – i.e. for which purpose(s) – should access by provided?
- What about data privacy in case of personally identifiable data?
- High workload/burden for researchers.
- Who decides when and to whom to provide access?
- …

Access to data

When? Access should be provided

- on request,
- after final study report.

What? to

- Data set used for analysis (may be aggregated data only, but should be the full set of data independent of whether all data or related results have been published or not).
- All scheduled interim and final study results.
- Description of how raw data were transformed into data set for analysis.

Minimum Access Criteria

The request for access to data is made

- for the purpose of verifying the study results with a view to improving **Public Health**, or
- to confirm **compliance with the Code**.

The requesting party can be **any third party** and

- shall be **clearly identifiable** (name of individual, affiliation and contact details), and
- shall **provide sufficient information** to confirm that the request is made for one of the above-mentioned purposes, including a sound justification and, in case of a request in relation to Public Health reasons, a **protocol** on the research for which the data will be used.

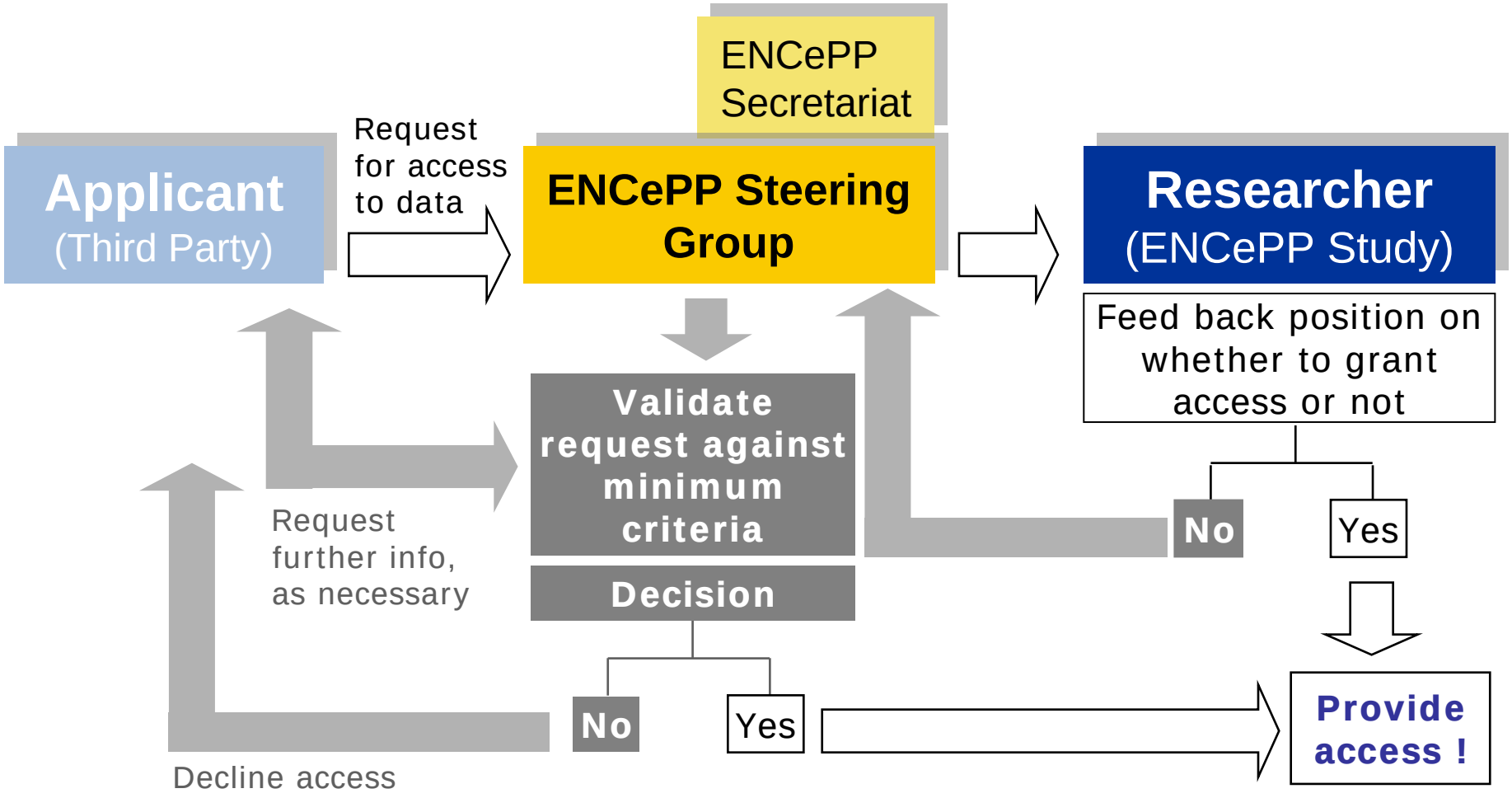
“Verification of study results”

- If there is evidence of conflicting results of different/separate studies addressing the same research question.

  ⇨ access may be restricted for the sole purpose of identifying differences (e.g. methodological) that explain the discrepancies between the reported outcomes;

- In case of suspected methodological issues which might impact on the study outcome, e.g. inappropriate accounting for confounding factors.

Procedure


ENCePP Secretariat
Applicant (Third Party)
Request for access to data
ENCePP Steering Group
Researcher (ENCePP Study)
Feed back position on whether to grant access or not
Validate request against minimum criteria
Request further info, as necessary
No
Yes
Decision
No
Yes
Provide access !
Decline access

Issue log for 1st review of the Code

⇨ **General review either 1 year after launch (8 June 2010) or after registration of 15 ENCePP studies whichever comes earlier – taking into account experience from practice.**

⇨ **Issue log: Critical aspects / areas to be actively monitored**
(public consultation, comments from ENCePP and Steering Group)

Access to data:

- Licence or governance rules of databases might prevent researchers from providing access to data to third parties.
- How to provide access, i.e. locally within the research organisation of the data owner sufficient?
- Experience/suitability of researcher (to ensure proper research) to be taken into account?
- Conflicts of interest of applicants (competitors, etc).
- Reimbursement.