

Confidentiality of ethical assessment in the context of animal use for scientific purposes

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Despite advances in *in vitro* and *in silico* models, medical and more broadly health research still requires the use of living animals that, in France, is subject to prior ministerial authorization for each scientific research project. European Directive 2010/63/EU, transposed into French law in 2013, requires ethics committees to respect the confidentiality of information that is considered implicit by the” Ministère de l’enseignement supérieur et de la recherche” (Ministry of Higher Education and Research).

Until recently, the documents for this authorization describing the projects and the conditions of their implementation were not intended to be made public, except for a non-technical summary used to inform the European Alures database. However, based on opinions issued by the “Commission d'accès aux documents administratifs” (Commission for access to administrative documents), and confirmed by several administrative court rulings, animal rights associations opposed to the use of animals for scientific purposes have requested the disclosure of authorization application files for this type of projects.

The French Academy of Medicine, the French Academy of Pharmacy, the French Academy of Sciences and the French Veterinary Academy consider that disclosure of all information contained in the application file would seriously harm France's research and innovation capabilities and would lead to a loss of opportunity for patients, without improving animal welfare.

- It leads then to the public disclosure of files containing original working hypotheses and innovative research methodologies to competing teams, even before the project implementation.
- Moreover, although in theory the names of the researchers must be hidden by the competent authority, the exhaustive bibliography on the subject required by the project authorization application contains naturally previously published

articles of the applicants in connection with the project theme. This makes it easy to trace back to the applicant, with all the pitfalls that this can entail. Putting the names of people and institutions involved in projects into the public domain exposes them to the risk of pressure and violent actions such as those frequently observed for several years in many countries.

- Finally, in economic terms, placing the project's content in the public domain, before it has been implemented and the results obtained, not only enables competing teams to seize the French teams' lead, but also creates an anteriority in the context of a patent application. Given that experimental data on animals is a prerequisite for filing a patent application for a medical innovation, and that this patent cannot be accepted if there is precedence in the discovery, this makes it, de facto, impossible for this type of work.

- Considering (1) the importance of biomedical research in improving patient “healthcare pathway”, (2) the still necessary use of animal models before implementing new therapies in humans, and (3) the economic role of the biomedical sector in France, and considering further that the law explicitly states that information affecting the safety of individuals and secrets protected by law may not be disclosed, and that disclosure may only be made if subject to intellectual property rights, the French Academy of Medicine, the French Academy of Pharmacy, the French Academy of Sciences and the French Veterinary Academy request:

-The withdrawal of any information that could identify, directly or indirectly, the persons involved in the design and implementation of the project, as well as the contact details of the user establishment where the project will be implemented. This deletion applies to the entire authorization application, and in particular to the bibliographic paragraphs.

-Information prior to placing the designer of the application in the public domain by the Ministry of Higher Education and Research after hiding the sensitive information.

-A right to review by the project designer in accordance with the regulations on intellectual property. This right must be able to be exercised before all or part of the document describing the project being placed in the public domain. It must also be able to be exercised on the concealments proposed by the Ministry of Higher Education and Research. In all cases, the Ministry of Higher Education

and Research must obtain a written authorization from the designer(s) before disclosure of all or parts of the authorization application project.

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