



Confidentiality ethical assessment in use of animals for scientific purposes

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Despite advances in *in vitro* and *in silico* models, medical and wider health research still requires the use of live animals. In France, the use of animals in scientific research is subject to prior ministerial authorisation for each research project. European Directive 2010/63/EU, transposed into French law in 2013, requires ethics committees to respect the confidentiality of information. It is considered implicit at the level of the Ministry of Higher Education and Research.

Until recently, the documents describing the projects and the conditions under which they were implemented, which led to this authorisation, were not intended to be made public, with the exception of a non-technical summary used to populate the European Alures database. However, basis of opinions issued by the Commission d'accès aux documents administratifs (Commission for Access to Administrative Documents), confirmed by several administrative court rulings, animal rights associations opposed to the use of animals for scientific purposes have requested the disclosure of authorisation application files for projects using animals for scientific purposes .

The Académie nationale de Médecine, the Académie nationale de Pharmacie, the Académie des Sciences and the Académie Vétérinaire de France consider that disclosure of all the 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.

- This means that files containing original working hypotheses and innovative research methodologies are placed in the public domain, and are therefore available to competing teams, even before the project is implemented.
- On the other hand, although in theory the names of the researchers must be masked by the competent authority, the exhaustive bibliography on the subject required by the project authorisation application is naturally enriched by the articles of the authorisation applicants. This makes it easy to trace back to the applicant, with all the pitfalls that this can entail. Placing the names of people and institutions involved in projects in the public domain exposes them to the risk of pressure and violent action of the kind that has proliferated in recent years in many countries.
- Finally, in economic terms, placing the content of the project in the public domain before it has been implemented and the results obtained not only enables competing teams to take advantage of the lead given by the French teams, but also leads to the creation of a prior art in context of a patent application. Bearing in mind that experimental data on animals is essential for filing a patent application for a medical innovation, and that the latter

cannot be accepted if there is prior art, which makes it de facto impossible to obtain a patent for this type of work.

- Considering (1) the importance of biomedical research improving care, (2) the still necessary use of an animal model before implementing a new therapy in humans and (3) the economic role of the biomedical sector for France, considering also that the law explicitly states that information affecting the safety of individuals and secrets protected by law may not be communicated and that communication may only be made subject to intellectual property .. the Académie nationale de Médecine, the Académie nationale de Pharmacie, Académie des Sciences and the Académie Vétérinaire de France request :The deletion of any information enabling the direct or indirect identification of 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 application for authorisation and in particular to the bibliographic paragraphs.
- The Ministry of Higher Education and Research informs the creator of the application before it is placed in the public domain, after sensitive information has been removed.
- A right of inspection by the project designer in accordance with intellectual property regulations. This right must be exercised before all or part of the document describing the project is placed in the public domain. It must also be possible to exercise this right with regard to the blackouts proposed by the Ministry of Higher Education and Research. In all cases, the Ministry of Higher Education and Research obtain written authorisation from the designer(s) before disclosing all or part of the project authorisation request.

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