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Technical Briefing

for Members of the European Parliament
on the proposals to replace Directive 86 609:

Authorisation process: Ethical, Scientific and Replacement Review

Revised directive reference: Articles 1, 4, 13, 26, 33, 35, 36, 37, 45, 53, – ethical and scientific review, transparency, public accountability and authorization of projects.

ADI recommendation: It is essential that the review process for project authorization is seen to be independent, transparent, and accountable at every level.

It is also essential that the review process includes both scientific justification and consideration of replacements, as well as ethics.

Ethical, scientific and replacements review should take place at both national and local level.

The review process should allow public access to anonymised applications with confidential and proprietary information removed, in order to facilitate a wider scientific scrutiny of project proposals, over the internet.

Wider scientific scrutiny can be time-limited to, say 60 days.

ADI is concerned that Recital 29 is not fully reflected in Articles 25 and 26.

A model for a Local Ethical, Scientific and Replacements Review Process

It is essential that the proposed local ethical review process is independent of the establishment, is inclusive of a wide range of expertise, and considers scientific justification and replacement options, as well as ethics.

A model of independent review committees already exists, in the human research ethics committees framework. This can be adapted for animal research project applications.

ADI believes that ethical and scientific review bodies should include experts in the field under discussion (not connected to the laboratory), experts in ethics and welfare, experts in replacements and at least three lay persons.

We would envisage this local ethical review process to feed into the review conducted by the national authority prior to authorisation, providing the national authority with advice and expertise.

The framework for human research ethics committees (REC) in the UK is as follows:

- Human RECs are accountable, transparent and completely independent and no members of the research team or subsidiary workers play a role in decision-making.
- The RECs are permanent and recognised by the government.
- REC members undergo continual training appropriate to their role and adhere to standard operating procedures, which are compatible with European and UK law.
- Members are recruited from a range of backgrounds, taking ethnicity, age and gender into consideration.
- Composition and structure of a REC is standardised, with a mixture of independent scientific experts and lay members. Around a third consists of lay members. Expert members are chosen to ensure a balance of expertise in research methodology, statistics, data analysis, pharmacy and clinical and general practice.
- Due to the permanency of the lay members' roles and signatures to confidentiality clauses, indiscretion is not viewed as a problem.
- If the content of the proposal falls outside the remit of any committee members, a REC may call upon a specialist to provide additional advice.

- At meetings where an ethical opinion of research is provided a quorum consisting of 7 members (out of 12) is present, including the Chair and Vice-Chair, an expert and a lay person. A meeting does not take place if a quorum is not available.
- Applicants are invited to attend and will be questioned about the validity of their research. A decision is made in 60 days.
- A REC will request, at a minimum, an annual report from a researcher, at which time it may reconsider its opinion. On completion of a project it will receive a final report within 3 months.
- RECs may carry out site-specific assessments.
- An independent overseeing body is responsible for monitoring the operational management of RECs. We would envisage this role being fulfilled by the national authority.

Standard Operating Procedures for Research Ethics Committees, May 2008 <http://www.nres.npsa.nhs.uk/news-and-publications/publications/standard-operating-procedures/>

Aims and purpose of an Ethical, Scientific and Replacements Review Board (ESRB)

Using the human research ethics committees as a template can guide us to the appropriate composition and functions of an animal ethical and scientific review body.

It has been suggested that in order to improve the ethical and scientific review process for animal research, there should be three main objectives. The process should:

- “ensure the ethical acceptability of all research projects involving animals” . Thereby ensuring the research is scientifically necessary, high quality and that alternatives are considered.
- Improve public confidence in the review process
- Give researchers, who need to ensure the acceptability of their work, the ability to work more effectively and efficiently

(Ethical review of research involving animals: A role for institutional Ethics Committees? (March 2005) The Boyd Group <http://www.boyd-group.demon.co.uk/ethicscomms.htm>)

Factors for consideration in ethical and scientific review

In addition to carrying out a **cost-benefit analysis** of the proposed research (see ADI cost – benefit analysis technical brief), it is also possible that “*certain ethical limits may also be identified*”. This is because it may be judged that certain reasons for using animals are unacceptable, irrespective of the how ‘little’ harm is caused to the animal. This would be the case if the purpose of the research was of insufficient seriousness or there existed alternatives to animal use. In addition certain procedures may be judged as unacceptable, irrespective of the likely benefits, because the harms are too severe, or alternatives exist (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

Following the initial ethical review, “**Effective on-going review should be incorporated into the ethical review process**”. This could be achieved if there was on-going monitoring and evaluation by all the staff involved and also more formal processes such as an interim review of projects, thereby giving an opportunity to re-consider the ethical issues arising in the work.

The cost / benefit analysis could be re-evaluated in light of the actual harms suffered and any benefits (such as in the Swiss severity system, see ADI cost-benefit analysis TB). Implementation of the 3 R’s and the need for any training or additional advice could also be assessed.

Retrospective reviews, when the study has been completed, will help to inform future ethical evaluations and allow the various parties to learn from the process.

(FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

The benefits of the system

Benefits of animal ethical and scientific review bodies include:-

- The opportunity for the members to discuss “best practise” and ethical issues which will assist in the cost / benefit analysis.
- Best practice in animal welfare and science will be encouraged within institutions, including learning about advanced alternative methods.
- Widening the consultation on research issues, thereby improving the soundness of such decisions and also public confidence in these decisions.
- The institution possibly deriving broader educational benefits and providing them with a way of communicating with external groups

(Ethical review of research involving animals: A role for institutional Ethics Committees? (March 2005) The Boyd Group <http://www.boyd-group.demon.co.uk/ethicscomms.htm>)

Composition, organisation and roles of the ethical review bodies

The experts sitting on the ethical review body should have the same status as scientists performing the scientific evaluation (European Commission: Ethics for Researchers <ftp://ftp.cordis.europa.eu/pub/ftp7/docs/ethics-for-researchers.pdf>) . Recommendations by ethical review bodies should hold enough weight that their decisions are implemented. This should include being given the power to stop animal studies where necessary, for example if the authorisation is exceeded (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

The composition of the committee should encompass a wide range of views, foster an atmosphere of public trust and confidence in the work, to command respect within the institution and to have the support of the institutions management (Ethical review of research involving animals: A role for institutional Ethics Committees? (March 2005) The Boyd Group <http://www.boyd-group.demon.co.uk/ethicscomms.htm>)

The participants involved in the ESRBs need to be from diverse backgrounds. It should be a requirement for the composition of the panel, to reflect a range of expertise. Aside from those who actually use laboratory animals it should be mandatory for the body to include at least:

- One member from an animal welfare background
- One alternatives expert (for the relevant field of research)
- External expert in the relevant field.
- Three lay members

In order to ensure that the highest level of assessment is being made, Member States should provide a panel of alternative experts, each specialising in a particular field of research. Depending on the application to be reviewed, it would then be possible to involve an alternatives expert who can provide the best advice for the application. The same should apply to animal welfare experts who should have specific competence in the relevant species in question (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

The importance of lay members should not be underestimated. These members, who could be from various backgrounds such as human resources, sociologists, legal experts and academics from the arts, can provide novel and independent perspectives on the issues and allow for a measure of public representation (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

Although researchers at the establishment should be involved in the process to the extent that it will provide them with 'educational benefits', they need not be present at deliberation or decision making as it is important to ensure that the independence of the ethical review process, and its members, is not compromised (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

Ethical review bodies should involve local elements to their work, such as visiting animal facilities so that they can 'see for themselves' the standards of animal husbandry and care and expertise of personnel involved (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf) This would be particularly beneficial to members who are not familiar with how animal facilities are run, such as lay members.

The current situation in some Member States

Although almost every Member State has some form of ethical evaluation, they differ to a great extent. Differences include the legal status of the system, level of implementation and elements involved in the process Commission staff working paper 05.11.08 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2410:FIN:EN:PDF> . Some consistency is needed throughout the EU, so that benefits gained from such reviews can be shared and can inform Member States.

Lessons can be learnt from the member states with the strictest requirements, for example, in the composition of the ethical review body. In the Netherlands, it is mandatory to include an alternatives expert and Regional committees in Sweden require 5 lay people and 2 representatives of animal protection organisations (FELASA: Principles and practice in ethical review of animal experiments across Europe, December 2005 http://www.felasa.eu/Documents/Workinggroups/final_reports/WG_ethical_review.pdf)

If a Europe-wide framework for ethical reviews were to be laid down, the information and advice produced could be disseminated across the EU, allowing for common ethical goals and outputs to be developed. This would then permit laboratories across Europe to become aware of developments in animal welfare, the 3Rs and alternative approaches to animal use as well as engender openness and allow scrutiny by the public.

ADI and Advocates for Animals recommend that a framework similar to the human research ethics committees be incorporated into the proposed Directive, with the local ethical review feeding into the decision-making process at national authority level.

February 2009

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