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Ensuring ethical animal welfare research: Are more ethics review committees the solution?

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Abstract

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The issue…

The question raised in the title may appear to be easy to answer: If enough ethics review committees are available to allow assessment of each and every scientific protocol involving animals then, surely, we can ensure that no unethical animal research will be carried out. Unfortunately, the answer is not that simple in an international research community where ethics approval systems differ across jurisdictions and between institutions (Olsson et al., 2022). Here, we aim to highlight the inherent challenges and propose some ways to mend the gaps in the system. The examples given in this article have all been encountered by one or more of the authors in their roles as researchers, ethics committee members, reviewers or journal editors. Although they pertain mainly to animal welfare research, the take-home messages from this opinion paper are also relevant for applied and fundamental ethology.

What do ethics committees do?

The main task for an ethics committee for animal research is to assess experimental protocols to ensure that animals are subjects in experiments only when absolutely necessary for the scientific question posed. When animals are involved, the committee weighs up the predicted benefits of the results against the potential suffering of the animals (Bateson, 2005), which must be minimised, in terms of severity and number of animals involved, whilst still providing sufficient statistical power to enable conclusions (Lakens, 2023). Whereas this largely utilitarian approach is not consensual among animal ethicists (see de Grazia 1999 for a discussion), it is what is prescribed in legislation (e.g., Directive 2010/63/EU, Laber et al., 2016). Depending on jurisdiction, animal ethics committees may have additional tasks, and their work is often more complex than this very condensed description, which nevertheless suffices to illustrate the task in focus in this opinion paper.

When is ethics approval needed in animal welfare research?

For any study involving animals (or human subjects studied for animal welfare purposes), the first task is for the researcher to design their study to the highest possible standards following the principles described in the paragraph above. Once a protocol has been designed, does the study need ethics approval (Gloy et al., 2020)? Depending on the country, the rules of their institution and the demands of the journals in which to publish the work, the researchers themselves are often the first to gauge if an ethics committee needs to approve the protocol. In the European Union, for example, Directive 2010/63/EU (2010) on the protection of animals used for scientific purposes applies only to practices above a certain level of impact (the so-called needle-prick criterion); hence the implication is that – in the EU – ethics approval is not required for animal research unlikely to cause pain and suffering equivalent to, or higher than, that caused by the introduction of a needle. For many, non-invasive observational studies fall into this category. However, this is not straightforward when the study is concerned with housing and management practices that are common for the husbandry of farm and laboratory animals.

Consider an observational study in a location where tail docking of lambs is performed as part of industry practice. The researchers will access farm and veterinary records to look at the association of this practice with outcomes such as body weight gain, disease incidence, and mortality. The ethics committee will consider the impact that the research has on the animals involved when reviewing the harm-benefit and the implementation of the 3Rs (Replacement, Reduction, Refinement; Russell & Burch, 1959). However, in this case, the *research study* has no direct negative impacts, because the procedure would occur anyway, and by using these existing data, we would potentially improve our understanding of the consequences of tail docking. If, however, the committee takes the alternative (and legitimate) view that all ethical issues inherent in the study should be included in the assessment, i.e. the ethics of docking and how this should be best performed, the committee may decide that the harm outweighs the benefit, and approval will not be given. In this example scenario, the docking would still occur as it is part of the local routine-practice, and the researchers may have limited ability to intervene, such as instigating the use of analgesics. In most countries, this procedure is not considered a veterinary practice and is commonly

performed by competent stockpersons, which further complicates the reach of jurisdiction. A noteworthy aspect of doing harm-benefit analyses on routine farming procedures is that many practices would be classified as severe under animal experimentation legislation. But, in the EU at least, procedures that are part of normal animal husbandry routine, are explicitly excluded from the current Directive (2010) on the use of animals for scientific purposes, unless these procedures are carried out solely for research purposes.

Problems associated with the ethics approval process

When ethics approval is needed, the process is not without flaws. The ethical assessment carried out has been found to differ between ethics committees (Harries et al., 1994; Goodyear-Smith et al., 2002; Hearnshaw, 2004; Brønstad et al., 2016). There is a risk that the needle-prick criterion is taken too literally, with committees not being ethically critical of projects where animals are exposed to psychological stress without any physical harm, or where repeated minor harms can accumulate into more significant harm.

Even within committees, there is likely to be variation, simply because they are composed of human beings and, as members, we should be cognizant of how we can be affected by what we have just read. Is a moderately stressful protocol judged perceived differently when assessed immediately after one or two more severe studies than if it was assessed after a mild procedure?

It is not always possible to send all experimental protocols to an ethics committee. In some countries, such as Denmark and Sweden, the ethics review system is built to cater to the legal requirements, with officially instituted committees having a mandate only to review projects when this is required by law, and hence they do not evaluate projects that fall below the needle-prick criterion, nor when recognised animal husbandry practices are undertaken. Also, some researchers do not have access to an ethics committee at all; this is more common in developing countries but can also be the case for unaffiliated researchers working outside of academia. Seeking approval from committees based in another institution could be a solution, but they may be reluctant to assess projects that are carried out in facilities they do not know, or they may require specific legal agreements or payment to do this, which disadvantages researchers with limited access to resources. Some independent ethics committees exist (e.g., the UK Royal College of Veterinary Surgeons operates a non-statutory ethics review panel for research carried out by veterinarians in clinical practice, https://www.rcvs.org.uk/who-we-are/committees/standards-committee/ethics-review-panel/), but they are not common.

In some cases, the available committee does not have competence in the proposed research area, such as when human behaviour (e.g., surveys) is part of a study located in an institution with only an animal ethics committee. Again, in several European countries, human ethics review systems are designed specifically for medical research and studies involving surveys fall outside their scope of review. Surveys and interviews are relevant tools in animal welfare research, where it is often of interest to assess the attitude and knowledge of human stakeholders such as farmers or companion animal owners. Many animal scientists resorted to collecting survey data for the first time during the COVID-19 pandemic, sometimes unaware of the requirements to select subjects fairly, obtain consent, assess potential psychological effects, and protect participants' privacy (Whicher & Wu, 2015).

More ethics committees would solve some of these issues, but they still need resourcing, either through a user-pays system or by institutional support. The limited scope of the national ethics committees in some Scandinavian countries has led to an increase in local ethics committees in some institutions. Whereas influential researchers may be able to convince their institutions to establish local committees, this is less likely for more junior researchers, who usually also have fewer funds to pay for external review. Also, any increase without proper oversight and training will increase the variability among ethics assessments of similar protocols (e.g. Harries et al., 1994).

Ways to move forward?

We do not have the perfect solution to the abovementioned issues on ethics approval of studies involving animals and humans. Simply demanding that all studies undergo ethics review and criticising those that have not (or barring them from publication) without providing solutions to make robust ethics review available to all, is unlikely to solve the current problems. Also, reviewing all protocols involving

animals is a lot of work and may run the risk of becoming a box-ticking exercise if there is not enough time available for and value associated with sitting on an ethics committee. We have some suggestions on how the process can be improved in terms of uniformity of assessment and achieving the aims the approval procedure has been put in place to ensure.

One good place to start is with ourselves: as researchers, reviewers, editors, and members of ethics committees – and not least as supervisors and mentors of students. In that role, we need to ensure that ethical thinking is taught early and made an integral part of the research process, pivotal to the way we approach any animal research. Ethics is more than culture-of-care, and long before any protocol is written, we need to take a long hard look at our research question to evaluate if live animals (human or non-human) are needed. We must from the outset be our own ethics reviewers and assess the harms and benefits of our protocols if we are to justify the use of animals in our research. This does not replace the assessment of an ethics committee, but the protocol submitted to them should always be optimised in terms of minimal harm and maximal benefit. Application of the 3Rs is not in itself an ethical assessment, but a way to evaluate and minimise the risk of harm done (but see Olsson et al., 2011; Sandøe et al., 2015), in the same way that we make use of the available guidelines (ARRIVE: Percie du Sert et al., 2020; PREPARE: Smith et al., 2018), some of which have been simplified for easier application (Katsnelson, 2020).

We may be stating the obvious, but far too often animal research protocols are constrained by existing housing facilities and management procedures. A lot of research is planned around the capacity of the animal facility, and the 'we have always done it like that' mentality. When more senior colleagues have already published results using protocols that may not be appropriate (either statistically or ethically), it can be difficult for younger colleagues to break the tradition. Researchers, including the authors, may also make use of the model species that happens to be available, without sufficient consideration for their suitability for the question asked or whether it is the species and experimental approach which will incur the least harm.

Most journals demand that articles based on research involving animals have undergone ethical assessment, and if not, an explanation for this should be given. However, a number referring to an approval document that is unlikely to be available to readers, or a sentence saying that ethics review was deemed not to be required, will not do much for transparency. Instead, we would encourage journals to allocate space and incentive for authors to provide more details on the ethical considerations behind the study, whether approval was obtained or not. What were the potential harms to the animals, how were these mitigated, and what were the predicted benefits that justified the study? This does not need to be the complete approval statement from the ethics committee, but the main issues explained in a few sentences in the manuscript with additional information in the supporting material if need be.

Journal editors and reviewers often come from different countries with different regulations than those applied where the study was carried out. Many journals have an explicit policy about ethics assessment, but even when the authors confirm an ethics review of the research to be published, the reviewers and the editor still need to apply their own judgement as to whether the study was ethically justified at the outset. That an ethics committee has approved a study should not lead to reviewers omitting to consider the ethical implications of the protocol being assessed, in the same way as they assess the scientific quality of the study. This can be facilitated by including an ethics checklist as part of the review process.

Another way forward is methodological review boards or Registered Reports (Chambers & Tzavella, 2021; Lakens, 2023). Submission of the experimental plan for review prior to carrying out the study opens up the possibility of obtaining also an opinion on the ethical acceptability of the study from the reviewers and editors assessing the submitted manuscript. It can be discussed whether this suffices on its own or whether an ethics committee also needs to be involved. If the (scientific) reviewers assessing a protocol (submitted as a Registered Report) also had appropriate training in the 3Rs and ethics of animal research, it could reduce the number of times a protocol needs to be seen by competent authorities. This would not only save work for the busy scientists, but also prevent that unethical research is carried out as the assessment is done prior to the experimental work, and either adjustments can be made, or the project rejected.

Are more ethics review committees the answer to ensuring ethical animal welfare research? Clearly not without caveats. Although an increase in local committees would help tackle some of the issues raised here, we need to make sure that the quality of the assessment is guaranteed, otherwise committees could – in theory – be created just to assign (unfounded) approvals merely to fulfil journal requirements.

Rewarding the work of ethics committee members, either financially or through recognition of their time and effort, may be a way to give fair compensation for those who contribute to the common good that is functioning ethics committees. We also need to find ways of ensuring ethics committees are more harmonised across regions, in terms of appropriate size and composition, with sufficient resources and by means of systematic training (Laber et al., 2016), global guidelines (Petkov et al., 2022), and communication between ethics review bodies (https://science.rspca.org.uk/sciencegroup/researchanimals/ethicalreview). This would ideally include the possibility of assistance from another ethics committee when a protocol involves methods or species outside the competences of the local committee. It should also be made easier for independent scientists and for researchers in regions where resources and infrastructures are lacking to get affordable access to ethics reviews. Some developments are underway (e.g. Mohr et al., 2023), but more is needed. More ethics committees (new and existing) should be willing (and allowed) to deal with proposals below the needle-prick criterion, and trained in assessing observational studies and social science studies, such as surveys, that are unrelated to medicine. But there is no one-size-fits-all solution. We should not reject *a priori* the idea that some studies may not require ethical approval (e.g. Pierret & Jiguet, 2018; Samet et al., 2023), and rather than requesting one from an ethical review board "to-be-on-the-safe-side", we recommend always explaining the ethical reasoning for a study in the scientific article(s) arising from it, whether or not an ethical approval has been/needs to be obtained. This will demonstrate the ethical thoughts behind the chosen protocol, making comparisons easier, and educate us on where the thresholds for approval are placed across jurisdictions. For this to work in practice, journals need to ensure that editors have access to expertise in animal research ethics that they can consult in case of doubt. COPE (Committee on Publication Ethics) provides a forum (https://publicationethics.org/copeforum) where publication ethics issues can be discussed, and some of the existing cases do indeed include questions about how to deal with research for which ethics approval had – for various reasons - not been obtained. By reducing the number of requests ethics committees get, the more time they will have for the studies that really need a diligent review.

Conclusions

How can we ensure ethical animal welfare research? More committees will – all other things being equal – improve accessibility, but a number of other factors needs to be included: Animal welfare researchers must think about the ethical aspects of their work from the outset (also when working with human subjects); better training of committee members is needed to improve quality and consistency of reviews; we call for more awareness among editors and reviewers of differences between jurisdictions as some countries only have national ethics committees that won't assess below-threshold protocols, and we encourage the ethical considerations behind a study to be explained and included in scientific articles (not just an approval reference number), and especially when ethics review was not obtained or waived.

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