Who qualifies as an investigator?

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Abstract

Sometimes a seemingly simple, well understood concept becomes more diverse once we start to examine it more closely. One of the first things applicants consider in an ethics application form is who to list as investigators. 'Investigator' is such a well used term that we sometimes forget to question what it means and who qualifies. From an applicant's point of view the list of investigators is usually determined from a research project perspective and technical expertise requirements. However, Animal Ethics Committees (AECs) have additional aspects to consider. Some of these are: How much or what level of involvement in a project is needed to list a person as an investigator in research involving animals? What about the 'investigators' who provide methodological or scientific advice? What about those who provide practical supervision of particular procedures or elements of a project? What about those who will receive tissues or samples for later analysis? How do we ensure that an AEC has all appropriate information to make its assessments and is aware of all people who will be involved in a project? From an institutional point of view: which researchers need to demonstrate competency in animal procedures? What AEC approval number do researchers quote in their publications and grant progress reports if they are not listed under a specific project? While some of the questions are very pragmatic, they allude to more significant issues in the application of animal ethics.

Introduction

The *Australian code of practice for the care and use of animals for scientific purposes* defines an investigator (researcher or teacher) as 'any person who uses animals for scientific purposes'. One of the first items in the animal ethics application process is to list all investigators who will be involved in the project and to provide details about them and their competencies. In the vast majority of cases the alignment between an animal ethics application and the investigators conducting the work is straightforward. It is usually a simple matter to list all the people who will be involved on a protocol. This list serves numerous purposes, including enabling an AEC to verify and monitor/oversee the skills, expertise, training and accreditation of the investigators. The list of investigators serves as a checklist to ensure that all those involved with the protocol have the relevant expertise and training and as a trigger for providing any training that may be required before an individual is permitted to participate in an AEC approved project. It is also commonly a condition of an institution's licence to use animals that a register of investigators and their expertise is maintained by the institution. Thus, when the question is asked about who qualifies as an investigator, in most cases the question makes little sense as the answer seems fairly obvious – it is an appropriately skilled person who is either experienced or who is under relevant supervision and who is listed

on the institution's register having provided evidence of education and awareness of the Code.

From the investigator's perspective, being listed on an AEC protocol has a number of benefits and obligations. The benefits include access to an ethics approval number – which may be required in order to publish results or obtain access to research material and data; it may even signal authorship on future papers. The obligations include animal welfare obligations. This can include the need for relevant animal welfare training and provision of evidence of an understanding of the Code; it may also involve specific competency training in animal handling and procedures and it may necessitate taking on defined responsibilities for the animals within a project.

There are cases where the question about who is listed as an investigator on an animal ethics protocol needs to be examined more closely. The AEC needs to know who is involved in a research or teaching exercise and needs to be able to maintain appropriate oversight including of each person's skills and expertise and familiarity with the Code. The question raised is two-fold: whether every person involved in an investigation actually needs to be listed, and whether it is even possible, at the outset, to identify every person who will be involved. Questions are occasionally asked by AECs about Chief Investigators who are involved in a large number of protocols, and whether a single person is able to have solid oversight over the number of approved protocols. However, there are other elements which also need to be considered.

Case examples

Some case examples of the kinds of exceptions or issues that have been raised can be used to illustrate the point:

1. Wildlife studies often involve researchers taking students and other volunteers to assist with setting up traps, handling equipment and taking notes on behalf of the researchers. Unless specifically trained, these volunteers usually do not handle animals but simply observe the researchers as they retrieve, measure and weigh the animals. Often the motivation for the volunteers is to see animals they could otherwise only see in a zoo and to learn about the animals and their environment. However, it only requires an unexpectedly successful trapping session, a very keen volunteer or a minor event such as a change in weather conditions, for the volunteers to be assisting with animal handling. Handling the animals to assist the researcher can be the next logical step to this enthusiasm. How often is such an occurrence likely, and does it justify an AEC asking researchers to list all volunteers on their application? If yes, could this potentially impede research especially when recruitment of volunteers realistically often occurs at the last minute before a field trip? In some instances neither the number nor names of volunteers will be known until just before each field trip and the individuals may vary from trip to trip. It also raises the further question about how an AEC may monitor and register the training of volunteers if they are to be listed on a protocol.
2. A researcher (with AEC approval) asks fishers to provide fish frames and tissues for a large population sampling project. Over time, samples from certain species have not become readily available; so the researcher attends at the boat launching jetty each morning (but does not go out on the boats) and asks the fishers to retain the specified species – either by directly targeting them or by ensuring they are retained if caught. Later the researcher goes out on some of the boats and participates by advising the fishers which fish to retain. At any point, should the fishers be educated about the Code, listed on a protocol or trained in some way? Is there a distinction between this kind of activity and the wildlife volunteers? What implications would this have for the research institution in terms of responsibility for actions by the fishers who are neither staff, honorary/adjunct appointments or students? To what extent do the fishers need to have an understanding of the Code if all they are doing is routine practice and retaining samples as requested by the researcher?
3. Tissue sharing arrangements generally depend on surplus tissues being available from another project at an exact time point and in specified conditions. Sometimes it is simpler to produce tissues deliberately for large projects.

   Imagine a large research group with multiple projects under way, many of which need access to specified tissues and samples often with specifically detailed criteria. A number of the researchers in the group obtain AEC approval to breed animals in order to produce the requisite tissues and samples

(e.g., antibodies /specific organs from GMO mice) for their own use and for use by other researchers and students. The AEC application lists those individuals involved in the direct breeding and production of the animals. But, to what extent, if any, do others who will receive tissues or antibodies need to be listed? The breeding is being undertaken with the specific purpose of making samples available to a wider group of researchers. However, most of these wider investigators will not see a live animal; they work in laboratories with animal sourced tissues, cells or products. Does it make sense to list them all? On one view there is an animal welfare and training perspective from which it makes sense to ensure that all those involved are fully aware of the issues related to the animals from which the tissues or products they seek to use are derived. Furthermore, listing investigators even if they have no direct contact with animals gives them an AEC approval number which may be required for publication. However, this broad listing can obscure the relationship between those investigators who handle the animals and all investigators linked to a particular AEC approved protocol, as it may no longer be clear who is involved with 'hands on' animal work. Furthermore, it is sometimes not known at the start of the project who may receive the various tissues and which precise tissues or quantities of tissues will be needed, especially if these are to be stored for a time before being made available. The fundamental question is to what extent does an AEC need to be aware of the wider use of the animal products and to what extent do they need to examine the justification of these extended uses?

Would it make any difference if the tissues being used were by-products from a totally different experiment rather than from purpose bred animals?

While AECs commonly imagine that tissue sharing can easily be accomplished, often it is a complex matter to align available tissues to the precise requirements of researchers. It is generally important to undertake tissue sharing in a planned fashion rather than fortuitously, as samples need to be available at exact time points and in specified conditions. Thus, procedures can sometimes be designed with tissue sharing opportunities in mind. Regardless, the underlying issue is that the participation and influence of the investigators in matters of animal welfare needs to be assessed by an AEC, including the timing of experimental procedures and the death of animals. The primary issue for the AEC remains oversight of the animal welfare and an application of the Three Rs. The question though is who are the investigators in instances which revolve around tissue sharing arrangements? Would a tissue and cadaver notification process help to resolve this? Would listing the precise role of each investigator assist this? Are there mechanisms to identify instances where only cadavers or tissue samples are being obtained and where the investigator has not participated in any way with the live animals or in decisions about their deaths? If a relatively simple process could be implemented, this would provide the investigator with the formal verification necessary for publishing data. It could also be used to provide at least some evidence for the institution's overall reduction in the use of live animals.

4. A large project involves animals on the farms where they are routinely housed. Each farmer provides all routine care and welfare for the animals, and the researcher attends only to undertake the particular sampling or investigation. This type of project may include feeding trials, field trials of vaccines, or trials of new devices (e.g., electronic ear tags). To what extent should any of the farm staff be listed on a protocol? To what extent is there a requirement to ensure that farm staff are aware of the Code and animal welfare legislation in relation to the research elements of the project, even if they are unlikely to participate directly in any of those elements of the research? If any kind of adverse event ensues, this can become an important issue as it is important to understand where the responsibilities for animal welfare lie at any specific stage of the process. However, it is not always possible to know in advance who will be responsible for the animals on a day-to-day basis, especially where multiple farms or large numbers of staff are involved.
5. Teaching exercises may not always list all investigators. Such exercises can vary from simple animal handling to more complex animal medicine or surgical learning, and can even involve collaborative work with animal shelters or wildlife experts. In many instances it is not possible to know in advance who may be part of the activity, especially when collaborating with other organisations. Even where complex skills or

surgical procedures are being taught, it is usual to list only the responsible teaching staff (lecturers). It can sometimes be difficult to obtain a list of all participating tutors or demonstrators as they are often appointed close to or even after the start of semester and well after the protocol has been approved. To what extent should such people be listed for the AEC, or should the primary investigators be able to take overarching responsibility? To what extent should tutors or demonstrators be required to undergo animal welfare training or should the primary teaching staff hold this overarching responsibility? Is the information given to an AEC such as the number of students, staff-student ratios, and the expected level of prior learning of the students sufficient? Should an AEC be made aware of other issues such as whether any of the students are repeating the unit due to previously failing it?

6. Research collaborations frequently involve researchers in other jurisdictions and even in other countries. While it is a relatively simple matter to ensure that a researcher from the same country is conversant with the Code, how can this be achieved for researchers from other countries? What is necessary if a researcher will only receive tissue samples or be involved in data analysis? If a researcher attends for only a very short period of time to assist with a project, should the local researcher have responsibility, or should the visiting researcher be required to demonstrate awareness of the Code?

Conclusion

Sometimes simple issues or standard practices become complex when outlying cases come to light. The solution here is not about changing our fundamental practices. The solution is to be aware of the kinds of exceptions to or extensions of normal AEC practice that may be encountered and for an AEC to have practical responses to these so that there is clarity about the listed investigators and the responsibilities of all those involved with animals and their welfare, whether directly or indirectly. There is also the need to be aware and prepared for changes in research culture and what this means for AEC practices. The biggest change we face right now is the rapid increase in collaborative research, especially with non-traditional areas. This means that researchers who are not traditionally familiar with animal welfare considerations are becoming involved with animals. To what extent do they need training in the Three Rs and considerations pertaining to the design of animal projects? There are a number of elements to consider as part of the solution. These can include the idea of a cadaver notification process, a mechanism for listing the level and type of involvement each investigator has in a protocol, a means for linking researchers who obtain tissue samples to a protocol, and a method for registering the involvement of 'late comers'. The precise solutions may vary from institution to institution, however the issues we face are common.