Brian Schrag's Commentary on "Counting Sheep: Ethical Protocols in Animal Research"

Commentary On
Counting Sheep: Ethical Protocols in Animal Research

Parts 1 and 2

Mariel and Jorge are graduate student research colleagues. Paid on the same grant, they share the same animal subjects for their research work, but they are working on different research projects. It is important to note the unequal relationship between Mariel and Jorge: Mariel is a first year graduate student with no advanced degrees while Jorge, already a veterinarian, is nearing the end of his Ph.D. program. Thus, the two students differ in graduate experience as well as recognized expertise in veterinary surgery. A dependency relation is evident here as well. Since Mariel is not a veterinarian, she is dependent upon Jorge to do the surgery she needs for her research. The differential in credentials is significant. Although Mariel has four years of experience as a veterinary surgical technician, and may be very well qualified to recognize deviations from surgery protocol, she lacks the credentials to challenge Jorge should their assessments differ on deviations from surgery protocol.

Furthermore, Mariel and Jorge have potentially conflicting interests in carrying out this protocol. After a first round of surgery, it becomes clear that the surgery protocol will take much longer than they anticipated and hence much more time will

be required to process all the animals they need for their research. Jorge is on a tighter time schedule. He is considering a job offer and wants to graduate on time; thus, he has an incentive to rush the work. Since Jorge's research requires only tissue samples obtained during surgery, it will be unaffected if the sheep die a result of rushed work. Mariel's research will be severely affected, however, if the sheep die shortly after surgery.

At the completion of the second round of surgery, three facts are undisputed: 1) Following surgery, several of the sheep show signs of increased agitation and discomfort. This outcome is a departure from the first round of surgery. 2) Three of five sheep die within a day of surgery; no deaths occurred after the first round. 3) An autopsy of the three animals shows signs of tissue damage and bleeding at the site of the insertion of the sampling tubes. Presumably this result did not occur after the first round of surgery.

All the researchers in this case are expected to comply with *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.For a definitive guide to care and use of laboratory animals, see Institute of Animal Resources Commission on Life Sciences, Guide for the Care and Use of Laboratory Animals (Washington, D.C.: National Academy Press, 1996). The U. S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training are included in Appendix D. For an overview of regulations and requirements in the care and use of animals in research, see B. T. Bennett, M. J. Brown and J. C. Schofield, eds., Essentials for Animal Research: A Primer for Research Personnel (Beltsville, Md.: National Agriculture Library, 19994), pp. 1 - 7. Reprinted in Deni Elliott and Judy Stern, eds., Research Ethics: A Reader (Hanover, N.H.: University Press of New England, 1997).* One of the nine principles in that document (Principle IV) states an obligation to ensure "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practice." Principle III states, "The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results." Animals should not die needlessly. The researchers also are expected to comply with the "Guide for the Care and Use of Laboratory Animals," which spells out procedures to ensure that these principles are observed.

Mariel believes that she observed Jorge rushing through surgery, paying less attention to surgical details (e.g. careful tissue handling and proper suturing during

the cannulation procedure). Suppose that Mariel is right and that Jorge did deviate from the surgery protocol, which led to distress in the animals and caused their deaths. If nothing changes, one can assume that the same outcomes will be encountered in varying degrees in future surgeries. Sheep will suffer needlessly and will die needlessly; both outcomes are violations of the guidelines.

This situation presents a potential moral problem for Mariel. She has an obligation to observe the research principles for animal use and protect the animals from needless pain, suffering and death. What is her moral obligation to act if she has reason to believe that Jorge is violating those principles? At a practical level, she has another problem. If she does nothing, she may lose a substantial numbers of the sheep, and her project may be significantly delayed.

As the least senior and, in some senses, the most vulnerable member of the research team, Mariel is forced to pit her expertise against Jorge's in challenging his surgical techniques as well as his possible violation of surgery protocols. In the second scenario, Mariel and Jorge differ on the facts in this case: whether Jorge deviated from the surgery protocol and what caused the animals' deaths. Because, as a veterinarian, Jorge can claim more expertise in these matters, Mariel may have difficulty in making her case, even if she is right. In addition, she runs the risk of losing the cooperation of the person she is dependent upon to finish her research.

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Preventive Ethics

Sometimes it is easier to prevent an ethical problem rather than try to determine what to do after it arises. Mariel's "problem" is due, in part, to the failure of other members of the team to meet their ethical responsibilities. Jorge has a responsibility to show collegial regard for the effect of his actions on Mariel's research, and Carroll has a responsibility to oversee the research to minimize the likelihood that such problems will develop. A wise adviser might recognize the potential for problems, given the conflicting interests and the unequal power relationship between Mariel and Jorge. She could set up the protocol to prevent or minimize the chances that Mariel will be forced to decide whether to "blow the whistle" on Jorge.

One technique used in other organizational settings is making the reporting of bad news mandatory, not optional, thus relieving the most vulnerable persons of decision-making pressure. This strategy helps to eliminate concerns about disloyalty to a colleague or fear of reprisal.

In this instance Carroll, Jorge and Mariel all collaborate in developing the animal use protocol, which includes the surgery protocol. What Carroll could do is to specify in the surgery protocol that, after each round of surgery, any deviations from expected outcomes of surgery must routinely be reported to her, including evidence of post-surgical suffering or death of sheep. In the unexpected death of a sheep, an autopsy would be done automatically and the reports forwarded to her. Carroll could then decide whether the information warrants investigating to determine if the protocol needs to be changed for reasons that could not be or were not anticipated or whether any violations of protocol have occurred. This approach would also make Carroll aware of the unacceptable implications of high death rates of the sheep for Mariel's research project.

Recommendations in the *Guidelines* regarding surgery and the monitoring of post-surgical pain and stress in animal subjects suggest preventive measures that could be taken in the planning of the protocol.

1. In developing the surgery protocol, Carroll could ensure that pre surgery planning includes a careful preoperative animal health assessment to be sure the animals are healthy enough to withstand surgery.Institute of Animal Resources Commission on Life Sciences, Guide, p. 61. That judgment could be made by the supervising veterinarian rather than by Jorge. If sheep have been so certified any post-surgical deaths should trigger a review of surgical procedures.
2. The development of the surgery protocol would be an appropriate point at which to estimate the amount of time required to properly carry out the surgery protocol on each sheep and the implications of that time frame on Jorge's research program. If an honest assessment indicates that they will only be able to do, for example, five sheep per day, that provides an opportunity to discuss alternate ways of meeting the protocol requirements. The pressure on Jorge to rush the surgery could be thus anticipated and dealt with. Carroll could build into the protocol a requirement that significant deviations from the anticipated time required for surgery be reported to her after the first round.

3. Carroll should ensure that it is clear who is responsible for monitoring and keeping records of evidence of post-surgical stress and pain in the sheep. She could require that such evidence must be reported to her.Ibid., pp. 63 - 64

If such provisions were in place, then it would be Carroll, not Mariel, who would confront Jorge about the post-surgical suffering and death of the sheep. Carroll could ask Mariel for her observations of the surgical procedures, rather than leaving it up to Mariel to volunteer them. These measures should help to preserve a working relation between Mariel and Jorge and also provide an occasion for Carroll to have a frank talk with Jorge and Mariel about expectations of mutual collegial responsibility. If Jorge's actions are interfering with Mariel's research, that problem needs to be addressed. Carroll could take action at the earliest instant to get Mariel's research back on track.

If Jorge were to deny that his surgical technique caused the sheep's suffering and deaths, arguing instead that the diseased state of the sheep caused the problem, then that claim could be tested by referring to the pre-surgery certification of the health of the animals. It is possible that Jorge is correct. That may indicate the need to radically redesign the protocol or perhaps the need for a more refined certification procedures to identify diseased sheep that are sufficiently healthy to withstand the surgery.

If Jorge's technique is the culprit, that problem can be addressed and corrected more quickly than is likely if Mariel is carrying the whole burden of correcting the situation. The net result of involving Carroll is that the research is more likely to go smoothly and to be completed sooner with the research animals experiencing less suffering and pain.

These provisions allow Carroll to do at a lower level what the IACUC has formal responsibility to do. More importantly, it shields the most vulnerable member of the research team and gives Carroll an opportunity to nip a problem in the bud. At minimum, this strategy prevents wasted time in her research program.

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Dealing With the Actual Situation

Suppose, however, that Carroll has not had the foresight to build in these preventive measures and Mariel must deal with the situation. What should she do?

Given the animals' suffering and distress and the number that have died, Mariel cannot justifiably choose to do nothing. She must at least begin to address the cause of their suffering and death and whether anything can be done to alleviate it. If something can be done and she fails to do it, she has not exhibited proper care for the animals.

Since she suspects Jorge's surgery procedures, it will probably be least threatening to Jorge if she goes directly to him, rather than to Carroll or the IACUC. She needs to approach him in a collegial manner, point out the post surgery results and the autopsy findings, and ask if he thinks he rushed the surgery in the second round. He may be willing to concede that he rushed the work and try to take more care on the next round. If so, that may solve the problem.

Suppose Jorge denies that he is responsible and blames the poor outcomes on the diseased state of the sheep. He may be right. Perhaps he did not violate protocol. The sheep may have experienced discomfort and died because of their weakened condition. This possibility raises a question of whether the animal protocol is adequate. Mariel is now put in the position of having to press her case, increasingly alienating Jorge and /or watching her research go down the tubes because she loses his cooperation as well as a significant number of sheep.

As a next step, with or without Jorge's cooperation, she can ask the supervising veterinarian to review the necropsy reports of the sheep who died in the current round and to certify the preoperative health of the next set of sheep. If the problem persists in the sheep after the third round of surgery, she will have stronger evidence and the expertise of the supervising veterinarian to buttress her claims that Jorge's technique is causing the problem. She may convince Jorge and win his cooperation. If so, the delay, loss of time and sheep may be justified by the need to secure his cooperation. If not, she has little alternative but to go to Carroll or report the situation to the IACUC in order to correct the problem.

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Part 3

Suppose the sheep do not die but show signs of pain and discomfort during the recovery period. If the sheep are in distress for any significant length of time, should Mariel keep them alive and suffering and continue to collect research data or should she euthanize them and thus lose the possibility of data collection?

Recall that the first round of surgeries produced no signs of suffering or distress in the animals during the recovery period. That suggests that it is possible to perform this surgery without the undesirable side effects. Hence, it is reasonable to expect that the protocol, if followed, will not cause post-surgical distress in the animals.

This scenario suggests several possible outcomes from surgery. 1) Some of the animals exhibit distress for a short recovery period (perhaps 1-2 days). 2) Some of the animals exhibit distress for a longer period after surgery (several days). 3) Some of the animals experience chronic pain induced by the surgery that lasts for the entire month of the experiment.

Mariel's team's first obligation is to see if the sheep's pain can be relieved. If it can, it should be done. If not, then she will have to consider euthanizing this batch of sheep.

Her second obligation is to determine the cause of suffering and whether it can be prevented. If it is the result of a deviation from protocol, then that needs to be addressed before the next batch of sheep are subjected to surgery.

Suppose, however, the sheep's suffering is not the result of deviation from protocol but is, as Jorge suggests, the inevitable result of the weakened state of some of the diseased sheep. There are several possibilities here: 1) The pain occurs only in sheep in which the disease is too advanced. Furthermore, these sheep can be detected in a pre-surgical screening and eliminated from the group. The result is that the remaining sheep will not experience post-operative distress. If that is the situation, then the team should revise the protocol to ensure proper screening. 2) The pain is the result of the weakened condition of some of the sheep that cannot be detected by pre-operative screening. In that case, it is likely that some animals will experience post-operative distress.

It now becomes crucial to know whether the post-operative distress can be eliminated or controlled by analgesia or other means. If it can, then the IACUC must decide whether to permit the experiment with the proviso that the anticipated suffering can be alleviated for the duration of the animals' post operative discomfort.

The ethical and practical issues for the IACUC may be especially difficult if pain control were to be required for the entire month of the experiment.

Finally, it may be the case that the pain (apparently) inevitably induced by the surgery in some of the diseased sheep cannot be alleviated for any length of time. This possibility puts in starkest terms, the trade off between the animals' discomfort and the knowledge gained by Mariel's experiment. It is now clear that the price of Mariel's research will be that some of the animals may experience stress, pain and discomfort for some length of time. This issue must be brought to the IACUC for review, and the IACUC will now need to decide whether that suffering can be justified.For a beginning discussion of some of the relevant moral issues in the use of animals in research, see Deni Elliott and Marilyn Brown, "Animal Experimentation and Ethics" and Richard P. Vance, "An Introduction to the Philosophical Presuppositions of the Animal Liberation/Rights Movement," both in Elliott and Stern, Research Ethics. For a discussion of pain in vertebrate animals, see Fred. W. Quimbly, "Pain in Animals and Humans: An Introduction" and Francis J. Keefe, Roger B. Fillingim and David A. Williams, "Behavioral Assessment of Pain: Nonverbal Measures in Animals and Humans," both in ILAR News 33 (1-2, Winter/Spring 1991). For a discussion of the moral relevance of animal pain, see P. Harrison, "Do Animals Feel Pain?" Philosophy 66 (1991): 25-40; Ian House, "Harrison on Animal Pain," Philosophy 66 (1991): 376-379; and Gordon M. Burghardt, "Heeding the Cry" in Hastings Center Report 21 (2, March-April 1991): 48-50.

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