Ethical or Not: A Case of Personal and Agency Guidelines

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At one time or another, all scientific researchers who use human and non-human animals as subjects must face the dilemma of whether or not to conduct the study. Evaluation of ethical practices involving the use of animals in scientific research is typically viewed from the perspective of established guidelines generated by scientific governing organizations. However, in the end it is the researcher who must live with what he/she has done, be it good or bad. Thus, there is another set of ethical principles carried into each research situation– that of the investigator. This paper presents a decision-making model, which integrates the ethical guidelines of the researcher with those of the scientific governing organization, for determining whether or not to perform a study using human and non-human species.

Considerable attention has been focused on the issue of ethics in research through guidelines that have been generated by governing agencies such as Sigma Xi (1992), American Psychological Association (APA, 1996; Sales and Folkman 2000); the United States Government (National Research Council 1996, National Institutes of Health 2000), Animal Behavior Society (1997), among others. Such guidelines serve to ensure the welfare of the subject used in experimentation by placing limits on what the investigator can or cannot do, as well as what the investigator *must* do, to the subject. Research involving animals or humans falling outside the boundaries of what is acceptable by the governing organizations may result in professional sanctions such as loss of APA membership, loss of government funding, institutional loss of license to practice research on animal or human subjects, and/or stiff fines (Black 2000; Smith 1977; Staff 1986). Such violations may also lead to failure of the general scientific community to readily accept the findings of such research. [An example of this condition would be the controversy surrounding Milgram's Obedience Study (Milgram 1963, 1965) with the major focus on ethical rather than content implications of the study; see Jung 1971.]

The researcher has a clear choice: to violate the established ethical guidelines and, if caught, to suffer the possible consequences; or to abide by the guidelines, not taking the professional risk. The latter option is becoming more of a mandate than a choice because many research oriented institutions have developed internal review boards (Black 2000; Stopp 1985) and governing agencies such as the National Institutes of Health are performing unannounced spot-checks of institutional research facilities.

It is not always the guidelines of the scientific governing agencies that limit what can or will be done by the investigator. The ethical guidelines of the individual researcher must also be considered. Some investigators will be willing to expose their human subjects to personal risk (Smith 1977) and their animal subjects to severe pain and physical destruction ("Animal Research" 1986, Johnston and Calvert 2000), while others restrict their own research by imposing severe limits on what they are willing to do to subjects.

It is the contention of the present author that the limits of what can and will be undertaken by the researcher are regulated by the scientific governing agencies and each investigator's personal ethics, professional goals, and willingness to take risks. The professional goals may range from the desire to "get ahead," or become prominent in one's own field, to the desire to contribute to science purely for the benefit of humanity. Risk taking may include the violation of one's own ethical principles (with the possibility of associated feelings of guilt), or the violation of the guidelines set up by the scientific research governing agencies (which, if discovered, could result in professional sanctions).

Thus, the ethical decision to undertake an investigation involves a number of variables that the researcher must evaluate through a cost-benefit analysis. The remainder of this paper will attempt to examine the researcher's dilemma associated with the decision to pursue or not pursue an investigation as a function of the costs and benefits associated with each decision.

A Decision Model for the Researcher

Table 1 shows the overall decision matrix that the researcher should address prior to conducting research with animals or humans as subjects. This table can be viewed similarly to the decision making process involved in deciding whether to reject or retain a null hypothesis (H_0). The H_0: "study is ethical" can be tested by subjecting all aspects of the proposed treatment of subjects to evaluation in terms of both the governing agency ethical guidelines and the researcher's personal ethical guidelines. The overall decision matrix yields four possible outcomes. These are analogous to the correct decisions to fail to reject or reject the null hypothesis (boxes A and D, respectively) and to the Type 1 error (reject a true null hypothesis = not conducting an ethical study) and Type 2 error (fail to reject a false null hypothesis = conducting a study that is not ethical) errors (boxes B and C, respectively).

In order to test the H_0, the proposed study must be evaluated against the ethical guidelines of the investigator and agency(ies) in terms of the costs and benefits associated with each decision. Tables 2 and 3 present the decision matrices and consequences for the agency and personal guidelines, respectively. Notice that three of the four possible decisions (boxes A, C, and D) in each matrix have relatively clear consequences. However, when the guidelines are met and the decision is to not pursue the research (box B), the consequences are not so clear (although ethically speaking, this is an acceptable alternative). For example, because the investigator chose not to conduct the study, he/she will never know the outcome of the study.

The investigator is now faced with a decision matrix regarding whether to abide by the agency guidelines or to abide by his/her own personal guidelines. Table 4 presents such a decision matrix with its associated consequences. The investigator must evaluate the consequences of carrying out the investigation in the appropriate box based on his decisions for the two previous matrices (Tables 2 and 3). Finally, we return to the original decision matrix (Table 1). Using the cost-benefit analysis above, it should now be possible for the investigator to take his/her best guess regarding whether or not to carry out the investigation.

The decision to conform to agency or personal guidelines (Table 4) will vary according to which guidelines are more lenient (that is, the guidelines which permit the researcher to have more freedom to use obtrusive procedures; less concern for the welfare of his/her subjects). Conflict can arise in situations in which one of these guidelines is satisfied more easily than the other. When agency guidelines are more lenient than personal guidelines (box B), the proposed study violates personal but not agency guidelines. In this condition, the researcher will experience emotional consequences such as guilt if he/she pursues the project. However, if the probability of professional gain is high, the researcher may elect to carry out the study at the cost of the emotional consequences. If the study is not performed, then the researcher may be limiting his/her own professional achievements including "getting ahead" and making significant contributions to science.

When personal guidelines are more lenient than agency guidelines (box C), the decision to pursue the study will result in professional sanctions if caught, but possibly significant professional gain if not caught. From an agency perspective, this study would be unethical; from a personal perspective this study would be ethical.

Table I. Consequences of decision as a function of ethical and unethical investigations.

	TRUE STATE OF AFFAIRS	
INVESTIGATOR'S DECISION	ETHICAL (H_0 is true)	NOT ETHICAL (H_0 is false)
CONDUCT STUDY (Fail to reject H_0)	(A) Correct Decision: Possible professional and scientific gains	(C) Incorrect Decision: (Type II error) Professional sanctions if caught, guilt; possible professional and scientific gains
DO NOT CONDUCT STUDY (Reject H_0)	(B) Incorrect Decision: (Type I error) Forfeit possible professional and scientific gains	(D) Correct Decision: Prevent professional sanctions and/or guilt

Table II. Consequences of decision as a function of satisfying agency guidelines.

	TRUE STATE OF AFFAIRS	
INVESTIGATOR'S DECISION	AGENCY GUIDELINES SATISFIED	AGENCY GUIDELINES NOT SATISFIED
CONDUCT STUDY	(A) Correct Decision: Possible professional and scientific gains	(C) Incorrect Decision: Professional sanctions if caught; possible professional and scientific gains
DO NOT CONDUCT STUDY	(B) Incorrect Decision: Forfeit possible professional and scientific gains	(D) Correct Decision: Prevent professional sanctions; forfeit possible professional and scientific gains

Table III. Consequences of decision as a function of satisfying personal guidelines.

	TRUE STATE OF AFFAIRS	
INVESTIGATOR'S DECISION	PERSONAL GUIDELINES SATISFIED	PERSONAL GUIDELINES NOT SATISFIED
CONDUCT STUDY	(A) Correct Decision: No moral dilemma	(C) Incorrect Decision: Moral dilemma-feelings of guilt
DO NOT CONDUCT STUDY	(B) Incorrect Decision: Forfeit possible professional and scientific gains	(D) Correct Decision: Avoid moral dilemma

Table IV. Consequences of conducting study as a function of satisfying guidelines.

	TRUE STATE OF AFFAIRS	
INVESTIGATOR'S DECISION	AGENCY GUIDELINES SATISFIED	AGENCY GUIDELINES NOT SATISFIED
PERSONAL GUIDELINES SATISFIED	(A) Ethical: Possible professional and scientific gains; no risk of professional sanctions or moral dilemma (guilt)	(C) Conflict Situation: Personally ethical, professionally unethical; professional risk, but if not caught, possible professional gain
PERSONAL GUIDELINES NOT SATISFIED	(B) Conflict Situation: Personally unethical, professionally ethical; must live with guilt	(D) Unethical: Professional risks and personal risks

An Example

To illustrate the above ethical decision making process regarding whether or not the investigator will be willing to proceed with his/her proposed project, I will use myself as an example. A few years ago, I was working in a research laboratory where an executive monkey study was being conducted to determine the effects of stress on the cardiovascular system of rhesus monkeys. On one occasion, the computer began to malfunction, delivering shocks every 5-sec to the eight subjects. The monkeys began to "shriek" and I perceived this as an indication of their discomfort. Normally the shocks were to occur on the average of one per hour. The researcher tried to re-program the computer for approximately one hour, but was unsuccessful. During that time, I surely experienced at least as much discomfort, as did the monkeys.

This experience, which occurred in 1980, affected my personal ethical guidelines as to what extent I was willing to introduce obtrusive measures into a study. Even today, I study fish because I find it personally difficult to perform surgery on other vertebrates such as rats or birds. According to my perception, fish do not have behavioral repertoires with components indicative of experiencing discomfort.

Lets assume that the agency guidelines for the use of animals in research are more lenient than my own guidelines. Suppose, hypothetically, that I wish to extend my findings of stress effects on fish to mammals. I would devise the analogous procedures to be used on the laboratory rat. I must tie the rat down in order to eliminate its locomotive ability. Unfortunately, from observations in the previously mentioned rhesus lab, I have observed that when rats are tied down, they tend to bite off their own limbs (probably in order to free themselves from the restraint). Now, I begin by asking the question, "Is this study ethical?" (referring again to Table 1).

According to the APA *Guidelines for Ethical Conduct in the Care and Use of Animals* (American Psychological Association, 1996), it is permissible to use restraint and procedures which involve pain to the animal if "the objectives of the research cannot be achieved by other methods" and they "conform to federal regulations and guidelines" (Number V, Sections D and F). It is absolutely necessary for my study to use prolonged physical restraint by tying the subject down so that I can accurately compare the endocrine response of the mammal to the fish under identical situations.

Thus, if I conducted my study, I would be conforming to the agency guidelines and may add to my professional accomplishments, as this study will make a significant contribution to the understanding of the comparative effects of stress in vertebrates. If I choose not to do the study, then I may lose the above benefits (see Table 2 for consequences).

As this study will not conform to my personal guidelines (see Table 3), if I proceed, I will experience uncomfortable emotional consequences while pursuing the investigation, undoubtedly resulting in feelings of guilt. If I decide to not pursue the study, I will save myself from the emotional consequences of what I perceive to be inflicting severe pain, physical damage, etc. on my subjects.

I now must ask myself what the combined costs and benefits are of pursuing research that is ethically acceptable by APA standards (Table 4: Agency Guidelines Satisfied), but unacceptable by my own personal standards (Table 4: Personal Guidelines Not Satisfied). The answer to this question is perhaps the most difficult to determine because it depends upon the individual researcher's own moral values.

Personally, I feel guilt is a terrible consequence for any decision that I may make. Thus, I determine this study to be unethical because I will not sacrifice my own conscience in order to advance science or myself. Therefore, the correct decision will be to not conduct the study (Table 1). However, if this study was to have the potential to lead directly to the cure for stress-related cancer in human beings, then I would choose to conduct the investigation, thus taking the risk that the benefit to humanity will override the emotional consequences.

In conclusion, the decision to conduct or not to conduct a study using animals as subjects is a result of a complex analysis between personal and agency guidelines and their consequences for the individual researcher. The decision making paradigm presented in this paper incorporates the individual's own moral principles into the evaluation process involved in deciding whether or not to pursue research. Other factors may also be involved in determining whether to conduct a scientific research study using animals including funding issues, changes in societal standards regarding what is acceptable behavior, and changes in personal guidelines as a function of experience. It is these factors that make the research scientist's decision an ever-evolving process.

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What is wrong about Human Reproductive Cloning? A Legal Perspective

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I. Introduction

According to international consensus, reproductive human cloning is prohibited. It appears that no government is inclined to give permission to this evolutionary technique (1). Nevertheless, earlier this year, some scientists (2) announced their intention to produce a human clone within the next eighteen months. In fact, human cloning is expected to result in several miraculous medical breakthroughs (3). Therefore it is all the more remarkable that valid laws seem to underestimate possible