Caught Between a Hard Place and An Ethics Committee

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I would like to consider the concept of ethics in research from a pragmatic perspective and focus not on theoretical issues but the experiences that I have had with institutional review systems. I will outline the complexities of problems associated with the current procedures used in reviewing human research and extrapolate from these experiences to the question of ethics in animal research.

Several points should be considered. First of all, up to now the psychological research community has covertly accepted the notion of a dichotomy; animal research or human research. It is somewhat embarrassing to be part of a research symposium in which such a dichotomy has been expressly accepted. Such an acceptance ignores the continuity of consciousness and the continuity of behavior across species. Secondly, we should carefully review the complexities and absurdities of current practices in the review of human research in light of the growing controversy surrounding animal research. After the issues have been presented, I will suggest not only that institutional review boards or IRBs are an impediment to scientific progress as they currently stand and that the application of such review boards to animal research will not only further impede research in general but that these review system will further cloud the artificial animal/human dichotomy.

However, the application of a review system for animal research, one might argue, may be a worthwhile one. Let's examine the consequences of adopting such a position. For those of you

who have not had the opportunity to be "victimized" by an institutional review board, allow me to outline briefly what this phenomena entails. The review process is considerably more complicated than it may appear. In a typical academic review investigators initially submit a proposal to the Department Chairman, the Chairman passes judgment before forwarding the proposal to the Dean of the appropriate college or school, the Dean, then, reviews it prior to sending it to the Collation Officer of the Committee for Protection of Human Subjects (COPHS). At UNC-W, this committee is composed of nine individuals of which most do not engage in human research, if research at all. Finally, the proposal is forwarded to the Chancellor for Academic Affairs. The entire process ranges in terms of time from several weeks (and no hassles) to several years (and several migraines.) In our case, we submitted a proposal to examine the records of deceased mental patients in the state of North Carolina. The review process went relatively smoothly. However, in another case we submitted (myself being a secondary investigator in this case) two proposals to investigate the effects of certain pharmaceuticals on specific subject populations. In one of these studies we were interested in looking at the effects of Quaalude intoxication on brain functioning, specifically visual motor coordination. There is a paucity of research on this topic and we considered this an important project. The initial plan entailed using psychiatric residents from the UNC at Chapel Hill Medical School. For those who are familiar with psychiatric residents and/or Quaalude, one

can certainly imagine the potential confound in this study. Nevertheless, the second drug project focused on Ritalin and hyperactivity. Here we were interested in examining the effects of drug holidays versus chronic administration of Ritalin on brain functioning on hyperkinetic children. Neither of these two studies were ever realized. The Quaalude study took approximately two years to review. The Chairman, the Dean, the university COPHS (Committee for the Protection of Human Subjects), as well as local Hospital COPHS, and the COPHS from UNC-Chapel Hill's Psychiatry, Medicine, and Medical School reviewed the proposal (often with requests for revision). By the time the project was approved, Quaalude had been taken off the market. Oddly enough the Ritalin study passed review at our institution without difficulties. Nevertheless, the local Mental Health Center COPHS approved the proposal only to have the center's administration publicly state that they did not condone "Nazi-type research." As a consequence, this study was also never initiated.

These are only two examples, and I suspect two very unusual examples, but the point is clear. The cost of an IRB system is not worth the benefits they allegedly provide. The cost of copying, of collating, of mailing, and of telephone costs are not typically considered. There is also the cost of time engaged in submitting and reviewing the proposals.

The clinical IRB can be equally predictable and traumatic.

The clinical review system at the hospital begins with a

Department Head Review, the it proceeds to Clinical Director,

from the Clinical Director to the Superintendent of the hospital,

the Superintendent forwards the proposal to the District Review Board, and District Review Board sends it to the State Review Board. This process is often accompanied by trips outside the hospital to meet with the reviewing boards.

In my opinion, this process is unadulterated academic and intellectual infringement. Regulation of research is very different than the protections of subjects, human or otherwise. The regulation of research is imposing unnecessary restraints on the freedom of scientific inquiry. It is important however, to note that the concept of freedom of scientific inquiry is relative in that it is interpreted and implemented in terms of the prevailing social value and power relationships within a society. The society that I am referring to is that of an IRB. Clearly, research has to be politically acceptable in order to be conducted. The outcome of this extends to the restriction not only of research but of restriction of freedom and speech, basic rights of the United States. As Kallen and Stephenson (1978) have aptly put it, "Institutional Review Committees are essentially autonomous and unregulated bodies who have been given the power to determine the morality of all investigators in their institutions with no guarantee of consistency in time or between institutions... The privacy and lack of standardization and opportunity for arbitrary and capricious actions by some committees which have the potential for the serious of infringement of intellectual and academic freedom." As the World Health Organization has stated in their pamphlet on ethics and human research, "Experimentation is inseparable from the advances in knowledge." I submit to you that risk and progress are also equally inseparable. The current review process place, aside to the right to mankind to uphold the right of man. Eventually, the right of man is replaced with the right to value.

On the other hand, one may argue that IRBs and the process of ethics review is critical. One need not look further than the "nazi experiments on body temperature" to suggest that utilitarian approaches to research can result in unethical practices. The Tuskegee syphillis experiment or the research by Humphries are prime modern examples. The Humphries experiment is an especially interesting one, in that it examined sexual patterns of individuals frequenting public restrooms. Humphries recovered license plate numbers of individuals who engaged in sexual activities in public bathrooms and later interviewed them at their home to obtain additional information. The results suggested that individuals who frequented public bathrooms were not the sexual maniacs commonly perceived. Regardless of the usefulness of such findings, it could be argued that for some research and for some researchers, ethics review is warranted and needed for the protection of subjects, for the protection of investigators and finally, for the protection of society.

Nevertheless, the current approaches to ethics review for humans are obsolete at best in that they have ceased to protect and have begun to regulate. If we are interested in the regulation of research, then clearly, all types of research should be regulated, including computer simulated studies which do not use living subjects. If one argues that IRBs are indeed

needed then as psychologists we must also argue for the abolishment of the fichous dichotomy existing in ethics review. In other words, either we review all research with living subjects (including plants?) or review none at all. The literature, the theories point to the continuity of species, to the continuity of behavior, and to the continuity of consciousness. However, a continuity of ethics in research does not exist.

So where does this leave us? Do we all have to suffer the consequences of IRB reviews or do we leave it to the individual investigator to review his/her research? Some solutions exist. First and foremost, the continuation of open dialogue between researchers and with concerned citizens must continue. As Neil Miller and George Miller have aptly stated, it is the responsibility of the psychologist to dissiminate information to our peers and to the public. Examples of this include the Committee for Animal Research and Experimentation an the National Coalition for Science and Technology. Secondly, we must decide whether ethics review should be based on a utilitarian or deontological perspective. Finally, as Fred King has recently suggested, we must arrive at an understanding of what is the difference between the welfare and the rights of subjects. Regarding institutional review boards, I agree with the notion that developing adequate review boards can result in the safeguarding of subjects. However, it has been my experience that this is rarely the case. Therefore, it appears that the entire review system as it currently exists has to be abolished.

Additionally, we must become more aware and responsible, aware of not only ethical issues but of existing research in order to avoid the unnecessary replication of research. Finally, we need to regulate and protect our subjects and ourselves (as well as our IRBs).

In summary, the IRB system currently used in humans research has impeded and is continuing to impede the progress of human research. The argument could be made, regardless of this issue, that ethic review systems must be implemented at the animal level. If this is to be realized, an adequate system should be developed by circumventing the problems which have arisen with human IRBs.