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Ethics and non biomedical research with human subjects

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Editorial

Imagine that you develop a streptococcal throat infection. Since you are currently in military service, you go to your infirmary. The doctor gives you injections. Without telling you, however, he is conducting a randomised experiment on the effects of antibiotic therapy on the risk of rheumatic fever. As chance would have it, you received a placebo.

Now, imagine you respond to an advertisement in your local newspaper asking for assistance in an experiment on the effect of punishment on human learning. In the course of an afternoon, you are introduced to a number of persons. The researcher instructs you to ask them pre-set questions, and to shock them with increasing voltages of electricity if they answer inaccurately. They often do, and manifest increasingly violent pain as the voltage indicated on the machine which you operate increases. You find this very difficult to bear. At several points, you ask to stop, but the researcher tells you that you must continue.

Both of these are real examples. The first was made famous by Henry Beecher's 1966 paper denouncing "increasing employment of patients as experimental subjects when it must be apparent that they would not have been available if they had been truly aware of the uses that would be made of them" [1]. The second is, of course, Stanley Milgram's landmark experiment on destructive obedience [2]. Both starkly illustrate some of the moral wrongs which can occur in research involving human beings. Over the past fifty years, our awareness of ethical requirements for research has progressed considerably, as have the codes and institutions developed to protect human subjects of research. These protections, however, have mostly focused on human participants in biomedical research. Although exactly repeating Milgram's experiment does seem out of bounds today, the degree to which we protect human subjects in similar research today is unclear, may depend on local institutional rules, and remains controversial [3].

From an ethical standpoint, this double standard seems strange. Protections for human subjects of research exist because we ask these persons to take risks for the benefit of others [4]. It is difficult to see how the area of research where this risk arises can make such a difference. Nevertheless, risks encountered in biomedical research have received more attention; and biomedical researchers thus became aware of requirements for ethical research earlier than investigators in other fields of knowledge. In turn, this led to the development of ethical codes and oversight bodies which are often younger, fewer, or even non-existent in other fields. So we now have a situation where, although we have duties of protection towards human subjects of research whatever the field, it is not so clear exactly how best to fulfill these duties in all areas of study.

The article "The impact of forensic investigations following assisted suicide on posttraumatic stress disorder" provides a good illustration of some of these difficulties [5]. Wagner and her colleagues conducted a survey of family members and close friends who were present as assisted suicide was performed – legally – by a Swiss Right-to-die association. Wagner et al.'s results are intriguing, shed light on usually less examined aspects of a controversial practice, and are certainly useful. There is, however, a hitch. Had this study been conducted by researchers situated in a Medical School, it would have required independent review by an ethics committee. As it was conducted while all the authors were situated in a Department of Psychology, however, this was not done.

Had the investigators been physicians, this would have been grounds to refuse publication. Should it constitute such grounds here? From an ethical standpoint, the requirement for review by an ethics committee exists for two interconnected reasons. First, to ensure that appropriate protections are applied to human subjects of research, and limit the risks they run for the benefit of others to just those cases where such risks are minimised, and justified. Second, by entrusting such judgments to third parties, ethical review ensures that these are not biased by any considerations, including enthusiasm, which may lead researchers to accept excessive risks for research subjects. The first function, to protect human subjects, certainly seems fulfilled here. The authors' claim that "The study was conducted following the ethical standards of the German and Swiss psychological associations" does seem to be correct [6]. Were this not the case, I trust this paper would not have been published in this journal, "even with stern editorial comment" [1]. The problem is not that this study seems to have breached any substantial standards in the protection of human subjects. Rather, the problem is that it could have gone the other way. In assessing their own research rather than going

through an ethics committee, even thoughtful and well-intentioned investigators have clear incentives to label risks as low, or in any case to accept them, even when they may not have seemed reasonable to a neutral third-party.

Should review by an ethics committee be required for research with human subjects outside the domain of biomedicine? This was a difficult point of debate as the current project for a federal law on research involving humans was in development. When it came to defining the required protections' scope of application, the authors of the law project considered several options [7]. They rejected application based on the discipline or professional group of the investigators as too difficult to define exhaustively, and too likely to include research involving no risk to human participants. They also rejected applications based on the degree of risk, for just the reasons outlined above: the lack of bodies competent to review such research outside the scope of biomedicine. Overall, the current law project is thoughtful and welcome, but on this point it accepted an – arguably reasonable – compromise.The current project defines the scope of protection, which includes ethics committee review, based on two criteria [7]:

1 Research on human disease and the development and functioning of the human body, where the term "disease" is understood broadly and of course includes psychological health impairments;
2 A risk threshold based on the possibility of harm to human dignity and personal integrity: this is defined by the exclusion of research on in vitro embryos, anonymous biological material, and anonymously obtained or completely anonymised health-related data.

A study of factors associated with posttraumatic stress disorder fulfills the first condition. Whether or not this particular study fulfills the second condition depends on how complete anonymisation was. Unless the scope of the law is modified before its application, then, it will require submission of studies like this one, or very much like this one, for ethics committee review.

This law, however, is currently not in effect; and currently applicable regulations do not mandate ethics review in this case. The research ethics committee of the Canton of Zurich, where the study was run, describes its scope in the following way: *"Drug studies, as well as studies in the areas of transplantation and research with embryonic stem cells must be presented to the responsible ethics commission for approval. The patient law of the Canton of Zurich additionally requires that all research involving humans, that is, research not involving drugs, be presented to the ethics commission, if it is conducted in hospitals, long-term care institutions, outpatient institutions, and penal institutions."*[1] In other words, from a regulatory standpoint, ethics review was not required for this study.

Medical journals also have standards for publication. In this regard, the *Swiss Medical Weekly* adheres to the Uniform Requirements of the International Committee of Medical Journal Editors, [8] which in turn refer to the declaration of Helsinki on the topic of the protection of human subjects [9] This declaration states that "The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins." It also states, however, that "Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles." Although the spirit of both documents clearly encourages ethics review in all research with human subjects, neither of them technically requires it.

The authors of this paper seem to have done right by the rulebook they were given. In this specific case, moreover, the protections they provided participants may well have worked entirely adequately. This study, published at this time, however, should provide us with an occasion to question the rulebook they followed. Indeed, it seems to be currently under revision. The Swiss Psychological Association, for example, openly encourages the creation of ethics review committees in Swiss universities. This is not unique to Switzerland. More specific to our country, however, is the fact that the Swiss project for a federal law on research involving humans will require review by an ethics committee for studies very much like this one, and certainly for more studies with human subjects in the humanities than undergo ethics review currently. These developments should be welcome. From an ethical standpoint, human subjects of non biomedical research are currently more vulnerable than they should be [10]. Medical journals should take these changes on board, and be clear about any modification to publication requirements. Although progress in this area may seem more like a hindrance to some researchers, ethics review also protects investigators from ethical risks inherent to research with human subjects. Researchers too, then, should welcome these revisions. Indeed, they should participate in them, as this will also lead to processes better adapted to the requirements of their work.

[1] http://www.kek.zh.ch/internet/gesundheitsdirektion/kek/de/home.html Accessed September 8th 2011

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