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Informed Consent and Dual Purpose Research

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The ethical treatment of human participants in psychological research is regulated by both federal guidelines (Title 45, Code of Federal Regulations, Part 46, 1991) and APA's ethical standards (American Psychological Association, 1992). Both rely on a process whereby those not directly involved in the research review each research protocol and pass judgment on its appropriateness, and the researcher commits to conducting the research in strict accordance with what was approved by others.

The practice most frequently relied upon for protecting human participants is informed consent in which potential participants are told the conditions they will encounter and given the freedom to accept or decline participation. Federal guidelines and APA standards require informed consent for most all research. Scientific journals often demand it. This is particularly true of medical journals. However, many other journals that attract scholars from multiple disciplines, including psychology, demand informed consent as evidence of ethical treatment. Science requires informed consent. Instructions to authors in Psychological Science state, "Investigations on human subjects must include a statement indicating that informed consent was obtained...." (Psychological Science, 1999) (emphasis added). The instructions are unambiguous; psychological research without informed consent is not acceptable.

In spite of the ubiquitous demand for informed consent, those who have carefully considered the ethical treatment of human participants recognize that there are times when participants face little or no risk and informed consent is difficult or even impossible to obtain. Thus, both APA standards and federal regulations allow for exceptions to informed consent. Informed consent can be waived when the first three of the following are met and the fourth is considered (Title 45, Code of Federal Regulations, Part 46., 1991, Section 46.116, d):

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of subjects;

(3) the research could not practically be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In spite of the possibility of exception, a number of factors have created a situation in which it is very difficult to conduct and publish research that does not incorporate informed consent. As has already been mentioned, a number of important scientific journals exclude the possibility of exemption. In addition, in practice, institutional review boards (IRBs) often are reluctant to approve exemptions. Heavy workloads faced by IRBs create a press toward standard operating procedures that, by their very nature, are resistant to exceptions. Very real threats of litigation faced by IRBs favor informed consent, preferably with participants' signatures indicating that their voluntary informed consent. Finally, demands of the role of IRB member may lead their members to develop positions regarding informed consent that differ from the views of others. In this regard, we performed a study in which we asked IRB members, human resource professionals, and job applicants to evaluate the same research protocol. We found that IRB members were more likely than both the HR professionals and job applicants to believe informed consent was needed in the research and less likely to believe that obtaining consent would interfere in the work practice (Ilgen & Bell, in press).

Inflexible adherence to requiring informed consent is particularly problematic when the data serve two purposes – science and practice. These conditions occur frequently in education, health care, and research in business, industry and government organizations. For example,

implicit or explicit employment agreements between employees and employers often involve the right of the employer to observe and measure the quality and quantity of an employee's work performance. Such data serve a practice function in the ongoing operation of the business. These same data may also be of interest for research. One interest might be in the development of multidimensional criterion measures to capture overall performance. Another might be the development of ways to feed back performance data to maintain or change behaviors. Archival data often valuable for understanding human behavior often could not be used if informed consent were required from those who may have provided the data many years ago.

Two approaches must be considered to reduce the reluctance to consider exceptions to informed consent when the four conditions mentioned earlier are met. First, journals should not rely on informed consent as the method of screening research for the ethical treatment of human participants in research. Informed consent is neither necessary nor sufficient to guarantee protection (See Federal guidelines and both the APA Ethical standards currently in force (APA, 1992) and the revisions under consideration (APA, 2001)). Second, efforts must be made to work with IRBs and other units that review psychological research to insure that their members are aware of the conditions under which exemption from the use of voluntary informed consent is considered reasonable.

Without such efforts, two unfortunate consequences are likely. First, important psychological research that is accepted as representing no more than minimal risk will be more difficult, or worse, impossible to conduct if IRBs insist on informed consent. Second, if neither researchers nor those drawn from the potential participant populations believe particular research practices do not put participants at risk and that informed consent is not possible, they may risk conducting that research without review. We (Ilgen & Bell, in press) recently surveyed all first

authors of studies conducted in employment organizations that were published in two journals during 1997 and 1998. Forty-four percent of them reported having not submitted their protocols to an IRB before conducting the research. While we do not support such activity, we recognize the risks to regulatory standards and practices that are not seen as credible. For many reasons, efforts must be taken to insure that behavioral systems developed to regulate the fair treatment of human subjects focus on the underlying goal of protecting human subjects, not insisting on informed consent in all situations.

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