Informed consent in research and practice involving human subjects: History, theory and problems concerning contemporary practice

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Abstract
Obtaining informed consent is both a legal and moral requirement in scientific and clinical practice involving human subjects. However, the answer to the question of what it means for informed consent to be valid is not self-evident. First, we will consider the historical roots of informed consent and its philosophical assumptions as well as the implications of these assumptions for a theory of informed consent. Second, we will review a theory of informed consent using a principle-based approach. And third, we will discuss the status of informed consent using a principle-based approach in contemporary literature, along with the limitations and problems in translating theory into practice. It is stressed that subjective interpretation of relevant contextual factors necessarily remains an element in the process of obtaining valid informed consent.

Keywords: *Informed consent, principle-based approach, ethical conduct, human subject, ethical research, psychology*

Introduction

It is said that *informed consent* is primarily intended to secure the rights of human research subjects and patients. But the importance of informed consent goes still further. Informed consent is a fundamental expression of respect for human autonomy. In this way, informed consent relates to concepts used in, for example, the United Nations' Universal Declaration of Human Rights (Macklin, 2003). By law, all scientific research involving human subjects as well as all therapeutic interventions involving human patients have to satisfy the criterion of obtaining informed consent from every one of those subjects (Code of Federal Regulations, 2009). Thus, informed consent is an important feature of scientific research and therapeutic intervention. This observation gives rise to the following question: "what do we mean by informed consent?" We attempt to answer this question by exploring and combining historical, philosophical and contemporary sources. We give an account of the content of the notion of informed consent in terms of history and theory that draws primarily on the work of Faden, Beauchamp and King (1986), following a principle-based approach to ethical practice.

The second part of this paper concerns the contemporary use of informed consent in psychological research and therapeutic interventions. Can one identify the theoretical notion of informed consent in terms of autonomous action in the contemporary practice of obtaining informed consent in research and therapeutic intervention? And if so, is the application of such a theoretical notion of informed consent unproblematic?

What is informed consent?

When asking the question "What is informed consent?" most people can come up with an answer. "Why, informed consent is exactly that, someone must be informed of the treatment or research and must give consent on the basis of that information." And of course there is some merit in this reply. On the face of it, informed consent seems pretty straightforward. The narrative textbook history tells us that the term was first used in the context of a patient-physician relationship during the *Salgo v. Leland Stanford Junior University Board of*

Trustees (1957) case. It can be said that, for the purpose of conducting research using human subjects, an equally simple and definitive story of informed consent can be told. A set of rules concerning those subjects' rights was first formulated in the Nuremberg Code (1950), following the cruelties perpetrated on human test subjects in research conducted by Nazi doctors during World War II. These rules are crystallized in the Declaration of Helsinki (Saif, 2000), the Code of Federal Regulations (2009) and, in the case of psychological research and therapy, operationalized in the American Psychological Association's Code of Conduct (2002). In short, the notion of informed consent arose just over 60 years ago and is applied in research and treatment involving human subjects.

And again, there is some merit in this simple account of informed consent. The history of the institutional regulation of ethical practice is told in this way. But this is not the whole story. One does not have to be a radical constructivist in order to accept the proposition that social practices are embedded in tradition, history and systems of meaning. These necessary conditions or frameworks of social life influence the very meaning of social practices. Or as Katz (1977) puts it: "Dreams, fairy tales, even legal phrases and medical terminology have much in common; they seduce us to surrender our adult critical judgment. We remain all too prone to such surrenders so that, as fairy tales again instruct us, we can go to great lengths in denying that the emperor has no clothes" (Katz, 1977, p. 138). It is unlikely that a static account of "first-time" use of such an influential term can tell the whole story. There are reasons for the first use of informed consent in language, and these reasons can tell us more about the roots of informed consent in the history and theory of social practice.

This consideration leads to the question concerning the *origin* of informed consent. For instance, one could trace uses of guidelines that appear to represent certain features of informed consent in history. Or one could investigate the theoretical grounding of informed consent in morality. Faden et al. (1986) provide an account of the former and the latter, which is used in this paper. The following sections summarize their account of the theoretical basis and history of informed consent.

Philosophical framework: questions concerning a principle-based approach

Morality denotes a broad spectrum of philosophical, social and professional questions, debates and controversies concerning right and wrong, good and evil, virtues and vices, dos and don'ts. Faden et al. (1986) use the term "morality" to refer to the social institution concerned with practices defining right and wrong. Ethical theory and moral philosophy refer to the reflection on this institution. The latter consists mainly of *justification*: is there a philosophical basis on which morality as a social practice can be justified? The content of such a philosophical basis is highly controversial in the field of philosophical ethics. First, there is no definite consensus on the existence of a philosophical basis of ethics. Second, there are numerous competing views, for instance virtue, teleological, consequentialist and care approaches to morality.[1] However, in the case of informed consent (and other ethical guidelines in research or therapeutic intervention concerning human subjects) there seems to be a clear tendency to identify certain universal principles as a philosophical basis of professional ethical practice in psychological research and therapeutic interventions (Knapp & VanDeCreek, 2004). Knapp and VanDeCreek (2004) show that "almost all of the

[1] Moreover, a philosophical basis of morality should provide an account of the possibility of moral knowledge and status of moral entities, a theory of meaning, a superior explanatory power over other possible philosophical accounts of morality and all sorts of philosophical issues that arise when one gets involved on the battlefield of philosophical debate. Obviously, these issues are beyond the scope of this paper. As will be shown, Faden et al. (1986) use a principle-based approach as the philosophical framework of informed consent.

enforceable standards in the 2002 APA Ethics Code are based on or can be linked logically to the criteria of principle-based ethics" (p. 247).

Faden et al. follow this tendency and formulate three principles of reasoning that (at least partly) constitute the grounding of informed consent in philosophy, namely the principles of autonomy, beneficence and justice. The first of these, autonomy, is the most constitutive element of informed consent. Autonomy is grounded in the Kantian sense of the term, in which persons are never to be treated as a means to an end, but as ends in themselves. "Beneficence" (as will be seen in the section about the history of informed consent) concerns the duty of the researcher or therapist to comply with the Hippocratic oath, in particular the phrase "help, or at least do no harm" (Faden et al., 1986, p. 10). Finally, "justice" refers to justifying the way in which resources are distributed in a society. For instance, scarcity of resources compromises the ability to satisfy the demands that the principle of beneficence promises everyone. Beneficence, autonomy and justice are not independent principles and can conflict with one another in numerous ways. Ross (1930, in Faden et al., 1986), in response to problems concerning conflicting duties, proposes the notion of one duty overriding another. The weight of conflicting duties depends on the balance of right over wrong in a particular context. From these theoretical principles, practical rights and duties can be derived.

At this point, some reflection concerning the philosophical framework underlying informed consent seems in order. The choice of a principle-based approach from which rights and duties can be derived is indeed a choice, not a necessity. The tendency toward grounding research and therapeutic practice in such a principle-based approach clearly seems to be an expression of the Kantian tradition (i.e. it is essentially deontological, illustrated by considering rights as correlative to duties). In addition, utilitarianism or consequentialism seems to be employed by Faden et al. (1986) as well when they cite Ross (1930, in Faden et al., 1986) in contending that risks and benefits must be continuously weighed against each other. It is important to note that Faden et al. (1986), by choosing a deontological consequentialist approach, do not justify a particular philosophical framework for informed consent. Rather, they ground their account of informed consent in an existing position in moral philosophy. Consequently, they cannot trace the *true* origin of informed consent, but merely ground it in the position of autonomous choice and judge it as a *possible* basis of informed consent. Other possible frameworks are not explored, which results in the departure from the field of philosophy and the approach of principle-based ethics as a useful tool in describing existing ethical practice.

In short, in formulating a notion of informed consent, a principle-based approach based on autonomy, beneficence and justice provides a useful framework. However, as briefly discussed in the introduction, ideas, concepts and their uses do not originate from their first instance of use and articulation. Moreover, the content of a principle-based approach has been subject to constant change throughout history. In the following section we will review such a history of practices of informed consent through the second half of the twentieth century.

A brief history of informed consent

Faden et al. (1986) provide a history of "informed consent." Exploring the roots of an important aspect of ethical research is "essential for understanding the contemporary concept of informed consent" (Faden et al., p. 53). Clearly a comprehensive history of all elements of informed consent would require at least a book-length treatment. Consequently, only some aspects relevant to present purposes are highlighted. As has been said, the way we use *informed consent* now has its origins in the 1950s. However, there are competing views on whether there was something such as informed consent before that time. The historian Martin

S. Pernick and the psychiatrist Jay Katz analyze apparent instances of informed consent from Hippocrates onwards.

In Ancient Greece, the philosopher and physician Hippocrates wrote about the duties of the physican and his writings remain influential in medicine today. However, as Faden et al. (1986) state, it is not clear whether these writings are about ethics or about etiquette. Moreover, it is clear that, in contrast to informed consent as it is used today, all the rules reflected in Hippocrates' writing were based on the beneficence principle of moral philosophy. Informing a patient about the treatment or its possible consequences (i.e. both improvements and risks) were primarily aimed at securing and preserving the reputation of the physician. Consequently, the physician mainly talked to the patient in order to gain his confidence, while the patient had no say whatsoever concerning the intervention itself.

Later, most writings about ethical conduct in medicine consisted of elaborations of extracts of Hippocratic writings, transformed into works that best fitted prevailing traditions and theology (Faden et al., 1986). An example of this is the well-known rule that the main duty of the physician is "to help, or at least to do no harm," but the dominant Latin interpretation until recently was "primum non nocere," or "first - or 'above all' - do no harm" (Jones, 1988, in Faden et al., 1986, p. 10). The status of beneficence when interpreted in the latter sense differs from the interpretation in the former sense. While it is not clear whether such erroneous translations are intentional, it is clear that they can be extremely influential in shaping the concept of beneficence through history (namely, as *a* code of conduct rather than *the* most important code of conduct). Faden et al. (1986) suggest that during the Middle Ages, ethical conduct was still primarily based on the beneficence model.

Pernick (1982, in Faden et al., 1986) traces the first elements of informed consent to the work of the thirteenth-century French physician Henri de Mondeville, who counseled that the physician should provide his patients with information concerning their treatment. In addition, "Mondeville cautioned *not to treat* patients *without obtaining their consent*" (Pernick, 1982, in Faden et al., 1986, p. 64). But "on the other hand, patients should obey their surgeons implicitly in everything appertaining to their cure." (p. 64**)** Moreover, Mondeville also acknowledged that, in the interests of the treatment, it is permissible for the physician to deceive or leave out information as he sees fit. In other words, while communication between the physician and his patients became part of medical practice in medieval times, one can safely assume that the absolute authority of the physician still prevailed. Faden et al. (1986) follow Katz (1984, in Faden et al., 1986) in concluding that no meaningful concept of informed consent was employed during medieval times.

However, the practice of sharing information continued into the Enlightenment. Faden et al. (1986) mention Benjamin Rush, a founding father of the United States and physician during the second half of the eighteenth century. Rush held that as much disclosure of information as possible would foster understanding on the part of the patient concerning their illness. This insight into their own condition was thought to be beneficial. However, Rush at no time advocated the sharing of information in the context of a criterion for obtaining the patient's consent. Deception was approved of in the case of "unenlightened patients" (Faden et al., 1986, p. 65), and so the beneficence model of treatment remained prevalent. At the beginning of the nineteenth century, Thomas Percival proposed ethical guidelines for the patient-physician relationship. Percival's code of conduct was used as the basis for the very first Code of Medical Ethics of the American Medical Association in 1847. However, this code did *not* predominantly reflect the concept of autonomy, with its focus on the patient's respect, gratitude for and confidence in the physician.

With respect to the history of informed consent through the end of the nineteenth century, Faden et al. largely followed Katz in his thesis that no meaningful informed consent existed before 1957. But this position is not uncontested. In fact, Vollman and Winau (1996)

mention the obtaining of informed consent in medicine during the nineteenth century, well before the Nuremberg Code. For example, a professor of dermatology and venereology, Albert Neisser, in his search for a serum against syphilis, infected some of his patients with syphilis in 1898. The Royal Disciplinary Court of Germany ruled that Neisser should have obtained the patient's informed consent. This event led to the first government directive that "all medical interventions other than for diagnosis, healing, and immunization were excluded under all circumstances if (…) the subject had not given his or her 'unambiguous consent' after a 'proper explanation of the possible negative consequences' of the intervention" (Vollman & Winau, 1996, p. 1447). Principles of beneficence and autonomy were to be weighed against one another. During the first half of the 20th century in Germany, there was a notable increase in focus on autonomy and the legal doctrine of informed consent (Vollman & Winau, 1996). Additionally, research not strictly aimed at therapeutic intervention was "under no circumstances permissible without consent" (Sass, in Vollman and Winau, 1996, p. 1446).

Notwithstanding the different perspectives on the actual history of informed consent, a notable shift from beneficence-based thought towards autonomy-based thought can be detected. Ideas and requirements concerning ethical conduct towards patients and research participants become more demanding. The current concept of informed consent can be formulated in terms of balancing the principles of beneficence, autonomy and justice, with autonomy as the most important ingredient. In the following section we will consider one such contemporary theory of informed consent.

A theory of informed consent

A theory of informed consent following a principle-based approach is based on beneficence, autonomy and justice. In this section, the principle of autonomy is reviewed because it is considered to be the most crucial feature in the contemporary concept of informed consent (Faden et al., 1986). Faden et al. (1986) define autonomy of agents (acting individuals) as involving recognition "with due appreciation [of] that person's capacities and perspective, including his or her right to hold certain views, to make certain choices, and to take certain actions based on personal values and beliefs" (p. 8). Their definition derives from the Kantian notion that autonomous persons are ends in themselves and are not to be treated merely as means to the ends of others. Moreover, Faden et al. (1986) draw two distinctions concerning the concept of autonomy. The first of these is the distinction between an autonomous person and autonomous choice or action. This distinction provides (a) a way in which non-autonomous persons (for example a schizophrenic during a psychotic episode) can make autonomous choices, and (b) a way in which autonomous persons can make non-autonomous choices (for example a person qualified to act autonomously who does not read the consent form before signing). X acts autonomously only if X's act satisfies the criteria of intentionality, understanding and noncontrol. Acting autonomously exists on a continuum. Intentionality is dichotomous (i.e. either there is intention or there is not), whereas understanding and control can be matters of degree. Consequently, a second distinction is drawn between substantially autonomous actions and those actions that are less than substantially autonomous. The result of the emphasis on acting autonomously instead of the autonomy of the self (a more dichotomous philosophical notion) is the possibility of "autonomy by degree" (Faden et al., 1986, p. 240). The rationale in this concept of autonomy, and an important one in the second part of this paper, is that informed consent in practice can be a reality instead of an ideal. Autonomous action is carried out by the average autonomous actor, not the ideal autonomous one. For a better understanding of the concept of autonomous choice, the three criteria of autonomous choice will be considered briefly.

Intentionality, understanding and noncontrol

"Intentionality" refers to "action willed in accordance with a plan." (Faden et al., p. 243) This willing involves both *wanting*, the intentional goal-directed behavior towards the projected end, and *tolerating*, which is to be thought of as consenting to a sort of collateral damage necessary to arrive at the intended goal. "Understanding" can be analyzed as consisting of three components: knowing how (competence), knowing that (propositional knowledge claims) and knowing what (comprehending the communication, what is being said). The latter two are paramount to understanding applied to informed consent: "understand *that* they [patients or subjects] must consent to or refuse a particular proposal by understanding *what* is communicated in an informational exchange with a professional" (Faden et al., p. 250). As with the principle of intentionality, understanding one's actions and their consequences is defined in terms of *adequate* comprehension of all the *relevant* propositions, allowing the average autonomous actor to be the standard of comparison. The principle of noncontrol refers to the presence or absence of influence of others on the process of acting autonomously. This influence can take the form of coercion (i.e. always controlling), persuasion (i.e. always noncontrolling) or manipulation (existing on a continuum of noncontrol). Possible elements of a fourth principle can be rephrased as internal influences of noncontrol (i.e. neurotic compulsions, addictions and self-alienating psychiatric disorders) (Faden et al., 1986).

In the previous sections, we have seen a possible account of informed consent in terms of its history, philosophical framework and theoretical meaning. Usually, a study reports that full or *valid* informed consent was obtained. However, further information about the content of such informed consent is not always provided. In the remainder of this paper we will compare the concept of informed consent with uses of informed consent in contemporary research and clinical practice.

Contemporary practice of informed consent

Does the present use of informed consent represent a principle-based approach?

The American Psychological Association Ethics Code (2002) is intended to provide professional researchers and practitioners with an instrument for applying ethically sound standards to their conduct in client-clinician/researcher relations. One reason for issuing such a code of conduct would be the legal requirement of researchers and practitioners to protect the rights of human subjects. However, "Whether a psychologist has violated the Ethics Code standards does not by itself determine whether the psychologist is legally liable in a court action" (American Psychological Association, 2002, Introduction and Applicability). The Code is intended to be a set of principles, rather than a finite set of rules to be implemented in specific situations. It follows that these guidelines are never fully satisfied, but act as an ideal picture of ethical conduct. The professional has a constant duty to analyze his or her actions critically in terms of those principles. *Principles* is a key term in the Ethics Code, and together with the abstract nature of such principles one could hypothesize that the Ethics Code follows a Kantian principle-based approach as formulated by Faden et al. (1986). In fact, Knapp and VanDeCreek (2004) state that the Ethics Code largely satisfies the features of principle-based ethics as formulated by Ross (1930, in Knapp & VanDeCreek, 2004), of which principles similar to autonomy, beneficence and justice are part.

Anderson and Mukherjee (2007) describe the contents of contemporary informed consent in terms of *information sharing*, *decisional capacity* and *capacity for voluntarism*. These three criteria of valid informed consent are similar to the principles of understanding, intentionality and noncontrol respectively. Anderson and Mukherjee (2007) detect several problems concerning these criteria, some of which arise from the criterion of information sharing. The type and extent of information to be disclosed is controversial, but include "aims

of the study, potential risks and benefits of participation, alternatives to participation, and relevant study design features" (Anderson & Mukherjee, 2007, p. 647). There are several reasons for withholding information, one of them concerning the "therapeutic privilege," when it is felt that disclosure of the information could have an adverse impact on the patient's well-being (Levine, 2003, in Anderson & Mukherjee, 2007). When applied to the principle-based approach, withholding information for this reason amounts to valuing beneficence over autonomy or autonomous choice. This is a potentially harmful situation from the autonomous choice point of view, as a code of conduct based on abstract principles does not provide definite rules concerning the amount of information to be disclosed. In a research situation, such practices are even more harmful, since the purposes of research are often less focused on therapeutic benefit for the individual participants. Another potentially harmful effect of withholding information concerns noncontrol as a criterion of autonomous action. Withholding information can be seen as a manipulative strategy in order to obtain the client's consent. A third problem concerning information disclosure is the "therapeutic misconception." Research subjects are biased in the sense that they think experiments are primarily designed to benefit them instead of to obtain generalizable findings. Researchers are reluctant to inform participants accurately in order to correct this bias. (Katz, 1993, in Appelbaum, 1996; Appelbaum, 1987, in Appelbaum, 1996). In other words, at least some of the problems of obtaining informed consent in contemporary research and practice agree with Katz's thesis that "the beneficence model is overwhelmingly predominant (…) [and] informed consent has not changed the fundamental character of the physician-patient relationship" (Faden et al., 1986, p. 100).

Decisional capacity is all about comprehension of the information relevant to the study. To be able to give informed consent, a person must be able to think rationally about those relevant facts and the upcoming decision, and must be able to communicate their preference (Anderson & Mukherjee, 2007). Both Faden et al. (1986) and Anderson and Mukherjee (2007) detect a problem with this criterion. Many psychiatric illnesses (e.g schizophrenia, psychosis, amnesia and dementia) directly affect cognitive processes, intellectual functioning and communication skills. Take, for example, the issue of obtaining informed consent from schizophrenic patients. The issue concerning the ability of both schizophrenic patients and schizophrenic research subjects to give their informed consent has been studied thoroughly (see, for example, Moser et al., 1994; Appelbaum, 1996; Cuénod & Gasser, 2003; Andreasen, 2005; Kaup, Dunn, Saks, Jeste & Palmer, 2011; Carpenter et al., 2000). Opinions vary on whether persons with schizophrenia are able to give their informed consent in some or all situations, but it would be of enormous value to be able to assess a patient's decisional capacity by using an objective measure. Attempts at creating such a "capacimeter" are numerous, one of which has been undertaken by Grisso and Appelbaum (1995, in Kapp & Mossman, 1996), although they themselves warn that the MacArthur group's "experimental measures" of decisional capacity should not be interpreted as determinations of legal incompetence to consent to treatment" (Kapp and Mossman, 1996, p. 75). In fact, Kapp and Mossman raise objections that lead them to conclude that such a universally valid measure cannot exist. To name a few, there is the inevitability of clinical judgment, varying definitions of capacity, a huge variety of different types of choices to be made (amounting to different standards of competence or capacity), changes in decisional capacity over time, and so on (Kapp & Mossman, 1996). Perhaps the most important point in this connection is that "capacity is not an all-or-nothing property of persons" (Kapp & Mossman, 87). Faden et al. (1986) use the term "competence" when they speak about decision-making and indeed place it on a continuum. The fact that competence exists on a continuum means that there are more or less substantially autonomous choices, varying in appropriateness in different contexts. What it means to be competent or capable of making

decisions relies heavily on contextual factors such as the physical and psychological state of the individual at that time, the urgency of the situation, the nature of the experiment or intervention and the like. An objective test of decisional capacity necessarily uses cut-off scores and therefore has to deal with false positives and false negatives. Considering the volatile nature of the concept of decisional capacity, it could be argued that a clinician's or researcher's professional judgment can take into account all the relevant situational factors in a way that an objective measure cannot. However, there are certain problems with such subjective judgment. Kapp and Mossman propose that, instead of focusing on tests of decisional capacity, "time and resources be invested in the development and dissemination of relevant clinical practice parameters" (Kapp & Mossman, 1996, 93). Such systematically developed guidelines assist the clinician in making a judgment on an individual's decisional capacity.

The third criterion for valid informed consent, capacity for voluntarism or noncontrol is probably the most obvious criterion as well as the one that that is least understood. It seems fairly obvious because consent based on autonomous choice should not be influenced by involuntary processes such as external pressures. And it is least understood because such influences are numerous, can be very subtle and are barely noticeable. For example, a patient or research participant might be anxious to refuse his or her consent to the researcher, therapist or physician. The requirements for consent complying with the voluntarism requirement formulated by Anderson and Mukherjee (2007) largely correspond to the elements of noncontrol by Faden et al. (i.e. coercion, manipulation and persuasion).

Conclusion

The main question, "What do we mean by informed consent?," differs from the question "What is informed consent?" The latter suggests an answer in which practical guidelines with all the ingredients necessary to obtain informed consent are provided. An answer to the first question requires an overview of the elements constituting the concept of informed consent. In this paper we have considered three of those elements. The philosophical framework of informed consent consists of a principle-based approach to ethical conduct in the case of human subjects, the principles being autonomy, beneficence and justice. Autonomy is the necessary and sufficient element of informed consent. History supports this view, with autonomy gradually becoming a more important feature as informed consent becomes a part of research and clinical practice. Faden et al. (1986) identify autonomous action as a key component of informed consent. For an action to be autonomous it must satisfy the criteria of understanding, intentionality and noncontrol. Anderson (2007) labels these criteria as information sharing, decisional capacity and capacity for voluntarism.

This analysis provides us with a neat, conceptually valid and potentially useful tool for obtaining informed consent in contemporary research and clinical practice. However, great caution must be exercised when assessing the validity of any one instance of informed consent. Every situation that requires informed consent to be obtained is unique in that different contextual factors apply. It may well be that clinical judgment is the only possible way to assess those factors properly. Consequently, however conceptually valid and clear a theory of informed consent may be, in practice the transition of the theoretical notion into actual application using objective, generic methods may turn out to be flawed. Clinical judgment, assisted by evidence-based general guidelines, remains an important part of arriving at a valid informed consent. This subjective feature of valid informed consent entails the potential problems associated with subjective interpretation in science. Specifically, the principles of beneficence and autonomy, which have traditionally and constantly battled for supremacy, must be considered. As an example, consider a situation in which the clinician or researcher also functions as the professional judging the validity of informed consent

obtained. A possible conflict of interest arises. Maximizing potential benefits (such as treatment results or generalizable data) might violate the condition of autonomous choice and therefore harm the validity of informed consent. Of course, beneficence is to remain an important principle in the field of research, psychological treatment, medicine and so forth. However, the doctrine of autonomous action answers to the current ideas of freedom of choice and other fundamental human rights. While research and therapy might proceed faster by neglecting the individuals concerned, there is more to it than just results. In conclusion, if one values the Kantian notion of treating individuals as ends in themselves instead of treating them as a means to an end, the principle of autonomy necessarily applies, guarding individuals against possible harm inflicted "for the greater good."

References

Anderson, K. K., & Mukherjee, S. D. (2007). The need for additional safeguards in the informed consent process in schizophrenia research. *Journal of Medical Ethics*, *33*, 647-650. doi:10.1136/jme.2006.017376

Andreasen, N. C. (2005). Informed Consent in Medication-Free Schizophrenia Research. *American Journal of Psychiatry*, *162*, 1209-1211.

Appelbaum, P. S. (1996). Drug-Free Research in Schizophrenia: An Overview of the Controversy. *IRB: Ethics and Human Research*, *18*, 1-5.

Carpenter, W, T., Gold, J. M., Lahti, A. C., Queern, C. A., Conley, R. R., Bartko, J. J., Kovnich, J., & Appelbaum, P. S. (2000) Decisional Capacity for Informed Consent in Schizophrenia Research. *Archives of General Psychiatry*, *57*, 533-538.

Cuénod, M., & Gasser, J. (2003). Research on the mentally incompetent. *Journal of Medical Ethics*, *29*, 19-21.

Department of Health and Human Services. (2009). Code of Federal Regulations: title 45, part 46.

Ethical Principles of Psychologists and Code of Conduct. (2002). *American Psychological Association*. Retrieved from http://www.apa.org/ethics/code/index.aspx

Faden, R. R., Beauchamp, T. L., & King, N. M. P. (1986). *A History and Theory of Informed Consent*. Oxford: Oxford University Press.

International Military Tribunal. (1950). Trials of war criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Washington, D.C.: Government Printing Office.

Katz, J. (1977). Informed consent – A fairy tale? – Law's vision. *University of Pittsburch Law review*, *39*, 137-174.

Kapp, M. B., & Mossman, D. (1996). Measuring Decisional Capacity: Cautions on the Construction of a "Capacimeter." *Psychology: Public Policy, and Law*, *2*, 73-95.

Kaup, A. R., Dunn, L. B., Saks, E. R., Jeste, D. V., Palmer, B. (2011). Decisional Capacity and Consent for Schizophrenia Research: An Examination of Errors. *IRB: Ethics & Human Reasearch, 33,* 1-9.

Knapp, S., & VanDeCreek, L. (2004). A principle-based analyses of the 2002 American Psychological Association Ethics Code. *Psychotherapy: Theory, Research, Practice, Training, 41,* 247-254. doi:10.1037/0033-3204.41.3.247

Macklin, R. (2003). Dignity is a useless concept. *BMJ, 327,* 1419-1420. doi:10.1136/bmj.327.7429.14.19

Moser, D. J., Reese, R. L., Schultz, S. K., Benjamin, M. L., Arndt, S., Fleming, F. W., Schachter, D., Kleinman, I., Prendergast, P., Remington, G., & Schertzer, S. (1994). The Effect of Psychopathology on the Ability of Schizophrenic Patients to Give Informed Consent. *Journal of nervous and mental disease, 182,* 360-362.

Saif, M. (2000). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Journal of the American Medical Association, 284,* 3043-3045.

Salgo v. Leland Stanford Junior University Board of Trustees, 154 Cal. App. 2d 560, 317 P. 2d 170 (Dist. Ct. of App. 1957).

Vollman, J., & Winau, R. (1996). Informed consent in human experimentation before the Nuremberg code. *BMJ, 313,* 1445-1447.