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Informed Consent to Human Subject Research: Improving the Process of Obtaining Informed Consent from Mentally Ill Persons

Cover Page Footnote

J.D. Candidate, Fordham University, 1998; A.B., University of Delaware, 1994. Senior Articles Editor, Fordham Urban Law Journal.

INFORMED CONSENT TO HUMAN SUBJECT RESEARCH: IMPROVING THE PROCESS OF OBTAINING INFORMED CONSENT FROM MENTALLY ILL PERSONS

Dorothy Derrickson*

Introduction

Greg signed the informed consent provided by his doctor, and required for participation in the clinical research protocol.¹ Greg suffers, however, from schizophrenia, a disease that causes decreased cognitive abilities.² As a result, he did not understand that when the informed consent form stated his condition might improve, worsen or change, it meant that he may be taken off of his medication and experience schizophrenic relapse.³

* J.D. Candidate, Fordham University, 1998; A.B., University of Delaware, 1994. Senior Articles Editor, FORDHAM URBAN LAW JOURNAL.

1. See 45 C.F.R. §§ 46.116-117 (1997). Research conducted for the Food and Drug Administration follows regulations similar to the Department of Health and Human Service's regulations on the Protection of Human Subjects. See 21 C.F.R. §§ 50.20-27. This Note will discuss only the Department of Health and Human Services regulations.

2. Schizophrenia involves a range of cognitive dysfunctions. See AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 274 (4th ed. 1994) [hereinafter DSM-IV].

3. This anecdote is based upon a study that occurred at U.C.L.A. in 1989 and was widely criticized by the medical ethics field. See James Willwerth, *Madness in Fine Print*, TIME, Nov. 7, 1994, at 62; see also Philip J. Hilts, *Agency Faults a U.C.L.A. Study for Suffering of Mental Patients*, N.Y. TIMES, March 10, 1994, at A1; James Willwerth, *Tinkering with Madness*, TIME, Aug. 30, 1993, at 40. Gregory Aller, a subject in the study entered the second phase of the study on June 1, 1989. See Willwerth, *Tinkering with Madness*, *supra*, at 40-41. According to Aller, he began to suffer from relapse in October. See *id.* at 41. On January 15, Aller threatened his mother with a knife. See *id.* at 41-42. He tried to get to Washington, D.C. to kill President Bush because the voices in his head told him Bush was about to launch a nuclear attack on Russia in order to confuse the space aliens. See *id.* at 42. It was not until nine months after his relapse that he resumed taking anti-psychotic medication. See Hilts, *supra*, at B10.

The study's goal was to better identify factors that cause some persons to be more prone to schizophrenic relapse in order to develop "preventive intervention strategies in the future." *Problems in Securing Informed Consent of Subjects in Experimental Trials of Unapproved Drugs and Devices: Hearing Before the Subcommittee on Regulation, Business Opportunities, and Technology of the House Committee on Small Business*, 103rd Cong. 43 (1994) (statement of Don A. Rockwell, M.D., Director, Neuropsychiatric Hospital, University of California, Los Angeles) [hereinafter Rockwell Testimony].

The federal regulations regarding research involving human subjects provide extra protections for some vulnerable populations,⁴ but do not provide adequate informed consent protection for mentally ill persons. Patients like Greg may remain completely unaware of the true implications of the study; they provide their consent but fail to meaningfully understand the protocol.

The doctrine of informed consent has been debated and analyzed by numerous scholars.⁵ This Note focuses on one aspect of the process: to ensure a participant can provide meaningful informed consent.⁶ This Note demonstrates that the federal regulations regarding human subject research must provide more specific guidelines that emphasize the process of obtaining informed consent from persons with mental illnesses. Part I discusses schizophrenia as a case example of a mental illness that requires more stringent informed consent standards in human subject research, detailing the nature of schizophrenia and the diagnostic process. Part II describes the legal foundations of informed consent to

After the study, some of the patients stated that they were not warned about the severity of the potential relapse they could experience. The National Institute of Health's Office for the Protection of Research Risks ("OPRR") investigated the study and reported that it did not comply with the federal regulations since the extent of the risks taken by patients and the fact that ordinary treatment would be a safer course for most of the patients were not disclosed to the subjects. *See* Hiltz, *supra*, at B10. Even though OPRR criticized some aspects of the study, it "found 'no demonstrable basis for rejecting the U.C.L.A. IRB's determination that the design of the [study] is scientifically and ethically justifiable.'" Rockwell Testimony, *supra* (quoting OPRR Report at 17 (May 11, 1994)). In response to the criticisms advanced by the OPRR, U.C.L.A. added information to the consent forms that previously was presented orally, and included additional information about the risks and procedures of the study. *See id.*

4. *See* 45 C.F.R. §§ 46.201-46.409 (1995).

5. *See* GEORGE J. ANNAS, ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION (1977); PAUL S. APPELBAUM ET AL., INFORMED CONSENT (1987); RUTH R. FADEN TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986); JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT ch.3(1984) [hereinafter THE SILENT WORLD]; ROBERT J. LEVINE, ETHICS AND REGULATIONS OF CLINICAL RESEARCH (1986); Bartolo, *Tales of Informed Consent: Four Years on an Institutional Review Board*, 2 HEALTH MATRIX 193 (1992); Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63 (1993); Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7 (1993).

6. This Note further develops and analyzes the basic proposition advanced by Anne J. Ryan in *True Protection for Persons with Severe Mental Disabilities, Such as Schizophrenia, Involved as Subjects in Research? A Look and Consideration of the "Protection of Human Subjects"*, 9 J.L. & HEALTH 349 (1994-95). Ms. Ryan recommended regulations that would provide true consent to persons with mental disabilities, by creating a separate section to the federal regulations for mentally disabled persons.

human experimentation and the current federal regulations for human subject research. Part III examines the inadequacy of current federal regulations for mentally ill research subjects and proposes revisions to ensure that mentally ill persons provide adequate informed consent to participate in research. This Note concludes that when the potential subject is a person with schizophrenia, the process of obtaining informed consent should require a conversation between the physician-investigator and the potential subject in the presence of a third party patient advocate.⁷

I. The Special Problem of Schizophrenia and Informed Consent

The diagnostic criteria⁸ and the nature and course of schizophrenia exemplify why the informed consent process for schizophrenic research subjects can be problematic. Schizophrenia is a disease that affects cognition; it disrupts a person's perceptual and emotional abilities.⁹ Some schizophrenics experience a relatively

7. This Note will focus only on schizophrenia, and does not delve into other disorders. Also, this Note discusses persons who are deemed to be competent to give informed consent. The discussion of incompetent person is too broad for the scope of this Note.

This Note also concentrates on the informed consent process for schizophrenics in non-therapeutic research, as opposed to therapeutic treatment. The conversation this Note proposes is aimed at the informed consent process for the potential subject to participate in the study, not a conversation regarding enrollment in the study.

8. The DSM-IV requires that the person must experience "a disturbance that lasts for at least six months and includes at least one month of active-phase symptoms". DSM-IV, *supra* note 2, at 274. There are six diagnostic criteria in the DSM-IV. DSM-IV, *supra* note 2, at 285-86. Criterion A requires that at least two of five characteristics (hallucinations, delusions, disorganized speech, grossly disorganized or catatonic behavior, and negative symptoms) be present "for a significant portion of time during a 1-month period". *Id.* at 285. The second criterion requires that a major area of functioning (interpersonal relations, work, or self-care) are markedly under the person's normal level prior to onset for a significant amount of time since the disturbance began. *See id.* Criterion C requires that the symptoms be present for at least six months, including a period of one month in which the person has symptoms that meet Criterion A. *See id.* Criteria D, E and F rule out the disorder being misdiagnosed as a mood disorder, schizoaffective disorder, due to drug abuse or medication, or pervasive developmental disorder. *See id.* at 285-86.

9. Schizophrenia is part of a set of psychotic disorders characterized by major disruptions "in thought, emotion, and behavior - disordered thinking in which ideas are not logically related; faulty perception and attention, bizarre disturbances in motor activity; and flat or inappropriate affect." GERALD C. DAVISON & JOHN M. NEALE, *ABNORMAL PSYCHOLOGY*, 389 (6th ed. 1996) [hereinafter DAVISON & NEALE]. Schizophrenia consists of various symptoms that can be classified into positive and negative symptoms. *See id.*; DSM-IV, *supra* note 2, at 273. Positive symptoms "include distortions or exaggerations of inferential thinking (delusions), perception (hallucinations), language and communication (disorganized speech), and monitoring (grossly disorganized or catatonic behavior)." *Id.* at 274-75. Negative

steady path, but others continually worsen.¹⁰ Even though schizophrenia usually follows a chronic course, antipsychotic medication can improve a patient's condition.¹¹ The side effects of schizophrenic drugs, however, leave most individuals in an altered state.¹² As a result, a person suffering from schizophrenia may be legally competent,¹³ but have impaired cognitive abilities.¹⁴

Studies illustrate that the cognitive deficits of schizophrenia greatly affect the ability of subjects diagnosed with schizophrenia to understand and appreciate the true nature of the research's protocol. One study found that persons with schizophrenia demonstrate more pronounced and consistent impairments in ability to reason, appreciate, and understand than persons not diagnosed with schizophrenia.¹⁵ The effects of schizophrenia produced two problems during the informed consent process: persons with schizophrenia "demonstrated poor understanding of scientific rationales

symptoms restrict the extent "of emotional expression (affective flattening), in the fluency and productivity of thought and speech (alogia), and in the initiation of goal directed behavior (avolition)." *Id.* at 275.

10. See DSM-IV, *supra* note 2, at 282. It is rare for a person with this disorder to have a complete remission. See *id.*

11. See *id.* at 281.

12. See *id.* The drugs given to schizophrenics are called "antipsychotic medications" and "neuroleptics" because the drugs produce side effects similar to neuroleptic disorders. DAVISON & NEALE, *supra* note 9, at 414. A new drug, clozapine, can cause damage to the immune system and produce seizures. See *id.* at 415.

13. See Paul S. Appelbaum & Thomas Grisso, *The MacArthur Treatment Competence Study*, 19 LAW & HUM. BEHAV., 105, 111 (1995); see also LEVINE, *supra* note 5, at 261-62.

14. See DSM-IV, *supra* note 2, at 274.

15. See Paul Appelbaum & Thomas Grisso, *The MacArthur Study III, Abilities of Patients to Consent to Psychiatric and Medical Treatments*, 19 LAW & HUM. BEHAV., 149, 173 (1995) [hereinafter *The MacArthur Study*]. The MacArthur Study investigated the ability of mentally ill patients to make decisions about their treatment. See *id.* at 149. The study found that persons with schizophrenia demonstrate more pronounced and consistent impairments in ability to reason, appreciate and understand than persons not diagnosed with schizophrenia. See *id.* at 169. The more severe the symptoms of schizophrenia, the poorer the performance was in understanding and reasoning, especially in patients with thought disturbances. See *id.*

The MacArthur Study was published as three papers. The first paper explored what is known about how mental illnesses can affect decision-making abilities and described the design of the MacArthur Study. Paul S. Appelbaum & Thomas Grisso, *MacArthur Study I, Mental Illness and Competence to Consent to Treatment*, 19 LAW & HUM. BEHAV. 105 (1995). The MacArthur Study Part II described the measures developed for the study to assess a person's ability to understand, appreciate, reason, and express a choice. Thomas Grisso, et al., *MacArthur Study II, Measures of Abilities Related to Competence to Consent to Treatment*, 19 LAW & HUM. BEHAV. 127, (1995). The third paper reported the results of the study.

and procedures and frequently perceived research participation in therapeutic and personalized terms."¹⁶

This study suggested that using a third-party investigator succeeded over unassisted investigator disclosures in transmitting high-quality information about the research to potential subjects.¹⁷ The MacArthur study suggested that the investigator should assess the potential subject's ability to reason, understand, and appreciate the significance of the information presented to the patient.¹⁸ Information disclosed part by part, rather than information disclosed as a whole, resulted in much greater understanding.¹⁹

II. The Development of The Law of Informed Consent to Human Experimentation And The Current Federal Guidelines

Informed consent in clinical research occupies an important role in safeguarding the rights and autonomy of human research subjects. In the area of research on human subjects, the informed consent doctrine first gained attention in international treaties that set forth the basic ethical principles (a person must provide voluntary, informed, competent, and knowledgeable consent to participate in the experiment) but lacked legal enforceability.²⁰ The United States codified these principles in federal regulations designed to protect persons in research studies at institutions that received federal funding for research.²¹

16. Paul R. Benson, et al., *Information Disclosure, Subject Understanding, and Informed Consent in Psychiatric Research*: 12 LAW & HUM. BEHAV. 455, 471 (1988) [hereinafter The Benson Study]. Many factors were significantly related to the subjects' comprehension of information. *See id.* The severity of impairment and the psychiatric diagnosis were high predictors of the subject's ability to understand the research, with schizophrenics "significantly more likely than others to display poor comprehension." *Id.*

The Benson Study examined whether and to what extent innovative disclosure methods affect the quality and quantity of information given to potential research subjects, and whether psychopathology, the quality of disclosed information, and sociodemographic factors can best explain variations in the understanding of the potential subjects. The study used four different disclosure techniques to analyze how different disclosure methods affect comprehension of information. *See id.* at 457-58.

17. *See id.* at 473.

18. *See The MacArthur Study*, *supra* note 15, at 173.

19. *See id.* Therefore, a patient who may seem to not be able to understand the information at first, may benefit from additional explanations. *See id.*

20. *See THE NUREMBERG CODE*, reprinted in, LEVINE, *supra* note 5, at 425.

21. *See generally* 45 C.F.R. §§ 46.101-24 (1996). The federal regulations require institutions to apply the regulations to department funded research, and to review research even if not funded by the government. *See id.* at 46.103. Most institutions inform the Department of their intention to follow the process detailed in the regula-

A. The Law of Informed Consent

The doctrine of informed consent evolved from judicial deference to individual autonomy,²² and demonstrates the American judicial belief that the right to be free of unwanted interference belongs to every person.²³ The doctrine also stems from the Western belief in the importance of personal freedom and choice.²⁴

The common law action for lack of informed consent developed through case law involving therapeutic physician-patient relationships.²⁵ The doctrine of informed consent arose from the common law action of battery, and eventually developed into an action based in negligence.²⁶ Under negligence theory, a doctor has a duty to provide the patient with the information required by the relevant standard of disclosure,²⁷ including a description of the diagnosis, the nature and purpose of the treatment, the risks of the treatment and the probabilities of the risks occurring.²⁸ The doctor must also disclose alternative methods of treatment, and the attendant risks and probabilities.²⁹

The first standard of disclosure adopted by the courts to test the adequacy of the physician's disclosure was physician-based.³⁰ This standard measures the physician's duty to disclose by the disclosure that would be made by a reasonable physician in similar circum-

tions for all human research studies. See BARRY R. FURROW ET AL., *HEALTH LAW* 551 (1995). Since practically every institution in the United States conducts some research that receives federal funds, the regulations essentially govern all research involving human subjects. See *id.*

22. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages." *Schloendorff v. Soc. of New York Hosp.*, 105 N.E. 92, 93, 211 N.Y. 125, 129-30 (1914); See also *Pratt v. Davis*, 79 N.E. 562 (Ill. 1906) (holding that the physician may not violate a person's bodily integrity without the patient's permission or operate on the patient without the patient's knowledge and consent).

23. See generally FURROW, *supra* note 21, at 409.

24. See FADEN, *supra* note 5, at 7.

25. See *id.* at 25. The doctrine of "informed consent" appeared for the first time in *Salgo v. Leland Stanford Jr. Univ. of Trustees* when the court stated that "[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment." 317 P.2d 170, 181 (Cal.App. 1957).

26. See *Williams v. Cordice* 418 N.Y.S.2d 995, 996-97, 100 Misc. 2d 425, 426-29 (App. Div. 2d Dept. 1979).

27. See FADEN, *supra* note 5, at 29. In addition, the injury must be a materialization of an undisclosed outcome, the patient would not have consented if the information was disclosed, and crucially, the non-disclosure caused the injury. See *id.*

28. See N.Y. PUB. HEALTH LAW § 2805-d (McKinney 1994).

29. See *id.*

30. See *Natanson v. Kline*, 354 P.2d 670, 671 (1960).

stances.³¹ In recent years, some states adopted the "reasonable patient" standard.³² This standard shifts the focus away from the physician by relying on the information a reasonable person needs to know about the risks, benefits, and alternatives.³³ A third standard, the subjective patient standard, is not embraced by the courts.³⁴ This standard requires a physician to disclose information material to that particular patient.³⁵

31. Over twenty-five states utilize this standard through statute or judicial decision. *See, e.g.*, *Fain v. Smith*, 497 So.2d 1150, 1152 (Ala. 1985); *McGrady v. Wright*, 729 P.2d 338, 341 (Ariz. 1986); *Aronson v. Harriman*, 901 S.W.2d 832, 839 (Ark. 1995); *Conrad v. Imatani*, 724 P.2d 89,91 (Colo. Ct. App. 1986); *Baylis v. Wilmington Med. Ctr.*, 477 A.2d 1051, 1057 (Del. Supreme 1984); *Ritz v. Florida Patient's Comp. Fund*, 436 So.2d 987, 990 (Fla. Dist. Ct. App. 1983); *Bernard v. Char*, 903 P.2d 667, 672-73 (Hawaii 1995); *Sherwood v. Carter*, 805 P.2d 452, 462 (Idaho 1991); *Coryell v. Smith*, 274 Ill.App.3d 543, 546 (Ill. App. Ct. 1995); *Kranda v. Houser-Norbotg Med. Corp.*, 419 N.E.2d 1024, 1038 (Ind. Ct. App. 1981); *Wozniak v. Lipoff*, 750 P.2d 971, 982 (Kan. 1988); *Gregory v. Poor*, 862 F. Supp. 171, 173 (W.D. Ky. 1994); *Ouellette v. Mehalic*, 534 A.2d 1331, 1332 (Me. 1988); *Howell v. Outerdrive Hosp.*, 238 N.W.2d 553, 557 (Mich. Ct. App. 1975); *Herrington v. Spell*, 692 So.2d 93, 97 (Miss. 1997); *Robinson v. Bleicher*, 599 N.W.2d 473, 478 (Neb. 1997); *Smith v. Cotter*, 810 P.2d 1204, 1207 (Nev. 1991); *Marchione v. State*, 194 A.D.2d 851, 853, 598 N.Y.S.2d 592, 593 (N.Y. App. Div. 1993); *Clark v. Perry*, 442 S.E.2d 57, 62 (N.C. Ct. App. 1994); *Baxley v. Rosenblum*, 400 S.E.2d 502, 508 (S.C. Ct. App. 1991); *Cradwell v. Bechtol*, 724 S.W.3d 739, 751 (Tenn. 1987); *Macey v. James*, 427 A.2d 803, 804 (Vt. 1981); *Rizzo v. Schiller*, 445 S.E.2d 153, 155 (Va. 1994); *Govin v. Hunter*, 374 P.2d 421, 423-24 (Wyo. 1962).

32. *See, e.g.*, *Korman v. Mallin*, 858 P.2d 1145, 1149 (Alaska 1993); *Arato v. Avedon*, 858 P.2d 598, 604 (Cal. 1993); *Gemme v. Goldberg*, 626 A.2d 318, 327 (Conn. App. Ct. 1993); *Cleary v. Group Health Ass'n*, 691 A.2d 148, 153 (D.C. 1997); *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 360 (Iowa 1987); *Zeller v. Greater Baltimore Med. Ctr.*, 506 A.2d 646, 651 (Md. Ct. Spec. App. 1986); *Feeley v. Baer*, 669 N.E.2d 456, 459-60 (Mass. App. Ct. 1996); *Cornfeldt v. Tongen*, 262 N.W.2d 684, 701 (Minn. 1977); *Herrington v. Spell*, 692 So.2d 93, 97 (Miss. 1997); *Adamski v. Moss*, 638 A.2d 1360, 1363 (N.J. Super. Ct. App. Div. 1994); *Patterson v. Van Wiel*, 570 P.2d 931, 933-34 (N.M. Ct. App. 1977); *Bedel v. Univ. of Cincinnati Hosp.*, 669 N.E.2d 9, 14 (Ohio Ct. App. 1995); *Goss v. Oklahoma Blood Inst.*, 856 P.2d 998, 1006-07 (Okla. Ct. App. 1990); *Nogowski v. Alemo-Hammad*, 691 A.2d 950, 957 (Pa. Super. Ct. 1997); *Wilkinson v. Vesey*, 295 A.2d 676, 689 (R.I. 1972); *Wheeldon v. Madison*, 374 N.W.2d 367, 376 (S.D. 1985); *Tajchman v. Giller*, 938 S.W.2d 95, 100 (Tex. App. 1996); *Villanueva v. Harrington*, 906 P.2d 374, 376 (Wash. Ct. App. 1995); *Adams v. El-Bash*, 388 S.E.2d 381, 386 (W. Va. 1985); *Johnson by Adler v. Kokemoor*, 545 N.W.2d 495, 501 (Wis. 1996).

33. *See FURROW, supra* note 21, at 414.

34. *See id.* at 415.

35. *See FADEN, supra* note 5, at 33 (citing *Wilkinson v. Vesey*, 295 A.2d 676, 687 (R.I. 1972)). Proponents of this standard argue that since every person has a right to make her own choices, one may require information that may not meet the "reasonable person" level of materiality, yet is material to that particular person. *See id.* at 33-34. A reason for the courts reluctance is the belief that the patient will use hindsight to promote the concept that the undisclosed information was important to her decision to undergo the treatment. *See FURROW, supra* note 21, at 415; *FADEN, supra*

Courts have expanded the type of information and scope of disclosure required to satisfy the doctrine of informed consent in the research setting. Early case law established that the duty of informed consent on physicians in a research setting at least equals the duty of informed consent on physicians in the therapeutic setting.³⁶ A researcher must disclose any information that might influence a patient's decision to participate³⁷ and is liable for a procedure or protocol performed on a person without that person's consent.³⁸ In addition, the physician-investigator has a duty to disclose to the patient the physician's research and economic interests in the procedure.³⁹

B. Informed Consent in Human Subject Research

Informed consent in the research setting developed not through case law, but through political occurrences, regulatory agencies, professional codes and statutes.⁴⁰

The Nuremberg Code is the most comprehensive authoritative declaration on the law of informed consent in the context of human subject research.⁴¹ It developed as a condemnation of the actions of Nazi physicians during World War II⁴² and established ten principles to guide experimentation on humans.⁴³ Principle One states that the consent of the subject must be voluntary, informed, and

note 5, at 33. In addition, opponents argue that this standard would impose a heavy legal burden on physicians. See FADEN, *supra* note 5, at 33.

36. See *Hyman v. Jewish Chronic Disease Hosp.*, 248 N.Y.S.2d 245, 42 Misc.2d 427 (N.Y. Sup. Ct. 1964); see also *Halushka v. Univ. of Saskatchewan*, 52 W.W.R. 608, 616-17 (Sask. 1965). A dissenting judge in *Smith v. United States* stated that during a non-therapeutic experiment, the experimenter has a duty to fully inform the subject and to obtain the subject's informed consent. 412 F.2d 791, 792 (9th Cir. 1969) (Hufstedler, C.J., dissenting). For a detailed discussion of cases involving informed consent in therapeutic and non-therapeutic settings see Goldner, *supra* note 5, at 77-87.

37. See *Hyman*, 248 N.Y.S.2d at 245, 42 Misc. at 427.

38. See *Schwartz v. Boston Hosp. for Women*, 422 F. Supp. 53, 56 (S.D.N.Y. 1976); see also, *Blanton v. United States*, 428 F. Supp. 360, 362 (D.C. Cir. 1977).

39. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 496 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

40. See APPELBAUM, *supra* note 5, at 211.

41. See THE NUREMBERG CODE, *supra* note 20.

42. See ANNAS, *supra* note 5, at 6; FADEN, *supra* note 5, at 153. The Nazi war crimes revealed that several leading German physicians forced subjects that were picked from the concentration camps "to drink seawater or breathe mustard gas, were exposed to such epidemics as malaria, jaundice, and typhus, or were placed in ice water until they froze." FURROW, *supra* note 21, at 546; See FADEN, *supra* note 5, at 153. The Nuremberg Court condemned their actions as crimes against humanity. See FURROW, *supra* note 21, at 547.

43. See THE NUREMBERG CODE, *supra* note 20.

competent.⁴⁴ The subject must also comprehend the nature of the research.⁴⁵ The Nuremberg Code fails to describe what method an investigator must use to obtain informed consent, or how to explain and define the risks to the potential subject.⁴⁶

The Declaration of Helsinki, adopted by the World Medical Association in 1964, elaborated on the Nuremberg Code.⁴⁷ Central to the Declaration of Helsinki was the requirement of written consent in all cases of non-therapeutic research.⁴⁸ It also acknowledged that special protections are needed for mentally ill persons, minors, and institutionalized persons.⁴⁹ The Nuremberg Code and The Declaration of Helsinki are considered customary international law, neither binding on United States courts nor relied on as persuasive authority.⁵⁰

Society's outrage over a series of biomedical abuses⁵¹ led to Congress' enactment of the National Research Act in 1974,⁵² establishing the National Commission for Protection of Human Subject of

44. See *id.* at Principal One. "The voluntary consent of the Human subject is absolutely essential." *Id.* The Nuremberg Code also provides that the study should be scientifically and socially necessary, based on the results of animal or other non-human experimentation, should avoid unnecessary suffering and injury, the doctor must be willing to terminate the experiment at any stage if it is appropriate to protect the subject, and the subject must be able to withdraw at any time without penalty. See *id.* at Principles Two, Three, Four, Nine, and Ten. See also *Id.* at Principles Five, Six, Seven, and Eight.

45. See *id.* at Principle One.

46. The Nuremberg Court believed that those conclusions were out of its sphere. See FADEN, *supra* note 5, at 155.

47. See FURROW, *supra* note 21, at 548. The Declaration of Helsinki was drafted in response to the medical community's perceived threat to the reputation of research as a result of the violations investigated at the Nuremberg Trials. See FADEN *supra* note 5, at 156. The World Medical Association drafted the document to further "distinguish ethical from unethical clinical research." *Id.*

48. See World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (*reprinted in* LEVINE, *supra* note 5, at 427) (hereinafter DECLARATION OF HELSINKI).

49. See FURROW, *supra* note 21, at 548.

50. See *id.* at 9.

51. For example, the Tuskegee Study was supported by the United States Public Health Service, and studied the course of syphilis. See FURROW, *supra* note 21, at 548. Starting in 1932, poor, African-Americans were injected with syphilis without their consent. See *id.* Even when penicillin was developed to treat syphilis, the men were denied and discouraged from seeking any treatment. See *id.* at 549. The experiment was uncovered in 1972, and was the topic of Congressional hearings in 1973. See *id.*

The public was also disturbed by the possibility of research on human fetuses. See FADEN, *supra* note 5, at 215. These developments led to public hostility and distrust of medical research. See *id.*

52. See 42 U.S.C. § 201 (1995).

Biomedical and Behavioral Research ("Commission").⁵³ The Commission conducted an extensive investigation to identify fundamental ethical principles to guide research involving human subjects.⁵⁴ The Commission also studied the ethics of research on vulnerable populations, including the mentally handicapped, prisoners, and pregnant women.⁵⁵ However, its recommendations concerning protections for the mentally ill were not incorporated into the federal regulations,⁵⁶ due to opposition from researchers of mental illnesses.⁵⁷

The Commission issued its findings in the Belmont Report which stated "that individuals should be treated as autonomous agents and . . . that persons with diminished autonomy are entitled to protection."⁵⁸ In addition, The Belmont Report stated that the information disclosed to a research subject must include the anticipated risks and benefits, the research procedure, the purpose, alternative procedures, the opportunity for the potential subject to ask questions, and the ability to withdraw at any time.⁵⁹ The Commission acknowledged that a simple listing of the items required by the regulations does not ensure informed consent.⁶⁰ The manner and context of the information conveyed must be adapted to the capacities of the potential subject.⁶¹ The report acknowledged expressly that respect for persons requires that people with limited comprehen-

53. See FURROW, *supra* note 21, at 549.

54. See *id.*

55. See FADEN, *supra* note 5, at 215-16. The Commission was also to investigate the IRB system, and procedures for informed consent. See *id.* at 216.

56. See APPELBAUM, *supra* note 5, at 228; LEVINE, *supra* note 5, at 271-72.

57. See APPELBAUM, *supra* note 5, at 228. These physicians claimed that the proposed protections would substantially hamper research on mental illnesses, and that mentally ill persons were not any more vulnerable than persons with serious physical illnesses. See *id.*

58. NATIONAL COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 10 (1978) [hereinafter THE BELMONT REPORT]. THE BELMONT REPORT promulgated three basic principles regarding the ethics of research upon human beings: "the principles of respect for persons, beneficence and justice." *Id.* at 4.

59. See *id.* at 11. THE BELMONT REPORT analyzed informed consent in three parts information, comprehension, and voluntariness. See *id.* at 10. It also provided that the risks to the patient should never be unrevealed because otherwise the patient may not participate. See *id.* at 11-12.

60. See *id.* at 11.

61. See *id.* at 12.

sive abilities, such as children and the mentally ill, must have the opportunity to choose whether to participate in the study.⁶²

The Nuremberg Code⁶³ and The Declaration of Helsinki⁶⁴ provided the ethical foundations on which American legislators relied when they promulgated regulations for human research subjects.⁶⁵ The federal regulations provide specific standards for obtaining informed consent from each potential subject.⁶⁶ The regulations apply "to all research involving human subjects" that is supported or conducted by a federal department or agency.⁶⁷ Research that is not supported or conducted by a federal department or agency, but occurs at an institution which receives department funding, must be reviewed to ascertain its appropriateness for human subjects.⁶⁸

The investigator must allow the subject to ask questions, and must present the information to the person "in language understandable to the subject."⁶⁹ The regulations list eight basic elements of informed consent:⁷⁰ "[a] statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject's participation; a description of the procedures to be followed, and the identification of any procedures which are experimental;"⁷¹ descriptions of any reasonably foreseeable risks,⁷² benefits,⁷³ and alternative treatments available;⁷⁴ an explanation that participation is voluntary and consent may be withdrawn at any time without penalty;⁷⁵ a description of the extent of confidentiality with respect to the patient's records;⁷⁶ an explanation of the proper person to contact for questions about the research and whom to contact in the event of an injury;⁷⁷ and

62. See *id.* at 13. The third element of informed consent, voluntariness, requires that a subject provides consent without any element of coercion and "undue influence." *Id.* at 14.

63. See THE NUREMBERG CODE, *supra* note 20.

64. See DECLARATION OF HELSINKI, *supra* note 48, at 429.

65. See ANNAS, *supra* note 5, at 6-9.

66. See 45 C.F.R. § 46.116. The Department of Health and Human Services codified the regulations on human subject research at 45 C.F.R. §§ 46.101- 46.409. (1995). The statutory authority for the regulations is located at 42 U.S.C. § 300v-1(b).

67. *Id.* at 46.101.

68. See *id.*

69. See 45 C.F.R. § 46.116.

70. See *id.*

71. 45 C.F.R. § 46.116(a)(1).

72. See 45 C.F.R. § 46.116(a)(2).

73. See 45 C.F.R. § 46.116(a)(3).

74. See 45 C.F.R. § 46.116(a)(4).

75. See 45 C.F.R. § 46.116(a)(8).

76. See 45 C.F.R. § 46.116(a)(5).

77. See 45 C.F.R. § 46.116(a)(7).

finally, an explanation by the researcher of any compensation and medical treatments available to the subject when the study involves more than a minimal risk.⁷⁸

Informed consent must be documented in writing by the researcher.⁷⁹ The regulations provide two different methods of obtaining informed consent: a short form and a long form.⁸⁰ In the long form, the investigator gives the patient "a written document that embodies the elements of informed consent."⁸¹ The short form provides for a written document declaring that the elements of informed consent have been read to the subject with a witness present, and a summary of that information signed by the subject.⁸²

Each institution must establish Institutional Review Boards ("IRBs") in accordance with the regulations.⁸³ An IRB contains at least five persons of varying backgrounds "to promote complete and adequate review of research activities commonly conducted by the institution."⁸⁴ To approve research, the IRB must make seven findings: the risks to the subject are minimized; the risks are reasonable in relation to the anticipated benefits to the subject; the selection of the subjects is equitable; informed consent is obtained; informed consent will be appropriately documented; the safety of the subjects will be provided for by monitoring the data, when appropriate; and the privacy and confidentiality of the patient is protected, when appropriate.⁸⁵ The regulations do not provide specific guidelines for implementing and monitoring these safeguards.

The federal regulations enunciate additional requirements for conducting research upon certain categories of human subjects, in-

78. See 45 C.F.R. § 46.116(a)(6).

79. See 45 C.F.R. § 46.117(a).

80. See 45 C.F.R. § 46.117(b)(1)&(2).

81. 45 C.F.R. § 46.117(b)(1).

82. See 45 C.F.R. § 46.117(b)(2).

83. See 45 C.F.R. § 46.103(b). A list of the IRB members and the written procedures the IRB will follow must also be submitted to the department or agency. See *id.* at § 46.103(b).

84. 45 C.F.R. § 46.107(a). The only restriction upon IRB membership is that one person on the IRB must not be affiliated with the institution. See *id.* at § 46.107(d). As a result, most of the members of an institution's IRB are members of that institution's faculty. See Katz, *supra* note 5, at 40-41.

85. See 45 C.F.R. § 46.111. Public access to IRB records can be limited. Even though they are established under a federal regulation, the Freedom of Information Act does not apply to IRBs because they are not federal agencies within that definition. See FURROW, *supra* note 21, at 558. An IRB may be held negligent for failure to exercise due care; immunity does not arise out of the federal law. See *id.* at 561. However, no board member has been individually liable because of the board's decision. See *id.*

cluding fetuses, pregnant women, prisoners, and children.⁸⁶ When the study involves vulnerable subjects, the IRB can consider including a person on the board who is knowledgeable in that area.⁸⁷ Also, additional protections must be in place "to protect the rights and welfare" of vulnerable persons in a study.⁸⁸ No special guidelines outline the process for obtaining informed consent from the mentally ill.

The federal regulations place a duty on the institution conducting the experiment to protect the rights of the subjects, unlike the Nuremberg Code which created principles applicable to researchers.⁸⁹ The institution cannot use federal funds if it fails to comply with these regulations.⁹⁰ The federal regulations do not contain a right to a private cause of action, but "courts are likely to perceive this [the IRB's] review as part of the ordinary standard of care with respect to the conduct of any formal biomedical research project."⁹¹

III. Reforming the Federal Guidelines

Although the federal regulations provide some protections for vulnerable classes of people, such as pregnant women, prisoners, and children,⁹² they do not provide specific protection for persons with mental illnesses, such as schizophrenia. Since persons with this illness suffer from impaired cognitive abilities, the federal regulations should provide protections for them during the informed consent process.

86. See 45 C.F.R. §§ 46.201 - .409. When the research involves fetuses, pregnant women, and human in vitro fertilization, the institution must establish an Ethical Advisory Board with persons selected who are competent to handle ethical, legal, medical and social issues. See *id.* § 46.204. With respect to prisoners, the federal regulations provide protections due to the possibility that a prisoner's incarceration may affect their ability to volunteer wholly uncoerced to participate in a study. See *id.* § 46.302. When the study involves children, the regulations specify guidelines for research that involves various degrees of risk and benefit to the child. See *id.* §§ 46.404-407.

87. See *id.* § 46.107(a).

88. See 45 C.F.R. § 46.111(b). The regulations do not specify what these "additional protections" are. Listed among the possibility of vulnerable populations are mentally disabled persons, pregnant women, children, prisoners, and economically or educationally disadvantaged person. See *id.*

89. See Goldner, *supra* note 5, at 103.

90. See *id.*

91. *Id.*

92. See *supra* note 86 and accompanying text.

A. Problem of Lack of Process in Obtaining Informed Consent

The federal regulations' provision on informed consent fails to provide adequate standards for the *process* of obtaining informed consent from mentally ill persons, such as persons with schizophrenia. The regulations must obligate physician-investigators to obtain informed consent in ways that produce true comprehension of the experiment's protocol and the subject's role in the experiment. Meaningful informed consent is not achieved by the potential subject reading a document and signing at the bottom of the page. This emphasis on form over substance results in a meaningless signature on the consent form.

Currently, a researcher may obtain informed consent by using the short form or long form method.⁹³ The long form method is insufficient because simply reading a long list of medical terms fails to ensure that the potential subject comprehends his/her role and the protocol of the study. In practice, many long form informed consent forms contain unfamiliar and opaque terminology.⁹⁴ The short consent form is inadequate because it asks only a "witness" to be present.⁹⁵ The federal regulations fail to elaborate on the identity and role of the witness. If the regulations identified the role of the witness, mentally ill persons could receive more protection to ensure that they provide meaningful informed consent. The present situation, in which the witness remains undefined, results in an unexplored protection for mentally ill persons.

Investigators may not always include information about the study's procedures, risks, benefits, and alternative treatments.⁹⁶ An investigator may downplay the scientific aspects of the study while emphasizing the therapeutic elements.⁹⁷ As a result, potential subjects may believe that the research's design aims to benefit them personally, instead of benefitting science.⁹⁸ For persons with schizophrenia, who already face problems providing informed consent due to the cognitive deficits of the disease, a conversation between the investigator and the potential subject can help ensure that the potential subject comprehends the risks and benefits of the protocol. A conversation can help because when an investigator

93. See *supra* notes 79-82 and accompanying text.

94. See Bartolo, *supra* note 5, at 193, 200. For example, such terms as "dose limiting toxicities, intrathecal injections, bone marrow aspiration, bilateral wedge and testicular biopsy" can be used in informed consent forms. See *id.*

95. See *supra* note 82 and accompanying text.

96. See The Benson Study, *supra* note 16, at 471.

97. See *id.*

98. See *id.*

discloses information verbally in parts, as opposed to an uninterrupted relay of information, a significant increase in comprehension occurs.⁹⁹

B. Proposed Changes to the Federal Guidelines

Changes must be made to the federal regulations to ensure that mentally ill subjects provide a more meaningful consent. The federal guidelines should be amended to require that when the potential subject is a person with a mental disability affecting cognition, such as schizophrenia, the informed consent process include a conversation between the investigator and the patient, with a third party professional selected by the patient, instead of the current short or long form.¹⁰⁰

1. Oral Conversation

The federal regulations should require a conversation between physician-investigator and potential subject in order to preserve the subject's autonomy and assist the patient in providing a meaningful consent to research participation. This conversation should be a dialogue that explains the elements of informed consent¹⁰¹ to the potential subject in layman's terms.¹⁰² The general language that the physician-investigator plans to use during the conversation, or an outline of the material to be covered, should be submitted for IRB approval.

During the conversation, the physician should also explain to the potential subject that the scientific interests will be superior to the individual subject's therapeutic interest, and that the potential subject may or may not improve physically or mentally in the study. The doctor must also clearly state that she will respect the choice of the potential subject to participate or not, in order to give the sub-

99. See *The MacArthur Study*, *supra* note 19 and accompanying text.

100. To amend an administrative law, general notice of the proposed changes to the rule must be published in the Federal Register. See BERNARD SCHWARTZ, ADMINISTRATIVE LAW 193 (1991). The Department of Justice, which issues the federal regulations discussed, must allow interested parties the opportunity to participate in the rule-making process. See *id.* 42 U.S.C.A. § 300v-1(b), requires that if the Federal agency receives a recommendation from the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the "Commission"), within sixty days the agency shall publish the recommendation in the Federal Register and "[p]rovide opportunity for interested person to submit written data, views, and arguments with respect to adoption of the recommendation." *Id.*

101. See *supra* notes 70-78 and accompanying text.

102. Many informed consent documents contain complex scientific terms incomprehensible to the ordinary person. See Bartolo, *supra* note 5, at 200.

ject a true idea of the differences between treatment received in a research study and personal physician care.¹⁰³ Though there will always be, with all subjects, a limit to comprehension because of the unknowns of research, the conversation that explains the aforementioned factors, and makes the various conditions of the experiment clear to the subject, will help the subject to truly understand the research.

Medical ethics experts believe, and research on the consent process demonstrates, that obtaining informed consent through a conversation from a potential subject with impaired cognitive abilities produces the highest rate of comprehension.¹⁰⁴ Professor Jay Katz discussed the need for a conversation between the physician-investigator and the prospective patient as necessary to preserve the patient's autonomy.¹⁰⁵ Some commentators believe that the federal regulations fail to sufficiently mandate that investigators devote the time to clearly explain the nature of the experiment to ensure that patients fully understand the protocol and their own role in the experiment.¹⁰⁶

When the experiment enlists a person with cognitive disabilities, the need for a conversation between the physician-investigator and the potential subject becomes more important. Persons with schizophrenia, for example, face many problems when trying to comprehend the protocol of the research.¹⁰⁷ Their ability to understand and reason is impaired.¹⁰⁸ However, their ability to understand information can improve from repeated presentation of information that can occur during a conversation.¹⁰⁹

Some commentators acknowledge that researchers will be disinclined to have a conversation because it would take hours, possibly even days, for the physician to be sure that the subject understands the experiment.¹¹⁰ They argue that it will take more time to recruit research subjects, and may take longer to complete research

103. See Katz, *supra* note 5, at 33-34.

104. See *supra* note 19 and accompanying text.

105. See THE SILENT WORLD, *supra* note 5, at 130-64. Katz places this need for a change in the informed consent process more upon the alteration in the mindsets of the physician-investigators than on the actual federal regulations themselves. See Goldner, *supra* note 5, at 115.

106. See Katz, *supra* note 5, at 24-25. A member of Bartolo's IRB believed that true informed consent involved a conversation over many hours, and even days. See Bartolo, *supra* note 5, at 206.

107. See *supra* note 15 and accompanying text.

108. See *supra* note 15 and accompanying text.

109. See *supra* note 15 and accompanying text.

110. See Katz, *supra* note 5, at 36-37.

projects.¹¹¹ When research involves human subjects, however, it should be more important that the subject's autonomy is respected, not that the recruitment process occurs quickly. Nonetheless, as researchers become more familiar with obtaining informed consent through a conversation, the researcher may become more adept at clearly and succinctly presenting the necessary information to the subject, thereby reducing the amount of time spent.

In addition, the long term benefits of preserving each individual's autonomy outweigh the short term risks of not completing a study. Informed consent means that each person has a right to decide what should be done with his or her own body. This right cannot be sacrificed simply because it takes too long to accomplish.

2. *Third Party Present at the Informed Consent Sessions of a Mentally Ill Person*

The current federal regulations state that when research involves vulnerable subjects, "[c]onsideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced with these subjects."¹¹² The statute does not specify that this third person must possess knowledge about the mental illness of the subject when the mental illness impairs the subject's ability to provide meaningful informed consent.¹¹³ The regulations also state that the IRB "may, in its discretion" ask people with "competence" in a certain area to help review issues beyond the expertise of the IRB members, but these people may not vote with the IRB.¹¹⁴ The regulations create many optional, ambiguous safeguards for mentally ill persons. The regulations should mandate that when the potential research subject has a mental disorder that is known to affect cognition, such as schizophrenia,¹¹⁵ a third person unaffiliated with the study, yet experienced in working with

111. *See id.*

112. 45 C.F.R. § 46.107(a).

113. *See id.* But see § 46.204 which requires an Ethical Advisory Board to be established as an additional protection for person as subjects in research involving pregnant women and fetuses. Also see § 46.304 which mandates that when research involves prisoners as subject, at least one member of the IRB must be a prisoner or prisoner representative, as an additional protection.

In fact, at a recent conference of IRB members, an informal and scientific poll of audience members revealed that only two or three members of an IRB had required a third person participate in the informed consent process. John A. Robertson, *Taking Consent Seriously: IRB Intervention in the Consent Process*, 4 IRB 1 (1982).

114. *See* 45 C.F.R. § 46.107(f).

115. *See supra* notes 9-14 and accompanying text.

mentally ill individuals, be present at the informed consent sessions.

The federal regulations provide that witnesses may be present during the informed consent process,¹¹⁶ but the regulations do not define "witness." The witness should be someone who possesses a medical background and experience in the mental illness of the potential-subject. The witness should not be one of the physician-investigators, nor a person involved in the study. Preferably, it would be the potential subject's personal psychiatrist. If that is not possible, because the potential subject does not have a personal physician or her personal physician is a part of the study, then the witness should be a mental health care worker who is disinterested in the study.¹¹⁷

A third party knowledgeable about the mental disorder present at the informed consent process is important for several reasons. Schizophrenics show decreased comprehension of information compared to non-mentally ill persons.¹¹⁸ In addition, the cognitive abilities of a person with schizophrenia can vary from patient to patient and from time to time.¹¹⁹ The use of a third party investigator can result in increased delivery of high-quality information and greater comprehension of information by the prospective subject.¹²⁰ The third party will be present to examine the current mental state of the subject to determine whether the patient understands the informed consent process at that time.

The subject should select the third party in order to reduce the invasion of the prospective subject's privacy.¹²¹ The third party should not be defined as an authoritative figure that "permits" the prospective patient to participate in the study. If the third party possessed this power, the autonomy of the subject would be diminished.¹²²

116. See *supra* note 84 and accompanying text.

117. Disinterested in the study means a person who is not a part of or participating as a physician-investigator in that particular research experiment. However, it should be okay for the witness to be a member of the institution at which the research is conducted if the potential subject chooses to work with such person.

118. See *supra* notes 9-14 and accompanying text.

119. See *supra* notes 9-14 and accompanying text.

120. See *supra* note 17 and accompanying text.

121. See LEVINE, *supra* note 5, at 131.

122. Having a third party overseer present is an invasion of privacy and should not be imposed frivolously. See LEVINE, *supra* note 5, at 131. A study by Stanley and Stanley concluded that since an overestimation of a mentally ill person's incompetence exists, paternalistic practices have been adopted that are detrimental to the interest of mentally ill person. See *id.* at 265. "Unwarranted deprivation of their

A family member or friend should also be permitted to attend during the conversation if the patient so requests, but a family member or friend alone cannot fill the role of a mental health care worker or physician. It is more likely that a person with a medical background will be familiar with the terminology used to describe the research protocol and aware of the differences between therapeutic and non-therapeutic research. Family members may not possess the ability to understand the technical language present in an informed consent form. The knowledge possessed by the third party can help to ensure that the potential subject truly understands the study and provides meaningful consent.

Since potential subjects may not understand medical terms that appear on a consent form,¹²³ a third party can help explain to the patient what the medical terms mean in layman's terms. Also, the third party can ask questions about the risks and benefits of the study that the investigator, though ethically bound to reveal, might fail to reveal.¹²⁴ Investigators, wittingly or unwittingly, often emphasize the therapeutic aspects of their study, while downplaying the scientific aspects, and omitting material information about the risks, benefits, and procedures.¹²⁵ The third party, because he/she is knowledgeable in the area of cognitive incapacities of mentally ill persons, can help ensure that the proper information about the study is effectively communicated to the subject.¹²⁶ A person chiefly concerned about the subject will be prepared to inquire about the side effects and convey the true implications of the protocol, even if the investigator attempts to minimize them.

autonomy and decision-making authority is an affront to their dignity; moreover, it lowers their self-esteem." *Id.*

123. See Sara L. Lawson & Helen M. Adamson, *Informed Consent Readability: Subject Understanding of 15 Common Form Phrases*, IRB, Sept.-Dec. 1995, at 16-18. This study used common words from informed consent forms to discover if consent forms contain language that people understand. See *id.* The authors, through a written survey, presented subjects with a written survey that presented a term in a sentence and then asked the subject to define the word. See *id.* at 17. The study found that in particular, medical and clinical terms should not be used in a consent form without further explanation. See *id.* "The results show that research subjects have poor or incomplete understanding of medical and research terminology." *Id.* at 17-18. See also William C. Waggoner & Diane M. Mayo, *Who Understands? A Survey of 25 Words of Phrases Commonly Used in Proposed Clinical Research Consent Forms*, IRB, Jan.-Feb. (1995) at 6-10 (finding a lack of understanding of more than fifty terms from consent forms).

124. See Katz, *supra* note 5 at 25; Sandra L. Titus & Moira A. Keane, *Do You Understand?: An Ethical Assessment of Researchers' Description of the Consenting Process*, The J. of Clinical Ethics, 61-62, 64 (Spring 1996).

125. See The Benson Study, *supra* note 16 at 471-72.

126. See *supra* note 17 and accompanying text.

Subjects in research experiments mistakenly may conclude that the experiment is conducted solely for their personal benefit.¹²⁷ Often potential subjects perceive the experiment in therapeutic terms as a means to provide personal medical help.¹²⁸ A third party should make clear to the patient that the patient's individual needs may be secondary to the experiment.

Some scholars support the basic idea of having available a third person present to provide additional safeguards for mentally ill persons.¹²⁹ One scholar proposed that the process of obtaining informed consent include a suggestion that the prospective subject might wish to discuss the proposed research with a trusted advisor, particularly if factors exist that limit the prospective subject's capacity for comprehension.¹³⁰ The advisor should be the person's doctor who occupies no role in the experiment, or another physician not involved if the patient has no personal physician.¹³¹ The prospective patient could also consult with another professional advisor, minister or a friend.¹³² Another commentator suggests assigning a "subject educator" to each research subject to assist during each phase of informed consent, and a "subject advocate" to oversee that experiment for unanticipated risks if the experiment involves more than minimal risk.¹³³

An argument researchers might put forth against this proposal is that the advocate will have a built-in aversion to using mentally ill persons as research subjects, and that therefore no informed consent session will ever satisfy the third party. If the third party is a doctor or mental health care worker, however, the person will be aware of the benefits derived from proper experimentation with human subjects. Another complaint is that it already takes too long to complete experiments,¹³⁴ and that this added requirement will further hinder research. Still others argue that increasing re-

127. See Benson Study, *supra* note 16 at 471-72.

128. See *id.*

129. See LEVINE, *supra* note 5, at 90-91, 11-12; Ryan, *supra* note 6, at 373.

130. See LEVINE, *supra* note 5, at 111-112.

131. See *id.*

132. See *id.* A community consultation, which consists of gathering groups of subjects to discuss the research's protocol, provides the subjects with the support of each other. See *id.* at 91.

133. See Ryan, *supra* note, 6 at 373.

134. "[S]cientists complain that it may take over six months to have a protocol approved The [IRB] committee has been described to me as cumbersome and obstructive to research." Bartolo, *supra* note 5, at 239. The federal regulations have "throttled research into many aspects of human psychology without quite killing it off." Morton Hunt, *Research Through Deception*, N.Y. TIMES, Sept. 12, 1982, at sec. 6 pg. 94; See Willwerth, *Tinkering with Madness*, *supra* note 3, at 40.

quirements such as having a third party present at the informed consent session will decrease research on mental illness and will hurt schizophrenics in the long run.¹³⁵ Stopping research and slowing down research, however, are two different effects. Stopping research means that no research at all will be done to study mental illnesses like schizophrenia. When research is slowed down, however, the illness is still studied, and clinical progress may still be made while respecting each subject's autonomy.

C. The Importance of Institutional Review Boards

Institutional Review Boards occupy the important role of approving and monitoring standards for informed consent.¹³⁶ However, the regulations regarding IRBs have several shortcomings for guarding the autonomy of persons with mental illnesses. A major drawback of IRBs is that they often are largely composed of colleagues of the institution's researchers.¹³⁷ This is problematic for informed consent because members of the IRB may not hold researchers to a measurement of consent and disclosure if that measurement has impeded the study, thereby affecting the standing of the researcher.¹³⁸ Even IRB members who hold positions outside the institution may not hold the researchers to a proper standard.¹³⁹

Another complaint set forth about IRBs is that the members of the IRBs rarely directly observe the informed consent process in research protocols.¹⁴⁰ The IRBs have the authority to "observe or have a third-party observe the consent process and the re-

135. See LEVINE, *supra* note 5, at 265 ("excessive bureaucratic procedural requirements designed to protect the mentally ill are likely to turn investigators away from their efforts to develop more efficacious therapy for this group and focus on goals that may be accomplished with fewer bureaucratic encumbrances.").

136. See *supra* notes 85-87 and accompanying text.

137. See Katz, *supra* note 5, at 39-42.

138. In Bartolo's biography of his four years on an IRB he noted that he, unlike almost all of the other IRB members, was not economically dependent on the institution. See Bartolo, *supra* note 5, at 200. He felt comfortable taking potshots without risking his standing in the institution. See *id.* A former IRB member recounted that he believed the members of the IRB were not satisfied with some of the informed consent forms, but approved the forms because they were important to the physician-investigator's work, which made the work important to the hospital. See *id.*

139. Outsiders appointed to serve on the IRB may not be truly disinterested because there are no controls on the selection process to ensure that these outsiders are not simply friends of trustees of the institution. See Harold Edgar & David J. Rothman, *The Institutional Review Board and Beyond: Future Challenges to the Ethics of Human Experimentation*, 73 *Milbank Q.* 489, 492 (1995).

140. See *id.* at 493; Nicholas A. Cristakis, *Should IRBs Monitor Research More Strictly?*, IRB 8, 9 (Mar.-Apr. 1988); Robertson, *supra* note 115, at 1.

search,"¹⁴¹ but very few do so.¹⁴² As a result, the time the IRBs spend approving the informed consent form does not ensure that subjects understand the words on the form or provide meaningful consent.¹⁴³

By mandating a conversation with a third party present during the informed consent process, the federal regulations create increased safeguards ensuring that the informed consent process is meaningful for the potential subject. Informed consent sessions will be observed and monitored better. The IRB may wish to have a list of medical workers familiar with mental illnesses to serve as third-parties if the potential subject does not choose a personal physician and does not know a health care worker to serve as a third party. By looking over the proposed language that the physician-investigator will use during his conversation with the potential subject, the IRB can provide feedback regarding the language's clarity and comprehensiveness. This task may require more time spent by the IRB on improving the informed consent process, but it is a necessary expenditure to ensure that potential subjects can provide true consent. As a result, the IRB can better fulfill its role as a protector of human research subject autonomy by ensuring that the informed consent process elicits a meaningful consent from the potential subject.

Conclusion

Past experiments and present day studies illustrate that the current regulations on informed consent do not adequately ensure that each subject can provide an informed and understanding decision to participate in an experiment. To ensure that persons with mental illnesses such as schizophrenia provide true informed consent when they are research subjects, the federal regulations must be amended. A conversation between the researcher and the potential subject enables a person with cognitive impairments associated with schizophrenia to better comprehend the nature of the research protocol and the risks and benefits of participating as a

141. 45 C.F.R. § 46.109(e).

142. A study conducted for the government found that "63% of IRBs surveyed never designated representatives to observe the manner in which a research project is being conducted." Cristakis, *supra* note 140, at 1 (citing R.A. Cooke & A.S. Tannenbaum, *A Survey of Institutional Review Boards and Research Involving Human Subjects* in, *Report and Recommendations regarding Institutional Review Boards* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL RESEARCH, (1978) 1.1-1.310, 1.205, 1.207.

143. See Robertson, *supra* note 115.

research subject. The presence of a third party facilitates the comprehension of this information. The autonomy of all subjects, especially those most vulnerable to misunderstanding the informed consent process, is too important to undercut for the achievement of short term research goals.

