1986

Protecting Autonomy and Personhood in Human Subjects Research

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I. INTRODUCTION

Recent commentary has criticized the current Health and Human Services (HHS) guidelines for inadequately protecting personhood and autonomy in human subjects research.[1] Scholars have pointed out that the guidelines do not require disclosure of all information material to a subject's decision to participate in a research project,[2] place responsibility to obtain informed consent on the individual who may be least able or motivated to obtain it (the researcher),[3] and provide no effective remedy for the subject whose right to make an informed choice has been violated.[4]

Several suggestions have been offered to increase the protection currently afforded human subjects in research settings.[5] This essay examines three new suggestions: (1) that greater use be made of third parties to

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1. *E.g.*, Delgado & Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67 (1987) [hereinafter *Bridging*]; Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484 (1979); PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, PROTECTING HUMAN SUBJECTS Appendix E (1981) [hereinafter PRESIDENT'S COMMISSION]; *Subcomm. on Health, Quality of Health Care—Human Experimentation, Comm. on Labor & Public Welfare*, Hearings on S. 974, S. 878, S.J. Res. 71, 93d Cong., 1st Sess. (1973) (Parts 1-3).

2. *Bridging, supra* note 1, at 77-78 n.8; Dresser, *Deception Research and the HHS Final Regulations*, 3 I.R.B. 3 (Apr. 1981).

3. *Bridging, supra* note 1, at 76-77; 45 C.F.R. § 46.116 (1985); *see* Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 415-16.

4. *Bridging, supra* note 1, at 78-86 (and cases cited therein).

5. *See supra* note 1; Interview with Angela Holder, Professor of Pediatrics, Yale Medical School, Chief Counsel, Yale-New Haven Hospital (June 15, 1985) (suggesting increased use of "consent monitors"); E. DIENER & R. CRANDALL, ETHICS IN SOCIAL AND BEHAVIORAL RESEARCH 95-96 (1978) (proposing use of "informed deceit" in deception research); S. BOK, LYING: MORAL CHOICE IN PUBLIC AND PRIVATE LIFE 194-95 (1978) (same).

obtain consent; (2) that human subjects review committees undertake more searching scrutiny of deception research than the federal guidelines currently require them to do; and (3) that training in the ethics of research with human subjects be required of all researchers in the social sciences.

To appreciate the need for reform, it is essential to have a general understanding of the history and provisions of the federal regulations. Part II provides this in brief form. Part III shows how the regulations in a few key respects fail to promote their core purpose—protection of subjects' autonomy in research settings. Part III also suggests new ways the regulations may achieve heightened protection and illustrates how these would work in practice. The essay also considers objections that could be made to the various reforms, together with answers to those objections.

II. Federal Regulation of Research with Human Subjects

The current federal approach to human subjects research stems from the 1960s, when revelation of widespread abuses, such as the infamous Tuskegee syphilis study, prompted a call for reform.[6] The National Research Act,[7] together with detailed guidelines enacted to implement it,[8] provides an extensive system of federal oversight.

The regulations require that every institution, including most United States universities, that receives federal funding for research have in place one or more Human Subjects Protection Committees (HSPCs), sometimes called Institutional Review Boards (IRBs). IRBs contain lay and scientific members and must include at least one person not affiliated with the research institution.[9] HSPCs meet regularly and have two principal functions: assuring that research proposals have a favorable risk-benefit ratio and seeing to it that human subjects give informed consent.[10] It is with the latter function—protection of informed consent—that this essay is concerned. Most IRBs seem to regard informed consent, rather

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6. *Bridging*, *supra* note 1, at 71-72; H. Beecher, Research and the Individual: Human Studies (1970); H. Metscherlich & F. Mielke, The Death Doctors (1962); J. Jones, Bad Blood: The Tuskegee Syphilis Experiment (1981) (describing federally funded experiment in which Black syphilis suffers were left untreated to enable researchers to study natural course of the disease); Goldby, *Experiments in the Willowbrook State School*, 1 Lancet 749 (1971) (institutionalized retarded children used in experiment to test new vaccine).

7. National Research Service Award Act, Pub. L. No. 93-348, 88 Stat. 342 (1974) (amending the Public Health Service Act, as amended 42 U.S.C. §§ 201-300t (1976)).

8. The federal guidelines appear in 45 C.F.R. §§ 46.101-409 (1985). For a review of the history of the regulations, see Robertson, *supra* note 1, at 486-89.

9. 45 C.F.R. § 46.107(d) (1985).

10. *Id.* §§ 46.111(a), 46.116.

than risk-benefit ratio, as their prime responsibility.[11]

The federal regulations under which IRBs operate do not define informed consent, but list a number of its components[12] and provide detailed machinery for assuring that subjects understand the risks and benefits of the research before agreeing to take part.[13] If the IRB is dissatisfied with a proposal's consent provisions, the principal investigator may be required to revise and improve them before proceeding.[14] In other settings, informed consent is said to promote a number of values, including minimizing the risk of harm and establishing cooperation between physician and patient.[15] The legislative history of the HHS guidelines, however, indicates that the principal purpose of the informed consent provision is protection of human autonomy and decisionmaking.[16]

III. Deficiencies in Federal Regulation of Research with Human Subjects and Three Proposals for Reform

In general, IRBs, operating under federal guidelines, do an adequate job of protecting human subjects' right of self-determination in research settings.[17] Yet, three areas remain troublesome: biomedical research that is highly competitive and technical—as is much research in cancer treatment and recombinant DNA, for example;[18] research that includes deception as an essential technique;[19] and research in the social sciences.[20] This part considers each of these three areas in turn.

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11. Interview with David Sears, Chair, UCLA HSPC, Los Angeles, Cal. (Apr. 1982).

12. 45 C.F.R. § 46.116(a) (1985) (requiring disclosure of purpose of research; procedures to be used; risks and discomforts; benefits; alternative treatments; confidentiality; compensation offered; treatment available if injury results; identity of an individual to contact regarding questions; right to terminate participation without penalty).

13. *Id.* § 46.116(b)(1)-(6) (requiring disclosure of any risk to embryo or fetus; circumstances when investigator may terminate subjects' participation; any costs subject will incur; effect of subject's withdrawal; information on new findings while research is in progress; number of subjects in study).

14. Address by Dennis Molfese, Chair, Southern Illinois University HSPC, Carbondale, Ill. (Nov. 19, 1986) (many research proposals require several revisions before approval); *see* 45 C.F.R. § 46.109(a) (1985) (IRB authorized to require modifications of proposal).

15. *E.g.*, J. Katz & A. Capron, Catastrophic Diseases: Who Decides What? 85, 90 (1975); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

16. *See* 45 C.F.R. §§ 46.101 - .116 (consent provisions).

17. *See* Robertson, *supra* note 1; President's Commission, *supra* note 1 (incidence of harm from research low).

18. *See infra* notes 21-44 and accompanying text (proposing that ineffective disclosure and consent in these settings be controlled by use of third-party intermediaries and consent monitors).

19. *See infra* notes 45-64 and accompanying text (proposing variations of "informed deceit" technique for protecting autonomy in deception research). By "deception research" we mean research whose purpose cannot be achieved, at least not so readily, unless the subject is uninformed or actively misinformed about its nature or purpose.

20. *See infra* notes 65-69 and accompanying text.

A. *Pressured Research and Conflict of Interest or Value*

In research that is highly competitive and "pressured," reports of abuses of informed consent and even outright scientific fraud are not uncommon.[21] Sociologists of science have written of a culture or atmosphere that prizes, above all, success and priority of discovery.[22] In such a setting, researchers may easily overlook or minimize the nuances of, or even the need for, informed consent.[23] In some cases, this tendency is exacerbated by a mechanistic view of human nature in which persons behave but do not think, feel, or make choices.[24]

In such a climate, the researcher may find it easy to shortcut informed consent and such nonscientific values as autonomy and respect for personhood. Yet, even when researchers scrupulously desire to protect these values and follow informed consent rules, their training and unconscious professional predilection may disable them from doing so. Informed consent, to be rendered effectively, requires, at a minimum, (a) good communication skills—that is, the individual obtaining it must be able to communicate clearly to the human subject; and (b) empathy—the ability to place oneself in the other's position so as to supply him or her with the information the other needs, given his or her fears, hopes, desires, and values.

Barriers to empathy have already been mentioned and will be discussed further later in this essay. Many researchers also lack the communication skills essential to convey full and accurate information to their subjects. Few are trained in how to communicate with lay persons;[25] moreover, the setting in which consent discussions occur is

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21. *E.g.*, W. BROAD & N. WADE, BETRAYERS OF THE TRUTH 66-87 (1982); R. FOX, EXPERIMENT PERILOUS (1977); Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978), *aff'd*, 727 F.2d 1112 (7th Cir. 1984) (decision without published opinion); Hyman v. Jewish Chronic Disease Hosp., 21 A.D.2d 495, 251 N.Y.S.2d 818 (1964); *see Researchers Retract Immune System Data*, S. Illinoisan, Nov. 22, 1986, at 6, col. 1; *Misconduct by Scientists Said to be More Common than Many Believe*, Chron. of Higher Educ., May 21, 1986, at 7, col. 1.

22. B. BARBER, J. LALLY, J. MAKARUSHKA, & D. SULLIVAN, RESEARCH ON HUMAN SUBJECTS: PROBLEMS OF SOCIAL CONTROL IN MEDICAL EXPERIMENTATION (1973); W. BROAD & N. WADE, *supra* note 21; Merton, *Priorities in Scientific Discovery*, 22 AM. SOCIOL. REV. 635 (1956); *see* B. BARBER, INFORMED CONSENT IN MEDICAL THERAPY AND RESEARCH (1980); E. FREIDSEN, PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE (1972).

23. *E.g.*, McClellan, *Informed Consent to Medical Therapy and Experimentation*, 3 J. LEGAL MED. 81, 82-83 (1982); Karp v. Cooley, 493 F.2d 408 (5th Cir. 1974); Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974).

24. *See* Shipley, Misinformed Research: An Enigma in Modern Social Science Research, ETHICS IN SCI. & MED. 93 (1977); Sieber, *Deception in Social Research I: Kinds of Deception and the Wrongs They May Involve*, 4 I.R.B. 1, 2 (Nov. 1982).

25. J KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984); *see* Boreham & Gibson, *The Informative Process in Medical Consultations: A Preliminary Investigation*, 12 SOC. SCI. & MED. 409 (1978); Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 354-55, 357-58 (1974); Waitzkin & Stoeckle, *The Communication of Information about*

fraught with hazards. For example, studies of interchanges between persons in roles of dominance and submissiveness indicate that communication and understanding between the two are often ineffective[26]—both parties tend to arrive at inaccurate conclusions about themselves, the other, and the situation.[27] For these reasons, it may be desirable, at least in some circumstances, to provide for third parties trained in communication skills to obtain consent.[28] Such an arrangement could improve the accuracy of the information conveyed, as well as reduce the potential for conflict of interest in the research situation.[29]

Although a few scholars have recommended their use,[30] at present few researchers use third party intermediaries in the consent process, and even fewer IRBs require them.[31] Some IRBs require "consent monitors," or provide all potential subjects with the telephone number of a committee member whom they can contact if they have questions or complaints.[32] Certainly these measures are helpful in expanding the range of resources available to potential subjects who wish information relevant to their participation in research. Nevertheless, if the autonomy of the subject[33] is considered to be at least as fundamental as his or her bodily security, then the issue of third party intermediaries is not merely a question of supplementing the consent process but goes to the heart of the human values the regulations were intended to further.[34]

The few institutions that use third parties in obtaining consent seem to have adopted the practice as much in the interest of economy and

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Illness, 8 ADVANCES IN PSYCHOSOM. MED. 180 (1972); Maguire & Rutter, *Training Medical Students to Communicate*, in COMMUNICATIONS BETWEEN DOCTOR AND PATIENTS 46 (A.E. Bennet ed. 1976).

26. Cegala, Brunner & Conrad, *An Elaboration of the Meaning of Interaction Involvement: Toward the Development of a Theoretical Concept*, 49 COMMUN. MONO. 229 (1982); Jaspars, King & Pendleton, *The Consultation: A Social Psychological Analysis*, in DOCTOR PATIENT COMMUNICATION 139 (D. Pendleton & J. Hasler eds. 1983); Nerem, *The Effect of Passive, Uninvolved Interactional Behavior in Dyadic Communication* (doctoral dissertation abstract, on file with authors).

27. *See supra* note 26.

28. *See infra* notes 39-40 and accompanying text (ways in which third parties can be used). Third parties could be trained social workers, nurses, or other professionals and paraprofessionals with good communication skills and a command of basic science.

29. *See infra* notes 37-39 and accompanying text (federal approach based on this "life plan" focus; purpose of informed consent is to permit subject to exercise his or her right of choice).

30. *See Bridging*, *supra* note 1, at 76 n.39; Robertson, *Taking Consent Seriously: IRB Intervention in the Consent Process*, 4 I.R.B. 1 (May 1982).

31. Interview with Angela Holder, *supra* note 5 (Yale-New Haven Hospital IRB sometimes appoints third-party "consent monitors" to oversee consent process); *see* 45 C.F.R. § 46.117(3) (1985).

32. *See Bridging*, *supra* note 1, at 116 & n.217; 45 C.F.R. § 46.116-8 (1985).

33. *See infra* notes 37-39 and accompanying text; *see supra* note 16 and accompanying text (autonomy and self-determination the prime values HHS guidelines seek to protect).

34. This is so because researchers are often inadequately motivated or trained to promote these values. *See supra* notes 21-29 and accompanying text.

convenience as of respect for subjects' personhood.[35] Practically speaking, the use of third party consent obtainers probably is most cost effective in research projects that include large numbers of subjects or are time-intensive biomedical projects combining therapeutic treatment with experimentation.

With respect to research falling in the latter category, most scholars agree that physician-researchers should be held to the standards outlined in the 1982 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[36] In that Report, the Commission recommended that physicians adopt a view of patient self-determination in which the patient's values and preferences are given priority.[37] In this "life plan" approach, the physician must tailor the information given the patient so that it will be relevant to him or her—an individualized standard of informed consent.[38] However, in light of the many reports emphasizing the disinclination and, sometimes, inability of physicians or researchers to take such a perspective,[39] it may be not only cost effective, but essential, if autonomy is to be protected, to use third party consent obtainers or intermediaries.

There are a number of ways this might be done; each would need to be used selectively, depending on the particular characteristics of the research, the subject pool, and the risks of the research. Among the possibilities are: providing "consent monitors" to observe the principal investigator and call attention to deficiencies in the consent process; using paraprofessionals, such as medical social workers or research nurses with communications skills or training to obtain consent; using paraprofessionals in tandem with the principal investigator to improve the quality of disclosure and consent.

There are a number of possible objections that may be made against the use of third parties in the consent process. First, with sensitive research there may be an increased risk of breach of confidentiality.[40]

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35. Interview with Paula Knudson, Staff Assistant, Committee for the Protection of Human Subjects, University of Texas Health Sciences Center, Houston, Tex. (May 15, 1986).

36. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS (1982); *see also* Hollander, *Changes in the Concept of Informed Consent in Medical Encounters*, 59 J. MED. EDUC. 783 (1984); *cf.* NATIONAL COMMISSION 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 (1978) (affirming principle of respect for persons) [hereinafter BELMONT REPORT; adopted as policy by HHS].

37. MAKING HEALTH CARE DECISIONS, *supra* note 36, at 21 n.19.

38. *Id.*

39. *See supra* note 26; *Bridging*, *supra* note 1, at 102-05.

40. The intermediary may carelessly or intentionally disclose personal or medical information concerning a patient-subject, or written records prepared by the researcher for the use of the third party intermediary may come to the attention of outsiders.

However, this risk may be slight if the third party consent obtainers are properly trained in the ethics of research and confidentiality of patient-subject records.[41] Such training is currently provided to most medical professionals and paraprofessionals, for example.[42]

Second, even if confidentiality is not impaired, interposing a chain of communication between researcher to subject may increase the risk that the flow of information to the subject will be impeded or distorted. One recalls the classic technique used in communications classes to illustrate the creation of rumors as information is passed from one person to another, or the familiar parlor game illustrating the same principle. Again, with proper training in communication skills and research methods (such as is incorporated in the training of medical social workers and research nurses), the risk of distortion may be controlled.

Finally, it may be argued that third party consent obtainers would simply add more layers to the bureaucracy that accompanies the research endeavor, increase the cost of research, and impede the progress of science.[43] Thus, while the results of the research would not be invalidated, the approach's cost might endanger the conduct of research at its starting point. This threat is partially mitigated if, as we believe, the use of third parties to obtain consent will often save valuable researcher time. Nevertheless, this will not always be the case, and there will be settings in which the costs of research are increased, and the flow of information to the subject not greatly improved. In those settings, the rationale for third parties loses force and IRBs should have discretion whether to use them.[44]

B. *Research Where No Disclosure is Required: Deception Research*

Even more troubling, to the authors' way of thinking, than pressured research where inadequate or halfhearted disclosure is given, is deception research,[45] for in this large category of social science research no

41. The Hippocratic Oath exhorts medical professionals to protect patients' privacy; all modern codes of medical ethics do so as well. W. WADLINGTON, J. WALTZ, & R. DWORKIN, LAW AND MEDICINE 170-202 (1979).

42. Interview with Theodore R. LeBlang, Professor of Medicine and Chief Legal Counsel, Southern Illinois University School of Medicine, Carbondale, Ill. (July, 1986).

43. Initiation of a research project is already costly and time consuming, often requiring writing a grant proposal; submitting it to a funding agency; obtaining departmental approval; obtaining HSPC approval; and arranging for equipment, workers, and subjects.

44. Thus, a proposed guideline might provide: "Third party consent obtainers shall be used whenever the IRB believes the quality of consent will be significantly improved thereby. Third party consent obtainers shall not be used where the benefits of their use are likely outweighed by increased risks to human subjects, or by prohibitive cost."

45. *See supra* note 19 (defining term).

informed consent at all need be obtained.[46] The current HHS guidelines exempt much deception research from review entirely, or empower the IRB to permit it without compliance with informed consent provisions—although, as will be discussed, "debriefing" is often required as a type of substitute.[47] The explicit rationale for this seeming disregard of autonomy is as follows: the subject would be susceptible to only minimal risk, the research may yield valuable knowledge, obtaining informed consent would invalidate the results of the experiment, thus informed consent may be disregarded.[48]

What this chain of reasoning accomplishes is a change of focus from the essence of research ethics—protection of human autonomy—to the important, but secondary, consideration of protecting research subjects from physical or emotional harm.[49] The research subject in this scenario is in a position similar to that of the victim of unconsented-to research who cannot obtain judicial relief unless he or she can demonstrate a tangible harm, usually a physical consequence of the research.[50]

The standard justification—that although the subject's autonomy may have been diminished or ignored, the minimal risk to the individual is outweighed by the benefits from the advance in knowledge—is unsatisfying. For this justification rests on an implicit and unrecognized shift in the ethical foundation of research with human subjects. The deontological principle[51] of respect for persons which the HHS regulations purport to implement is silently dropped in favor of a utilitarian ethic which aims to achieve the greatest good for the greatest number.[52]

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46. The justification for nondisclosure is that informing the subject of the purpose or nature of the study would render the results useless. For examples of deception research see S. MILGRAM, OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW (1974); Humphreys, *Tearoom Trade: Impersonal Sex in Public Places*, 7 TRANS-ACTION 15 (Jan. 1970).

47. 45 C.F.R. § 46.116(d)(4) (1985); *see generally* Dresser, *Deception in Social Research III: The Nature and Limits of Debriefing*, 5 I.R.B. 1 (May/June 1983); *Deception Research and HHS Final Regulations*, 3 I.R.B. 3 (Apr. 1981).

48. *See* Dresser, *supra* note 47 (discussing this rationale).

49. *See supra* notes 16 & 36-38 and accompanying text (federal guidelines' central goal to protect autonomy and personhood of subjects). Debriefing cannot promote human autonomy because it takes place after the fact—ater the decision to experiment with a human subject has been made and the research completed. If conducted expertly, debriefing may soothe the subjects' indignation and assure them that their autonomy was forfeited in a good cause. But these considerations do not restore the lost autonomy or respect for personhood or life plan. Instead, they only reconcile the subject to the loss.

50. Tort law makes it difficult to recover unless this is shown. *See Bridging*, *supra* note 1, at 80-87 (cases discussed therein).

51. There are two broad types of ethical principles or rules: deontological and teleological (or utilitarian). Deontological principles assert that certain behaviors—such as keeping promises or avoiding cruelty—are right in themselves, even though their consequences on particular occasions may be unfortunate. Utilitarian rules look to the consequences of conduct; they assert that actions are right or wrong, not by virtue of their nature, but according to whether they produce good results.

52. *See supra* notes 36-38, 51 and accompanying text (defining "utilitarian ethics"). Deception

Thus, while the regulations ostensibly seek to protect deontological values such as personhood, autonomy, and wellbeing, they permit a switch to utilitarian justifications when informed consent requirements might invalidate a research design, and count violations of autonomy as a mere emotional discomfort to be minimized, if possible, by debriefing.[53] What is most worrisome about this shift, however, is that the researcher often makes the decision to short-circuit consent and substitute debriefing without oversight of any kind.[54] Informal estimates indicate that as many as 70% of social science research projects using human subjects may never even be submitted to human subjects committees for review.[55]

Deontology aside, the short-term benefits to social scientists from ready access to deception may be outweighed by the long-term costs. The conduct of research rests finally on public support and favorable attitudes toward the research endeavor in general.[56] This support may be eroded if the public comes to believe that in certain areas of research scholars disregard human subjects as thinking, experiencing individuals in favor of viewing them as simply a collection of potential behaviors to be stimulated or elicited externally.[57] If potential human subjects come to regard researchers as ruthless, self-interested pursuers of their own gain, cynicism and public opposition may well result.[58] The pool of willing research subjects may contract, and research will become more difficult, not easier, to conduct.

Assuming, however, that deception research does provide us with valuable knowledge that can be obtained in no other way, we may wish to consider ethically acceptable means by which it may proceed. This will necessitate making explicit when and why autonomy is to be subordinated to scientific utility, and who is to make that trade-off. The

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research violates the deontological principle of respect for persons, but purports to find justification in utility: the research disrespects a few persons but will benefit even more. *See* M. SHAPIRO & R. SPECE, BIOETHICS AND LAW: CASES, MATERIALS AND PROBLEMS 72-93 (1981) (explaining ethical theories and their application to biomedical dilemmas).

53. *See Bridging, supra* note 1, at 92-97 (performing research on unconsenting subjects deprives their acts of "moral meaning," a gain many would have valued in their personal risk-benefit calculation, had they been permitted to make it).

54. *See supra* note 47 and accompanying text (little or no IRB oversight).

55. Address by Dennis Molfese, *supra* note 14 (high percentage of social science researchers do not submit proposed research for HSPC review, even where HHS regulations and campus rules require them to do so).

56. A high proportion of research is publicly funded. *See* Delgado, et al., *Can Science be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128, 175 (1983). The public, if disaffected, may simply withdraw its support. Municipalities and other government entities may also regulate or forbid research under the police power, if it believes it to be conducted unethically or in a physically risky manner. *Id.* at 152-53.

57. *See supra* note 24 (some researchers hold mechanistic view of human nature).

58. *See generally* Delgado, et al., *supra* note 56.

least troublesome solution would be to secure the prior consent of those to be deceived.[59] Autonomy is not abandoned if a person chooses to waive the right to information when he or she is in agreement with the purpose of the waiver—because he or she believes it will advance interests and values he or she embraces and believes in.[60]

A few writers have sketched variations on this "informed deceit" approach. Sissela Bok, for example, has proposed that research scientists engage in dialogue with the public in an effort to win approval of the use of deception in demonstrably useful research.[61] She argues that if such matters are thrown open to public discussion, and widespread agreement follows that the research is so valuable as to outweigh diminishing autonomy in certain restricted situations, then the research could be conducted without weakening public confidence or endangering human interactions.[62]

Less global solutions than Dr. Bok's are also possible. For example, social science researchers may create a "deception pool" by simply asking subjects, in advance, whether they would agree to be deceived in one or more future experiments. Alternatively, "proxy consent" could be required: IRBs could insist that deception researchers identify a group of subjects as similar as possible to the group to be deceived, and ask the former group how they would feel about participating in a research study in which the nature or purpose of the study was unknown to them. Finally, "representative consent" might be insisted on. In deception research involving lawyers, for example, the researchers might fully disclose the research to Bar Association leaders and obtain their support before conducting the research with lawyers.

Necessarily, all approaches imply that deception techniques must be used sparingly and only in compliance with explicit restrictions and conditions. Further, if deception research is to be based on utilitarian principles, then the regulations should reflect this shift and reconcile it with the deontological approach adopted by HHS.[63]

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59. The consent obtained would be consent *to be deceived*, not consent to take part in a particular research project. The latter would entail fully informing the subject about the project, which would, with deception research, render the project useless.

60. The subject thus in effect says: "I agree to be deceived and forfeit my right of self-determination. I do so autonomously and for reasons of my own, including my desire to help these investigators advance human knowledge—even though I do not know what sort of knowledge it is they seek to generate."

61. S. BOK, *supra* note 5, at 194-95.

62. *Id.*

63. *See supra* notes 36, 44 (proposed new guidelines for third-party consent obtainers). A new approach to deception research should require, at a minimum, that the regulations: (1) require that nondeceptive alternatives to generating the knowlege sought be exhausted first or be shown impracti-

C. *Habituating Researchers to Respect Informed Consent: Improving the Training and Education of Social Science Researchers*

Modification of the HHS guidelines to provide for third-party intermediaries and abolition of the current regulatory void for deception research will do much to ameliorate the worst abuses. Yet, in the long term, regulation will not be fully effective until researchers internalize the values of respect for persons and autonomy that underlie the regulations.[64] Researchers in many fields receive little formal training in the ethics of research. Additionally, most subjects have little or no information or awareness of their rights when confronted with demands from professionals who occupy positions of status and prestige higher than their own. Many studies indicate that laypersons in general are conditioned to accede to the wishes of such persons.[65] Training could sensitize social science researchers to the obligations of research ethics and inform potential human subjects of their rights in the research situation.

Unfortunately, many graduate social science departments do not require ethical training as part of their degree programs, much less as a prequisite for appointment of research faculty.[66] Traditionally, universities and professional groups are left free to regulate their internal affairs and the conduct of their members. If such groups are slow to monitor themselves, however, standards of conduct may be imposed externally. This may be necessary with regard to social science research that is sponsored by the federal government.[67]

One manner in which this might be done is to amend the federal guidelines to include a requirement of training in the ethics of human subjects research. Universities and other research facilities might be given a number of options in complying with this requirement. The IRB or campus research director might conduct seminars or periodic lectures. Graduate courses might be required as a degree requirement in all fields where research with human subjects is common. Such measures may not still the actions of the few willful and opportunistic researchers determined to conduct research at any cost, but they would sensitize all re-

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cable; (2) demand that the least deceptive alternative be selected; (3) insist on some form of prior informed deceit or proxy consent.

64. Many researchers currently do not. *See supra* notes 21-24 & 39 (many researchers work in a climate that values priority of discovery over deontological values of respect for personhood and "life plan").

65. *See generally supra* note 26.

66. A recent study showed only 10 graduate social science courses devoted to research ethics. ETHICS TEACHING IN HIGHER EDUCATION 166-67 (D. Callahan & S. Bok, eds. 1980).

67. *See supra* notes 7-8 and accompanying text (impetus for enactment of HHS Guidelines came from reports of human-subject abuses and uncaring behavior by researchers in the 1960s and early 1970s).

searchers to the ethical problems inherent in any research project that includes human subjects. Further, they would provide training in how to analyze and solve ethical dilemmas researchers will encounter in their professional work. Such requirements are commonplace in many professional fields, including law and medicine.[68] There is certainly as good, if not better, reason to institute such requirements in the training of social science professionals.

IV. CONCLUSION

The federal guidelines for human-subjects research, and the IRBs charged with effectuating them, provide a comprehensive approach to protecting autonomy and respect for persons in federally funded research. Yet, a number of areas remain troublesome. We have argued that greater attention than that currently afforded must be given to three problems—that of halfhearted or pressured disclosure, that of deception research, and that of the social science researcher who lacks training in research ethics. To avoid erosion of the ethical foundations of federal oversight, as well as to protect human autonomy and respect for science on the part of the public, reforms are needed. Provision should be made for third-party consent intermediaries in many settings. Deception research must be more closely monitored than it currently is, and provision for proxy consent or "informed deceit" must be made. Finally, as a supplement to heightened regulatory efforts and amendment of the regulations, graduate and research programs, especially in the social sciences, must offer training and education in the ethics of human research.

68. The ABA requires as a condition of accreditation that all law schools teach professional responsibility and ethics. *See supra* notes 41-42 (similar teaching in medical schools).