

INTRODUCING A NEW PARADIGM FOR ETHICAL RESEARCH IN THE SOCIAL, BEHAVIORAL, AND BIOMEDICAL SCIENCES: PART I

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“The first, indispensable steps in any philosophical inquiry are liable to seem entirely negative, both in intention and in effect. Distinctions are made, objections are pressed, accepted doctrines are found wanting, and such appearance of order as there was in the field is destroyed; and what, asks a critic, can be the use of that?”

“In immediate effect, the philosopher’s initial moves do certainly tend to break down rather than build up analogies and connections. But this is inevitable. The late Ludwig Wittgenstein used to compare the re-ordering of our ideas accomplished in philosophy with the re-ordering of the books on the shelves of a library. The first thing one must do is to separate books which, though at present adjacent, have no real connection, and put them on the floor in different places: so to begin with the appearance of chaos in and around the bookcase inevitably increases, and only after a time does the new and improved order of things begin to be manifest”

— Stephen Toulmin, *The Uses of Argument* 253 (1958).

INTRODUCTION

During the past thirty years, considerable attention and resources have been focused on the ethics of research involving human participants.¹ The

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¹ This article incorporates ideas and text appearing in *Antropologicheskii forum/Forum for Anthropology and Culture*. Brian Schwegler, *From the Power of Ethics to an Ethics of Power* (pts. 1, 2), 4 F.

ethical principles currently employed by regulators and ethics committees to govern human research are derived from the work of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The National Commission was established by the National Research Act of 1974 in response to public concern about unethical biomedical experiments. Two experiments were particularly troubling. One experiment involved injecting children at the Willowbrook State School for the Retarded with a form of hepatitis.² Another experiment studied the course of syphilis in several hundred African-American men and failed to treat these individuals after the subsequent discovery of penicillin.³ The National Commission was charged with reviewing the system of Institutional Review Boards (“IRBs”) that perform ethical review of research, identifying basic ethical principles for research with human participants, and recommending ways to ensure that research followed those principles. The commission consisted of three physicians, three attorneys, two bioethicists, one biologist, one physiological psychologist, and one community member who was president of the National Council of Negro Women, and hence also cognizant of minority issues. The commissioners, with the aid of staff members, derived a set of principles (beneficence, respect for the autonomy of persons, and justice) as set forth and discussed in the *Belmont Report* (named after the location where this group convened).⁴

The Belmont Report—the presumptive basis on which the entire enterprise of research ethics is based—has received little serious scrutiny during or since its inception. Conceptually, *Belmont* occupies a unique position: because it is outside traditional disciplines that deal with issues of morality and moral reasoning—e.g., moral philosophy, social and political philosophy, legal ethics, and anthropology—it appears to be unassailable to judgments from those disciplines. Yet, despite this separation from these more traditional disciplines, *Belmont* relies on their principles, without necessarily being sufficiently informed by them. Indeed, *Belmont*’s influence is nearly hegemonic in that, within IRBs and the broader research ethics community, all discussions must start (and sometimes end) with it in order to be considered morally legitimate. *Belmont* is treated as immutable to appeals to the philosophical requirements of the principles upon which it

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² See generally JAY KATZ, EXPERIMENTATION WITH HUMAN BEINGS 1007–10 (1972) (describing the events surrounding Willowbrook hepatitis experiments).

³ See generally J.H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1981) (providing an overview of the history of the Tuskegee syphilis experiments).

⁴ THE NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, PUB. NO. 78-0012, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://ohsr.od.nih.gov/guidelines/belmont.html> [hereinafter *Belmont*].

claims to be based. Moreover, within its implementation, it straddles a line between normative and practical ethics, leaving both unsatisfied.

The federal regulations governing research on human subjects⁵ draw from and underscore *Belmont's* principles—in particular, the respect for autonomy via an informed consent procedure and the protection of human subjects from harm via a presumed risk–benefit assessment on the part of investigators and IRB members. *Belmont* is the only statement of ethical principles endorsed as a legitimate foundation for ethical review processes by the U.S. government for institutions receiving government funds for research.⁶ Consequently, almost all U.S. universities and other research institutes hold their research practices to *Belmont's* ethical definitions. The IRB process and professional codes of conduct tacitly or explicitly incorporate the principles of *Belmont*. An IRB review typically documents that risks to participants are minimized within a study's design (*beneficence*), that the benefits and burdens of research participation are equitably distributed (*justice*), and that the informed consent of participants is prospectively acquired and documented (*respect for persons*).

We think that the time has come to examine this influential report and how it might be supplanted by a more cogent, logical, and ethical guide for research. This will be done in two separate documents. In this, the first paper to develop out of our project, we discuss some of the valuable ideas in *Belmont* and examine problems with the report's analyses of ethical principles. Later, we plan to draft and publish a second paper, covering more practical problems of applied ethics and regulation. Ultimately, we hope to revise both parts of our project and issue them as a unified report to guide ethical research and to serve as an alternative that reform-minded universities might adopt in place of *Belmont*.

In what follows, we argue that the principled model for ethical decision-making specified and implied in *Belmont* distorts the philosophical requirements of the ethical principles of beneficence, respect for persons, and justice in both their conceptual specification and practical application. In particular, we argue that *Belmont's* model relies on a simplistic accounting of the concepts of beneficence, respect for persons, and justice. Furthermore, *Belmont* conflates the requirements of these principles. Specifically, we argue that:

⁵ 45 C.F.R. § 46 (2005).

⁶ This contract, the Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions within the United States, outlines the terms according to which institutions will apply the federal regulations to research conducted by their affiliates. This assurance is required for the dispersal of any federal research funding and includes stipulations for the establishment of local IRBs, which must be registered with the federal government. Applicants may specify an alternate set of ethical principles to guide their ethics review processes, but little guidance about what, if any, alternatives the regulatory agencies consider equivalent is available. See Domestic FWA Filing Sample, <http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.htm> (last visited Dec. 3, 2006).

(A) *Belmont's* conception of beneficence relies on a conception of benefits and risks that cannot accommodate the various goods and harms that are legitimately given weight in risk–benefit calculations made by research participants. These include goods such as the altruistic, intellectual, and social interests of participants, and fears or perceived harms such as fear of signing a consent form that subjects are unsure they understand.

(B) In its conception of respect for persons, *Belmont* relies on a superficial view of choice. It ignores the range of contexts in which human research is conducted, as opposed to the medical model, where research typically occurs in highly controlled contexts, with the likely availability of a legally authorized representative who can consent on behalf of nonautonomous subjects. Similarly, *Belmont* ignores the many research contexts in which a signed consent form is inappropriate, insulting, or impossible to obtain, as in ethnographic research. And, *Belmont* would require full disclosure of every conceivable aspect of research in contexts in which this gives a false sense of the seriousness or risk or hassle involved and is likely to discourage participation. Further, *Belmont* regards competency only in terms of a cognitive model of decision that excludes the role of emotion.

(C) *Belmont's* narrow conception of justice involves a conceptual mistake that conflates the harms of exploitation with those of disrespect for persons. *Belmont* considers justice only in terms of distributive justice, ignoring concepts of justice that involve respect for persons. Its concern to protect the vulnerable tends to motivate overprotection, which diminishes the respect for autonomy of subjects. We will discuss how this narrow conceptualization came about and why it is inadequate to satisfy important aspects of the ethics of human research.⁷

I. THE *BELMONT* RESEARCH MODEL: HISTORY

The standard model of ethical decision-making in research on humans (*Belmont*) is based on the medical model of decision-making and shares with it the same core ethical principles of beneficence (or nonmaleficence), respect for persons, and justice. This is not surprising, since the group that was first charged with articulating the universal standards for ethical research practices were mostly physicians and others whose main focus was

⁷ Note that Part II of this essay, to be published separately, will include our suggested response to these problems. Specifically, we will suggest that a different conception of the requirements of these ethical principles is needed in order to specify an adequately informed and sufficiently robust system for ethical research. These include: a broader understanding of the requirements of beneficence that can be adopted to accommodate individual research participants' conceptions of the good; a reconceptualization of the requirements of respect for persons that includes an expanded and modified model of competence and a taxonomy of recognizable reasons that may legitimately motivate people to want to participate in research and so also meaningfully and legitimately inform their decisions to do so; and a conception of justice that distinguishes the harms related to coercion from those related to exploitation, which is needed in the context of research in order to adequately assess and address research-related injustices.

biomedical research and medical treatment.⁸ Some of the current confusion in the regulation of research ethics, reflected prominently in *Belmont*, stems not only from the field's medical origins, but also from the confusion of research participants with patients.

The need for ethical standards for medical research became clear during the trials of the Nazi doctors at Nuremberg. As part of their defense, the charged doctors argued that they could not have violated standards for the ethical conduct of research, since no such standards existed.⁹ It was at the request of the Nuremberg judges that the core ethical principles that would later become the Nuremberg Code¹⁰ were specified.¹¹ Although the Nuremberg Code was intended to be a clear and concise articulation of a universally applicable code of principles and practices for ethical research, its requirements were nonbinding, and it was largely ignored by American researchers who viewed it as irrelevant to their own practices,¹² since they were not Nazis.¹³ The need for ethical standards to guide the conduct of medical research in the United States did not become apparent to the American research community and policymakers until much later.¹⁴ This need came to light in part when, in 1966, the American physician Henry Beecher published an article in the *New England Journal of Medicine* documenting numerous cases of egregious, unethical research by American physicians.¹⁵ That same year, the United States Public Health Service issued a policy statement covering all research funded through their programs.¹⁶ The principles contained in that document shared many features with those included in the Nuremberg Code, including the primacy of informed consent.¹⁷ However, a key difference between the Nuremberg Code and the Public Health Service policy was that the policy was binding for re-

⁸ See *infra* notes 25–26 and accompanying text (discussing medical origins of the principle of beneficence).

⁹ ULF SCHMIDT, JUSTICE AT NUREMBERG: LEO ALEXANDER AND THE NAZI DOCTORS' TRIAL 234 (2004).

¹⁰ *Id.* at 3–5.

¹¹ PAUL S. APPELBAUM, CHARLES W. LIDZ & ALAN MEISEL, INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 212–13 (1987).

¹² One notable exception to this is Walter Reed, who, in 1900, sought consent from the subjects of his yellow fever vaccine experiments. John McManus, *Informed Consent and Ethical Issues in Military Medical Research*, 12 ACAD. EMERGENCY MED. 1120, 1121 (2005).

¹³ For similarities between American research on prisoners and some Nazi research, see Jon M. Harkness, *Nuremberg and the Issue of Wartime Experiments on US Prisoners: The Green Committee*, 276 J. AM. MED. ASS'N 1672 (1996). See generally APPELBAUM ET AL., *supra* note 11.

¹⁴ Rosamund Rhodes reports that she found 209 journal articles that mention the topics of research and ethics and 11 that mention the topics of research and informed consent in the thirty year period from 1940–1969 in a Med LINE/Pub Med search of English language articles. Rosamund Rhodes, *Rethinking Research Ethics*, 5 AM. J. BIOETHICS 7, 8 n.7 (2005).

¹⁵ See Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

¹⁶ APPELBAUM ET AL., *supra* note 11, at 217.

¹⁷ *Id.*

searchers funded by the Public Health Service. The policy represented the first enforceable regulation of the research process,¹⁸ a process that had previously been left to the judgment of individual researchers and the institutions in which they practiced.¹⁹

Though unquestionably devastating to the medical community, Beecher's article was but a precursor to the revelations of unethical research to come. Indeed, the revelations of the Nuremberg trials seemed to serve not as a precautionary tale, but as reinforcement for the notion that American scientists are by nature ethical and hence need not engage in deliberate proactive ethical problem solving. Even the Public Health Service seemed to subscribe to this over-simplified view. Then, in 1972, details were publicly revealed about a study funded and conducted by the United States Public Health Service targeting poor syphilitic African-American men living in Tuskegee, Alabama. As part of the Public Health Service-funded research program, these men were not only systematically denied existing treatments for syphilis as part of the research design, they were also effectively cut off from activities through which they would otherwise have routinely received such treatment, such as military service.²⁰

Amid these and other revelations of unethical research,²¹ in 1974 Congress passed the National Research Act,²² which called for the creation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was directed to:

- (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects. [and] (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles²³

The Commission proceeded quickly to develop its first draft of what came to be called *The Belmont Report*.

Several months and 15 meetings into their deliberations, the members of the commission and a few advisors retreated to Belmont House (an eighteenth-century estate in rural Maryland maintained by the Smithsonian Institution as a

¹⁸ *Id.* at 216.

¹⁹ *Id.* at 215–17.

²⁰ ALLAN M. BRANDT, HASTINGS CTR. REP., RACISM AND RESEARCH: THE CASE OF THE TUSKEGEE SYPHILIS STUDY 21 (1978); Centers for Disease Control and Prevention, The Tuskegee Timeline (2005), <http://www.cdc.gov/nchstp/od/tuskegee/time.htm>.

²¹ Other notable cases include Stanley Milgram's experiments on obedience to authority in which subjects were deceived into believing they were administering possibly fatal electric shocks to people, and the Willowbrook study of hepatitis in which mentally retarded children were deliberately infected with hepatitis. BRANDT, *supra* note 20; DAVID J. ROTHMAN & SHEILA M. ROTHMAN, THE WILLOWBROOK WARS (1984).

²² National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).

²³ *Id.* § 202(a)(1)(A), at 349.

conference center) for a long weekend to identify “basic ethical principles” for research involving human subjects. The final product of this gathering was published after three years—and considerable additional discussion—as “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” which was first published in the *Federal Register* on April 18, 1979. The report was purposefully brief, and its three basic ethical principles and concomitant applications can be stated with almost mathematical precision: “respect for persons” relates to “informed consent,” “beneficence” relates to “assessment of risk and benefits,” and “justice” relates to “selection of subjects.” Bioethicists generally agree that this report was and is a foundational document in the national and international development of research ethics.²⁴

In addition to specifying three core ethical principles that underlie the conduct of research with human subjects, *Belmont* contained examples of research activities that failed to meet the requirements of these principles. Among the cases featured in *Belmont* are the Tuskegee Syphilis Study and the Nazi doctors’ experiments. The ethical principles specified in *Belmont*—the principles of beneficence, respect for persons, and justice—form an essential part of the foundation of the research model. These will be considered in detail in the following sections.

II. THE BELMONT RESEARCH MODEL: PRINCIPLES

A. *Beneficence/Nonmaleficence*

1. *The Development of Beneficence.*—The principle of nonmaleficence, that doctors should “do no harm,” has long been an accepted part of medical ethics. In the 1860s, Claude Bernard expanded this commitment not to harm patients into the principle to do positive good, the principle of beneficence:

It is our duty and our right to perform an experiment on man whenever it can save his life, cure him or gain him some personal benefit. The principle of medical and surgical morality, therefore, consists in never performing an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, i.e., to the health of others. But performing experiments and operations exclusively from the point of view of the patient’s own advantage does not prevent their turning out profitably to science.²⁵

²⁴ Jon M. Harkness, Book Review, 355 N. ENG. J. MED. 634, 634 (2006) (reviewing *BELMONT REVISITED: ETHICAL PRINCIPLES FOR RESEARCH WITH HUMAN SUBJECTS* (James F. Childress, Eric M. Meslin & Harold T. Shapiro eds., 2005)).

²⁵ CLAUDE BERNARD, AN INTRODUCTION TO THE STUDY OF EXPERIMENTAL MEDICINE 99–103 (Lawrence Joseph Henderson ed., Henry Copley Greene trans., The Macmillan Co. 1927) (1865).

Like Bernard, *Belmont* treats beneficence as an obligation: “In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”²⁶ The Hippocratic maxim “do no harm” has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm.²⁷

It is a major leap from not harming subjects of biomedical research in the process of curing a disease or benefiting society with new health-giving technologies, to issues of whether one may inconvenience or upset subjects of social, educational or behavioral research in return for learning something about human behavior for the sake of knowledge, or for policy purposes. As application of the federal regulations of human research by IRBs moves into ever new areas of research, such as oral history, journalism, speech, and English literature, this “mission creep” raises new awareness and accompanying ambiguities and concerns in the minds of investigators and IRBs.²⁸

Before *Belmont*, many social science researchers probably would have assumed that surveys of the general public tend to benefit society by advancing knowledge, and perhaps providing a sound empirical basis for public policy. But, if they had thought about it, perhaps most would acknowledge that, on balance, participation as a respondent is usually not interesting enough to counterbalance the trivial “harm” or inconvenience of spending time participating in the survey. The idea that a researcher could not balance the expected social good of the research against a trivial harm to the subjects would have struck many researchers as odd—and contrary to well-accepted research ethics at the time. Yet even in the 1970s, some social science researchers understood that potential subjects would be more likely to participate in studies if a researcher appealed to the subjects’ desire to advance learning and to their interest in the world²⁹—in effect, that subjects might find participation intellectually stimulating or that subjects might altruistically benefit by the charitable act of donating their time to the study.

²⁶ *Belmont*, *supra* note 4, at 6.

²⁷ *Id.* at 6–7.

²⁸ Center for Advanced Study, *The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB “Mission Creep”* 2 (Univ. Ill. Law & Econ. Research Paper No. LE06-016, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=902995.

²⁹ DON A. DILLMAN, MAIL AND TELEPHONE SURVEYS: THE TOTAL DESIGN METHOD 12–14 (1978).

To make the principle of beneficence work for research outside the context of the doctor–patient relationship, it must be interpreted somewhat differently from how Bernard sees it: in a way that redefines whose interests matter; considers different kinds of harm; and respects the intellectual, social, and altruistic desires of participants. Although *Belmont* clearly endorses looking to societal benefits, it does not explain either the scope or the justification for its view of what counts as harm, and it adopts a cribbed and disrespectful view of the preferences, interests, and values of individual research subjects. For example, a major problem facing survey researchers and policy makers who depend on survey research is that many potential subjects, who would be happy to participate in the survey, fear signing a consent form that they do not understand. They have come to regard signing legal-looking documents as an act that likely binds them to some agreement that will place them in jeopardy.³⁰ Thus, the very procedure that was initiated in biomedical research to assure autonomy and protect subjects can have the opposite effect on potential participants in social research. The difficulty in getting potential participants to sign a consent form not only makes conducting an experiment or study more difficult, but it also lessens the benefits the research can provide to science and society.

2. *Minimizing Risks and Maximizing Benefits.*—As it is employed in research, the *Belmont* principle of beneficence/nonmaleficence incorporates at least two distinct but related duties for researchers. First, researchers have an obligation to design their research protocols in such a way as to minimize the risks of harm to research subjects.³¹ Second, researchers have an obligation to design their research protocols in such a way as to maximize the potential benefits (if any) to research subjects from participation.³² It is important to note that within the research context, the terms “risk” and “benefit” have specific meanings:

The term “risk” refers to a possibility that harm may occur. . . . The term “benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike “risk,” “benefit” is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits.³³

Thus, according to *Belmont*, “risk” is a probabilistic term, whereas “benefit” is not. An assessment of the comparative relationship between the risks and benefits associated within a given research protocol is required

³⁰ Eleanor Singer, *Informed Consent in Surveys: A Review of the Empirical Literature*, 9 J. OFFICIAL STAT. 361, 369 (1993).

³¹ *Belmont*, *supra* note 4, at 6.

³² *Id.*

³³ *Id.* at 15.

in order to determine whether the research is justified with regard to *Belmont's* requirements of beneficence/nonmaleficence.³⁴ Although there is no explicit requirement that the relationship between the risks and benefits be balanced or even favorable to the benefits, *Belmont* specifies how research must be justified under the requirements of the principle of beneficence/nonmaleficence:

- (i) Brutal or inhumane treatment of human subjects is never morally justified.
- (ii) Risks should be reduced to those necessary to achieve the research objective. . . . Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.
- (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in some rare cases, to the manifest voluntariness of the participation).
- (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated.³⁵

Note that the requirements of the ethical ideal of beneficence/nonmaleficence are significantly different in the research model than they are in the “medical model.” In particular, the requirements have been modified to accommodate the fact that the goal of research is different than the goal of medical practice. Whereas the goal of medical practice is to treat patients, the goal of research is to test hypotheses and to produce scientific knowledge. *Belmont* draws the distinction between the two as follows:

[T]he term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).³⁶

Likewise, the nature of the harms and benefits are also different within the research model as described in *Belmont*:

[R]isk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of

³⁴ *Belmont* suggests that, within the research context, respect for the immature (including children and persons with mental disabilities) and the incapacitated may require protecting them as they mature or while they are incapacitated. *Id.* at 5. Also, the judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. *Id.*

³⁵ *Id.* at 17.

³⁶ *Id.* at 2–3.

psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits.³⁷

Still, there are similarities between the two. Both medical practice and research have individual and social dimensions, and so the obligations of beneficence/nonmaleficence extend to individuals and to society at large:

In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.³⁸

Within the research setting, this means that the requirements of beneficence/nonmaleficence extend not only to particular research projects but also to the entire enterprise of research. It also means that both researchers and members of the larger society have obligations with regard to recognizing the risks and benefits of research. Thus, within the research mode, the ethical ideal of beneficence/nonmaleficence carries with it two related obligations for researchers: to maximize possible benefits and minimize possible harms.³⁹

B. Respect for Persons

1. *Protecting Autonomy.*—Within *Belmont's* research model, the principle of respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents; second, that persons with diminished autonomy are entitled to protection.⁴⁰ The principle of respect for persons thus divides into two separate moral requirements for researchers: the requirement to acknowledge those individuals who have autonomy and the requirement to protect those individuals who have diminished autonomy. According to *Belmont*, an autonomous person is an individual capable of deliberation about personal goals and who is acting under the direction of such deliberation.⁴¹ Thus, to respect persons' autonomy is to give weight to their considered opinions and choices while refraining from obstructing their actions unless those actions are clearly detrimental to others. Conversely, to show lack of respect for a person's autonomy is to repudiate that person's considered judgments, to deny him or her the freedom to act on those considered judgments, or to withhold in-

³⁷ *Id.* at 15.

³⁸ *Id.* at 7.

³⁹ *Id.*

⁴⁰ *Id.* at 4.

⁴¹ *Id.* at 5.

formation necessary to make a considered judgment when there are no compelling reasons to do so.⁴²

Belmont also recognizes that not every human being is capable of self-determination. For example, young children and persons with mental disabilities are not considered fully autonomous, since their decision-making is generally not fully mature. Thus, there is a continuum of self-determination, with the capacity for self-determination generally maturing during an individual's life. However, some individuals may lose, wholly or partially, their capacity for autonomy because of illness, mental disability, or circumstances that severely restrict individual liberty (e.g., incarceration, military service). In each of these kinds of cases—immaturity, mental disability, restricted individual liberty, and illness later in life—the degree of limitation on self-determination exists on a continuum. At one extreme of any of these continuums are persons who may be in need of extensive protection, even to the point of excluding them altogether from activities which may harm them; at the other extreme are persons who require little protection beyond making sure that they undertake activities freely and with awareness of possible adverse consequence.⁴³ *Belmont* suggests that within the research context, the extent of protection afforded a particular individual should depend in part on the risk of harm and the likelihood of benefit associated with any given research project.⁴⁴

Thus according to *Belmont*, not all individuals are free choosers. The immature and others lacking full decision-making capacities are among those who are not considered free choosers. Also included in this group are persons whose individual liberty is restricted in some significant way, usually by a third party, such as prisoners and members of the military. Thus, there is an apparent dilemma over how to meet the requirements of the ethical ideal of respect for persons with constrained liberty. Specifically, the dilemma is how to strike the appropriate balance between the requirements of respect for persons and paternalism, between allowing these individuals to “volunteer” to participate in research and protecting them “from activities that may harm them” by limiting, constraining, or disallowing their participation altogether.

Within the medical context, and in most biomedical research, the patient or research occurs within a highly controlled medical environment, and the nonautonomous individual is typically accompanied by an autonomous person who functions as their legally authorized representative. In contrast, social-behavioral research occurs in widely varying field contexts. Often, the presumably non-autonomous subject is going about typical daily activities, perhaps at school, at a shopping mall, online on their computer terminal, in some other community location, or at home. Determination of

⁴² *Id.*

⁴³ *Id.* at 18–19.

⁴⁴ *Id.* at 19.

the person's degree of self-determination, or status as a minor, must sometimes be made "on the hoof." Holding them to the same standard of protection that is appropriate to biomedical research or medical treatment is often impossible, and also inconsistent with the way they handle other everyday activities that involve talking, writing, or some other typical form of behavior.

2. *The Requirement of Informed Consent.*—The practice of acquiring the prospective informed consent of research participants is an example of a bureaucratic reduction of research practice to a static conception of the ethical. *Belmont* identifies the practice of informed consent as a manifestation of its principle of respect for persons. It stipulates that informed consent entails that participants are prospectively informed of the purposes and terms of study participation, that they are judged to meaningfully comprehend this information, and that the voluntary nature of participation be conveyed to them. It is only when these requirements are met that research demonstrates respect for persons, according to *Belmont*. In the practice of ethics review, however, *Belmont's* conception of informed consent "has become ensconced as the cornerstone principle of research ethics,"⁴⁵ and has also been largely reduced to paperwork, which is often meaningless to the prospective subject.⁴⁶

Most ethics review committees are bureaucratically unable to document that research projects meet definitions of the ethical unless they include provisions for acquiring such written consent or meet regulatory provisions for its waiver.⁴⁷ Unfortunately, many review committees improperly consider informed consent a manifestation of the inherent ethics of a study: if informed consent (typically a signed consent form) will be prospectively acquired, a project is ethical; if it will not, it is not.⁴⁸ To support their determinations, ethics review processes consistently focus on the artifacts of informed consent—"consent forms"—in their evaluations of the ethics of a research proposal. In accordance with federal regulations, committees require that these documents detail all prospectively determined entailments of the research encounter: study goals, methods, risks, benefits, confidentiality procedures, and reminders about the voluntary nature of participation.⁴⁹ In cases where informed consent will be sought orally, re-

⁴⁵ Rhodes, *supra* note 14, at 8.

⁴⁶ See PANEL ON INSTITUTIONAL REVIEW BOARDS, SURVEYS, AND SOCIAL SCIENCE RESEARCH, NATIONAL RESEARCH COUNCIL, PROTECTING PARTICIPANTS AND FACILITATING SOCIAL AND BEHAVIORAL SCIENCES RESEARCH 98 (2003) (elaborating on this problem).

⁴⁷ See, e.g., 45 C.F.R. § 46 (2005).

⁴⁸ This perspective miscomprehends the fact that "informed consent is not a principle, but a practice intended to embody and reflect the ethical principle of respect for persons." Mary Simmerling & Brian Schwegler, *Beginning Anew: Same Principles, Different Direction for Research Ethics*, 5 AM. J. BIOETHICS 44, 44 (2005).

⁴⁹ 45 C.F.R. § 46.116 (2005).

searchers are generally required to submit static scripts that will be performed at the start of the research encounter; these must include the same information as informed consent forms. One context in which investigators clearly need to have permission to waive the requirement of a signed informed consent form is that of the ethnographer who lives among members of a community as a participant observer, sometimes for periods of a year or more, in order to learn their culture and world view. The ethnographer who is able to persuade the IRB to waive written consent and a signature, typically must still present a script containing the elements of informed consent which ostensibly will be recited to those to whom the ethnographer plans to speak. If indeed the ethnographer actually does what the IRB requires of him or her, such a legalistic way of relating to community members, with a fixed script rather than a dialogue emerging out of their interactions, does not treat the potential informants “as autonomous persons engaged with the ethnographer in acts of interpretation and narration about the nature of social and cultural life.”⁵⁰ Such a procedure resembles the hierarchical relationship of the doctor–patient relationship, rather than the guest status of the typical ethnographer, and would surely destroy any possibility of doing valid ethnography. It is small wonder that ethnographers regard the typical regulatory and IRB requirements for informed consent (with or without a consent form and signatures) as a charade that requires them to violate the requirements of the IRB once they are in the field interacting with their informants.⁵¹

3. *Disclosure Necessary for Informed Consent.*—Although nearly all commentators on research ethics endorse the concept of informed consent, there is much confusion about both its theory and its use in practice. Not only have commentators tended to misunderstand the meaning of voluntariness, they have even failed to understand the scope of its current use in ordinary medical care.

For most of the first two hundred years of our nation, consent to medical care was little different than consent for other large and small things: consent to order a dress, have a horse shod, buy a book, hire an employee, order a dinner, get a haircut, receive a massage, or agree to a police search of one’s car. It was the patient’s choice whether to agree; he could simply give his consent. The patient’s choices were respected, not only for the treatment to be pursued, but also for how much information the patient needed to know before he was able to consent.

It was not until 1957 that the first major American case mandated “informed consent” to medical care in the modern sense, though it purported to

⁵⁰ Marilyn Strathern, *Introduction: New Accountabilities*, in *AUDIT CULTURES: ANTHROPOLOGICAL STUDIES IN ACCOUNTABILITY, ETHICS, AND THE ACADEMY* 1–18 (Marilyn Strathern ed., 2000).

⁵¹ Martin Tolich & Maureen H. Fitzgerald, *If Ethics Committees Were Designed for Ethnography*, *J. EMPIRICAL RES. ON HUM. RES. ETHICS*, June 2006, at 71.

be based on pre-existing legal principles.⁵² Because a typical medical operation involves cutting someone open, absent consent, a criminal battery has been committed. For that extraordinary situation—where consent would negate an assault or battery—more than ordinary voluntary consent was needed. The state paternalistically decided that a patient's attempt to consent would be ignored unless that decision was preceded by full disclosure of all substantial risks and usually a signed paper memorializing that disclosure and consent.

But what about ordinary medical treatment? When most of us go to a doctor or take our child to one, we are not asked whether we are willing to be touched, even though an unconsented touching is a battery. If an over-the-counter medicine is recommended, the doctor usually does not warn us of side effects. If she prescribes an antibiotic, a possible side effect might or might not be mentioned, but the general risks of antibiotics and the possibility of allergic reactions are rarely discussed, even though non-life threatening allergic reactions are common for many antibiotics. If a doctor sends us to have blood drawn, we are not usually orally warned about any risks, though we are often asked to sign a blanket consent at the time of check-in. Thus, even for having a sharp needle stuck in our arms, we usually consent without any effective disclosure of risks.

If full, written, informed consent emphasizing substantial risks is required only for medical operations, why is it routine for IRBs to impose such procedures on social science research, most of which is far less risky and painful than having blood drawn? For example, if a university researcher is conducting a typical, short political opinion poll on the street or by telephone, in order for a potential subject to make an adequately informed decision whether to participate, he would ordinarily need to know the general topic of the poll, the organization that is conducting the research, and probably an indication of the extent of the time required to participate. To require more disclosure without a sound reason for doing so may be less ethical because it might discourage participation by giving a false sense of the seriousness of the risk or the hassle involved in participating.⁵³ This discouragement to participate destroys the random sampling design of many research projects, resulting in a reduction in the quality of the data. If a subject on the street had a choice between participating anonymously or signing a consent form, it is likely that most would feel safer not having to sign anything. Most subjects are smart enough to realize that when they are required to sign something, it is usually for the benefit of the person or organization asking them to sign, not for their own benefit.

The regulatory emphasis on complete disclosure within informed consent processes endeavors to render the implicit entailments of research rela-

⁵² *Salgo v. Stanford Univ.*, 317 P.2d 170 (Cal. Ct. App. 1957).

⁵³ Eleanor Singer, Dawn R. Von Thurn & Ester R. Miller, *Confidentiality Assurances and Response: A Quantitative Review of the Experimental Literature*, 59 *PUB. OPINION Q.* 66, 74 (1995).

tionships transparent through contractual agreements. There is, however, little about the interactions between researchers and participants that is qualitatively different from other social interactions, or that justifies the suspension of social norms of interaction, which are not generally subject to prospective contractual limitation. Framing disclosure within informed consent processes as a response to irredeemably egregious violations of human dignity (i.e., Nazi medical experiments) is historically understandable; nonetheless it has taken research ethics away from, rather than closer to, the *Belmont* principles that the practice of informed consent is intended to embody and reflect—specifically, respect for persons and justice. This does not mean that the ethical ideals themselves are wrong or should be abandoned. Rather, it powerfully demonstrates the need to implement policies and practices that meaningfully embody and reflect these ethical ideals.⁵⁴

4. *Coercion and Undue Influence.*—Fundamental to informed consent is that it be voluntary. *Belmont* clearly states that consent can be considered valid only when given voluntarily, which requires “conditions free of coercion and undue influence.”⁵⁵ According to *Belmont*, coercion occurs when “an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.”⁵⁶ This is distinguished from undue influence, which occurs when “an offer of an excessive, unwarranted, inappropriate or improper reward or other overture [is made] in order to obtain compliance.”⁵⁷ In determining whether or not a particular inducement is undue, *Belmont* cautions that it is not sufficient to consider the inducement only, since “inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.”⁵⁸ *Belmont* indexes the appropriateness of the inducement based on the relative power and influence of the subject compared to the influencer:

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject.⁵⁹

Although *Belmont* draws a distinction between coercion and undue influence, the terms are often used interchangeably by IRBs. Coercion is of-

⁵⁴ Part II of this project will elucidate mechanisms for implementing the practice of informed consent and the principle of respect for persons as components of practices of disclosure and documentation. It will explore alternatives to the disenfranchisement of intent in the current model, for example, collaborative research models and participant advisory groups, to suggest ways in which the practice of informed consent can meaningfully manifest respect for persons while resisting reduction to the bureaucratic exercise of completing forms and checklists.

⁵⁵ *Belmont*, *supra* note 4, at 14.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

ten used to refer not only to actual threats of harm, but also to powerful influences or offers (undue influence). These influences include various types of pressure, intimidation, compulsion, obligation, and force.

Clinicians and clinical ethicists generally use the term coercion to refer to the nature and intensity of the pressures (both internal and external) that a potential research participant might face when considering whether to participate in a given study. In basic terms, they take “coerce” to mean to compel to act in a certain way. The classic example of coercion involves someone being told to do something with a gun held to her head: If she does not comply, she will be killed. Such a decision is not considered a free choice. Thus, to say that a person was coerced to act in a certain way means that the individual really had no meaningful choice at all.

In addition to the distinction between coercion and undue influence, *Belmont* also sets out a broader continuum of conditions under which undue influence may occur. This continuum includes not only the actual inducements themselves (e.g., money), but also the extent to which persons may be susceptible to their power. For example, a particular monetary inducement may be acceptable when offered to wealthy persons, but “undue” when offered to poor persons. Thus on this continuum, otherwise acceptable inducements may become “undue influences” in cases where the person to whom the inducement is made is “especially vulnerable” to its power.

Belmont includes a clear recognition that not all influences inhibit autonomy. Although not defined in *Belmont*, “justifiable persuasion” is used in contrast to influences that are undue:

A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person’s choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.⁶⁰

While these distinctions among degrees of coercion, undue inducement and persuasion are useful to bear in mind, they overlook some fundamental harms and benefits of inducements, undue and appropriate. For example, it is typically necessary to pay drug addicts in order to recruit them into research. Arguably, they are vulnerable in the sense that they desperately need money to support their habit, and hence one might think, as some IRBs have, that paying drug addicts for participation comprises an undue inducement. However, if they will obtain money to support their habit by any means, including robbery; obtaining money in return for research par-

⁶⁰ *Belmont* suggests that, within the research context, respect for the immature (including children and persons with mental disabilities) and the incapacitated may require protecting them as they mature or while they are incapacitated. *Id.* at 5. Also, the judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. *Id.*

ticipation is clearly preferable. Because of the difficulty in identifying a random sample of drug addicts, it has become a common practice to pay drug addicts a “capitation fee” for identifying other addicts who might be willing to participate in research. Both payment of subjects and payment of the capitation fee are justifiable in terms to the need for a valid sample.⁶¹

Concerns about the validity of research can also comprise an argument against “undue inducement.” A major inducement may be the only reason an individual decides to participate in a study, and may result in lying about qualifications to participate, and giving dishonest responses to the research itself.⁶²

In summary, it is time to move beyond simple concerns about coercion, persuasion and undue influence to include more nuanced concepts that recognize the particular issues that may arise in some of the diverse and far-flung research contexts of social, and behavioral research.

5. *Competency to Consent.*—When emotions are mentioned in the literature on mental competence, it is usually because of widespread recognition “that emotions can influence mental competence negatively.”⁶³ More specifically, emotions are thought to disrupt cognitive processes and compromise decision-making ability.⁶⁴ This understanding of the supposedly negative role of emotions in decision-making is ubiquitous in research ethics literature,⁶⁵ policy, and practice. Accordingly, to promote rational decisions by potential participants in research studies, it is sometimes stated or implied that the deliberations should be free of emotion.⁶⁶ Apart from the impossibility of achieving such an emotionless context, research into the place of emotion in organ donation suggests that emotions have a positive role to play in decision-making, a role that is needed in the context of research involving human participants.⁶⁷ Consistent with recent research,⁶⁸ we believe that emotions are an essential, positive ingredient of compe-

⁶¹ Craig L. Fry et. al., *The Ethics of Paying Drug Users Who Participate in Drug Research: A Review and Practical Recommendations*, J. EMPIRICAL RES. ON HUM. RES. ETHICS, Dec. 2006, at 21, 26–28.

⁶² Elizabeth B.D. Ripley, *A Review of Paying Research Participants: It’s Time to Move Beyond the Ethical Debate*, 1 J. EMPIRICAL RES. ON HUM. RES. ETHICS, Dec. 2006, at 9–10.

⁶³ Louis C. Charland, *Appreciation and Emotion: Theoretical Reflections on the MacArthur Treatment Competence Study*, 8 KENNEDY INST. ETHICS J. 359, 359 (1998).

⁶⁴ *Id.*

⁶⁵ Ruth Macklin, *The Ethical Problems with Sham Surgery in Clinical Research*, 341 NEW ENG. J. MED. 992 (1999).

⁶⁶ *Id.*

⁶⁷ See generally Mary Simmerling & Daniel Brauner, *Beyond Coercion: A New Paradigm for Understanding Donor Motivation and Informed Consent in Living Donor Transplantation (LDT)*, 20 CLINICAL TRANSPLANTATION: SUPPLEMENT 28 (2006).

⁶⁸ See, e.g., ANTONIO R. DAMASIO, *DESCARTES’ ERROR: EMOTION, REASON, AND THE HUMAN BRAIN* (1994).

tence.⁶⁹ As Louis Charland argues, not only is competence to consent to research a matter of practical, rather than theoretical reasoning, but emotions form a class of legitimate reasons for consenting to participate.⁷⁰

According to Charland, modern emotion theory presents four characteristics of emotions that are particularly relevant to discussions of competence to consent: (1) emotions provide us with information about both the outer world and the inner world (i.e., the world of our own internal states and conditions); (2) emotions serve to define an organism's overall biological and social goals and utilities; (3) emotions function as cognitive patterns of reasoning in their own right; and (4) emotions are what motivate us to action.⁷¹ Thus, emotions give meaning to our lives; they are a source of our most basic goals, values, and preferences; and without them reason is blind.

The usual IRB requirements of competence to consent are almost exclusively cognitive: they assure that prospective research subjects understand the purpose and rationale of the proposed research and appreciate the risks and benefits of participation. However, this may not tell us much about why a prospective research subject proposes to decide as she does.⁷² Thus, while understanding and appreciation might be necessary conditions for theoretical competence, they are insufficient determinants of practical competence absent consideration of emotions.⁷³

Belmont's model of competence, which is currently applied in the context of research with human participants, is based on the cognitivist model. We think there is something about the decision-making involved in consent to participate in research that is not captured in the informed consent requirements or process; the justification for the decision to participate cannot be reduced to mere conformity with the cognitive model of informed consent. We think that the kind of decision-making involved in research is different from what the informed consent requirements and process suggest, and that Charland's theory of competence can help explain the variance between the ideal of informed consent and the real life decision-making involved in the context of research. Competence to consent to research requires emotion if the practical consequences of such consent are to be considered fully assessed by research participants.⁷⁴ Consequently, the model of competence being applied in the context of research needs to be expanded and modified to accommodate the positive contributing influence of emotion in research participants' decision-making. Such an expanded model would allow for a different understanding of the identifiable influ-

⁶⁹ Louis C. Charland, *Is Mr. Spock Mentally Competent? Competence to Consent and Emotion*, 5 PHIL. PSYCHIATRY & PSYCHOL. 67, 78 (1998); Charland, *supra* note 63, at 359.

⁷⁰ Charland, *supra* note 69, at 76, 77; Charland, *supra* note 63, at 370.

⁷¹ Charland, *supra* note 69, at 71, 72.

⁷² *Id.* at 70.

⁷³ *Id.* at 70, 78.

⁷⁴ *Id.* at 78.

ences and motivations that appear to play a key role in participants' decision-making. In Part II of this project, we intend to describe how the practice of informed consent might be revised to facilitate a broader understanding of competence, thus promoting better decision-making by potential participants in research studies.

6. *Informed Consent and Justice*.—One important limitation of *Belmont* is the way in which focus on informed consent has resulted in a conception under which the ethical principle of respect for persons is treated as essentially equivalent to informed consent. That is, informed consent has been taken to be not just a necessary, but a *sufficient* condition for satisfying the requirements of respect for persons. Among the problems this has created is that it has reduced the harms associated with disrespect for persons to failures of informed consent rather than to violations of the fundamental principle of justice.

This understanding of the requirements of respect for persons involves a significant departure from the philosophical tradition in which disrespect for persons is seen as an injustice. Specifically, one of the consequences of *Belmont* is that injustices related to failures of respect for persons are seen solely as failures of “autonomy” and “consent,” rather than as injustices. For Rawls, exploitation and disrespect for persons are manifestations of injustice.⁷⁵ Rawls's *A Theory of Justice* is explicitly founded on the attempt to reconstruct an ideally just society whose “basic structure” is founded on Kantian principles of respect for personhood:

Justice is the first virtue of social institutions. . . . Each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override. . . . Another way of putting this is to say that the principles of justice manifest in the basic structure of society . . . men's desire to treat one another not as means only but as ends in themselves.⁷⁶

It is important to note that the terminology in research ethics and bioethics has evolved along a different path than mainstream philosophy in this regard, since *Belmont* was not created out of a strictly philosophical tradition. The consequences of this conceptual and terminological departure are significant in the research setting. In particular, they have resulted in the effective abandonment of the requirements of justice in this setting.

C. Justice

There are many conceptions of justice, such as procedural justice, formal justice, corrective justice, restorative justice, and distributive justice.⁷⁷ Within the research model set out in *Belmont*, the principle of justice ap-

⁷⁵ JOHN RAWLS, A THEORY OF JUSTICE 3 (rev. ed. 1999).

⁷⁶ *Id.* at 3–4.

⁷⁷ See, e.g., CHAIM PERELMAN, THE IDEA OF JUSTICE AND THE PROBLEM OF ARGUMENT (1977); Peter Westen, *The Empty Idea of Equality*, 95 HARV. L. REV. 537, 539, 556–58 (1982).

pears to be restricted to a narrow kind of distributive justice: it requires that the benefits and burdens of research be distributed fairly. The particular duties of researchers arising from this requirement for fair distribution of research-related burdens and benefits have both individual and population-based aspects. Moreover, the requirements of this principle with regard to research decision-making apply broadly to both research design and implementation. According to *Belmont*, justice requires that the rationale for the inclusion and selection of research subjects be justified with regard to the purpose and goals of the research in order to ensure that “some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions)” — what *Belmont* refers to as “vulnerable subjects” — are not being systematically included simply because of their “easy availability, their compromised position, or their manipulability.”⁷⁸

Thus, according to *Belmont*, justice requires that research “should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”⁷⁹ Within *Belmont*, justice requires that the selection of subjects be equitable in the context of the purpose and goals of the research, as well as the anticipated or expected burdens and benefits thereof. If a particular group or class of individuals is asked to assume the burdens of the research, there should be a clear research-related rationale for their inclusion as well as assurance that any research-related benefits will be accessible to them.

As noted above, *Belmont* has special language for referring to those subjects or classes of subjects who might be targeted for inclusion in research based on their availability or assumed willingness to agree to participation in research. These individuals are referred to as “vulnerable subjects”:

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects. . . . Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research . . . because they are easy to manipulate as a result of their illness or socioeconomic condition.⁸⁰

It is important to note that these groups’ vulnerability stems from their presumed limited autonomy and capacity for consent. Within the research context, the requirements of respect for persons include that persons with diminished autonomy are entitled to protection. Although the duties of researchers arising from justice and respect for persons may appear to be the same with regard to the treatment of these subjects, they are distinct; so too

⁷⁸ *Belmont*, *supra* note 4, at 10.

⁷⁹ *Id.*

⁸⁰ *Id.* at 19–20.

are the harms resulting from violations of their respective requirements. However, the cases included in *Belmont* as paradigmatic examples of violations of the principle of justice, are also examples of violations of the requirements of the principle of respect for persons. Rather than illustrating the specific requirements of justice and respect for persons in the research context, these cases conflate the harms related to violations of these principles.

For example, consider the case of research involving survivors of trauma or violence. The current paradigm for ethical research with subjects who are survivors of violence or trauma presumes that these individuals are vulnerable and have diminished autonomy by virtue of their victimization; accordingly, they require additional protections from research risks, including the risk of coercion. These additional protections purportedly arise from the requirements of the ethical principle of respect for persons. But conceiving of survivors of violence and trauma in this way—as necessarily altered by the experience of violence such that they are vulnerable, diminished, and less able to choose freely—would seem to be a mistake that not only fails to protect these subjects, but disrespects them in ways that may be reminiscent of some of the harms related to the trauma or violence that they experienced. Conceiving of these survivors as vulnerable and diminished suggests not only that they are less free than they may actually be, but that the violence or trauma has had the effect of necessarily, intrinsically, and permanently reducing them as people. In contrast to the assumptions implicit in this paradigm, recent research suggests that treating survivors of sexual assault as if they are “different” or “less worthy” persons—as though the assault permanently transformed them somehow—may exacerbate post-traumatic stress disorder symptoms among this population.⁸¹ Moreover, this research suggests that the survivor’s opportunity to talk about the trauma more extensively with others may be beneficial and therapeutic for them,⁸² not risky and harmful as many IRBs assert. Rather than respecting survivors’ autonomy and maximizing their power to make their own choices, the current paradigm disrespects the survivors’ ability to choose freely and their possibility for recovery from trauma. Rather than empowering them, the alleged requirements of justice under *Belmont* introduce the possibility of re-victimizing these subjects. Treating persons with respect should not mean treating adults like children, whose expressions of consent are to be discounted or disregarded. Justice and respect for persons requires something different for researchers working with these subjects. Specifically, while researchers need to anticipate and recognize the real, lasting, and at times unpredictable consequences of traumatic experiences, the respectful way to engage survivors of violence and trauma in research is through frank, open

⁸¹ Sarah E. Ullman & Henrietta H. Filipas, *Predictors of PTSD Symptom Severity and Social Reactions in Sexual Assault Victims*, 14 J. TRAUMATIC STRESS 369, 378–81, 383–84 (2001).

⁸² *Id.* at 383–84.

discussions of research goals and design at all stages of the research process, not through exclusionary tactics that presumptively reduce personhood.

CONCLUSION

As we reflect back on *Belmont* and the central role that it has played in protecting research participants and informing and enhancing the research enterprise, we also look forward to rediscovering and implementing the philosophical requirements that underlie *Belmont's* core principles. These core principles remain foundational for the enterprise of ethical research. However, their specification and application has at times departed from their spirit and their philosophical foundations. While recognizing the enormity of the task at hand, we look forward to expanding the possibilities and refining the applications of these principles by learning from the research experiences of the past thirty years and returning to a set of ethical principles whose spirit and meaning endure.

We have argued that the principled model for ethical decision-making specified and implied in the *Belmont Report* distorts the philosophical requirements of the ethical principles of beneficence, respect for persons, and justice in both their conceptual specification and practical application: the conception of beneficence relies on a simplistic conception of benefits and risks that cannot accommodate the various goods and harms that are legitimately given weight in risk–benefit calculations made by research participants; the conception of respect for persons relies on a superficial view of choice; and the conception of justice involves a conceptual mistake that conflates the harms of exploitation with those of disrespect for persons.

We will expand the conception of beneficence to include a more comprehensive and nuanced account of the values and concerns that research subjects are likely to have, and ways in which these can be supported through ethical research procedures. Similarly, we will expand the concept of autonomy and respect for the nonautonomous to better account for the ways in which respect for autonomy and protection of the nonautonomous may be appropriately respected in diverse research contexts. Finally, we will expand the concept of justice to include forms of justice in addition to distributive justice, and will examine the misguided ways in which overprotection of subjects comprises injustice.

